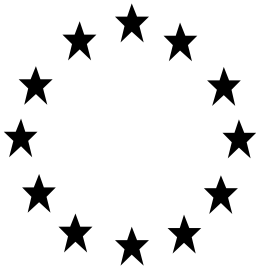
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



LIGNEX DEFEND

Product type 8

Permethrin

Case Number in R4BP: BC-UP024085-24

Evaluating Competent Authority: Austria

Date: 31/10/2022 (Final)

PUBLIC PAR

Table of Contents

1 CONCLUSION

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

The ready-to-use product LIGNEX DEFEND is a liquid, solvent-based formulation which contains 0.25%(w/w) of the active substance permethrin. Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics was identified as substance of concern and is present in a concentration of 96.5% (w/w).

The assessment considered:

- The conclusions and recommendations of the Assessment Report for the approval of the active substance 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 permethrin (Reg.(EU) No 1090/2014)

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

> The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. For biocidal products, authorisations are subject to the following conditions:
>
> (1) 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.
>
> (2) 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.
>
> (3) 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.
>
> (4) Products shall not be authorised for treatment of outdoor constructions near or above water or for the treatment of wood that will be used for outdoor constructions near or above water, unless data are submitted to demonstrate that the product will

not present unacceptable risks, if necessary by the application of appropriate mitigation measures.

For treated articles, the following condition applies:
Where a treated article has been treated with or intentionally incorporates permethrin, and where necessary due to the possibility of skin contact as well as the release of permethrin under normal conditions of use, the person responsible for placing the article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

The fields of use are as follows:
Use # 1 – wood boring beetles - Non-professional user – brushing – indoor/outdoor

Use # 2 – wood boring beetles- Professional and industrial user – brushing, dipping – indoor/outdoor

Use # 3 – wood boring beetles- Professional user – injection, borehole impregnation – indoor

Use # 4 – wood boring beetles- Professional user – combination of injection/borehole impregnation with brushing – 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 have demonstrated sufficient efficacy against the target organisms. No resistance is expected.
- The biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups or animals, directly or through drinking water, food, feed, air, or through other indirect effects.
- No unacceptable risk is expected for neither any environmental compartment nor for other non-target organisms since the treated wood will only be used indoors (UC 1). Therefore, no environmental exposure assessment and risk characterisation was performed.

The product contains the active substance permethrin which is a candidate for substitution.

There is no indication of concern regarding ED properties of any of the co-formulants, hence the product is not an endocrine disruptor.

It can be concluded that the conditions of Article 19 1)-4) of regulation (EU) no. 528/2012 are fulfilled and that the product 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.

There are no post-authorisation conditions.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
LIGNEX DEFEND	Austria

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	J.F. Amonn Srl/GmbH
	Via Altmann 12 I-39100 Bolzano Italien
Authorisation number	AT-0016053-0000
Date of the authorisation	Please see authorisation letter
Expiry date of the authorisation	Please see authorisation letter

2.1.1.3 Manufacturer of the product

Name of manufacturer	Amonn Coatings GmbH
Address of manufacturer	An der Landesbahn 7 A-2100 Korneuburg Austria
Location of manufacturing sites	An der Landesbahn 7 A-2100 Korneuburg Austria

2.1.1.4 Manufacturer of the active substance

Active substance	Permethrin
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz 1 50569 Cologne Germany
Location of manufacturing sites	Bayer Vapi Private Limited. Plot # 306/3 II Phase, GIDC Vapi – 396 195 Gujarat India

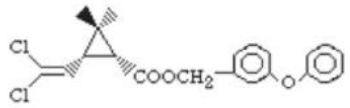
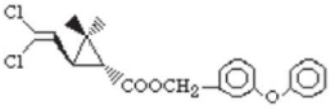
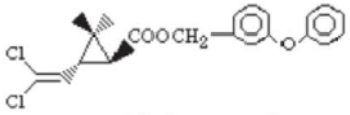
2.1.2 Product composition and formulation

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)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content	Specification ≥93.0%w/w sum of all permethrin isomers. Permethrin is a reaction mass of four stereoisomers: 1Rcis permethrin content =5.0–10.0%w/w 1Scis permethrin content =15.0–20.0%w/w 1Rtrans permethrin content =45.0–55.0%w/w 1Strans permethrin content =17.0–27.0%w/w
Structural formula	1Rcis isomer –  1Scis isomer –  1Rtrans isomer –  1Strans isomer – 

2.1.2.2 Candidate(s) for substitution

Permethrin fulfils substitution criteria (BPC Meeting Oct. 21).

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content % (w/w)**
Permethrin	3-phenoxybenzyl (1RS)-cis,trans-3-(2,2-dichlorovinyl)- 2,2-dimethylcycloprop anecarboxylate	Active substance	52645-53-1	258-067-9	0.25*
---	Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics	Solvent	---	---	96.5

*The amount of pure active substance without impurities: 0.2325%w/w

The full composition of the biocidal product is provided in the confidential annex and in the confidential annex restricted to authorities.

2.1.2.4 Information on technical equivalence

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 ☐

2.1.2.5 Information on the substance(s) of concern

The biocidal product contains Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics as substance of concern (SoC) in relation to human health.

Based on the harmonised classification in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) or the classification as provided in the SDS submitted by the applicant, the components listed below were identified as substances of concern (SoC) in relation to human health:
(Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics

Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics triggers the classification H304 (Asp Tox 1). According to the Guidance on BPR: Volume III Parts B+C (ECHA, 2017b) "Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products", the SoC can be assigned to band A. For the evaluation of exposure to SoC (Band A), it is considered sufficient to apply appropriate P-phrases associated with the concerned H-phrase.

No substances of concern were identified with respect to the environment.

Please see the confidential annex for further information.

2.1.2.6 Type of formulation

AL – Any other liquid

2.1.3 Hazard and precautionary statements

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

<table>
<tr><td colspan="3">Classification</td></tr>
<tr><td>Hazard category</td><td colspan="2">Asp. Tox. 1
Aquatic Acute 1
Aquatic Chronic 1</td></tr>
<tr><td>Hazard statement</td><td colspan="2">H304 May be fatal if swallowed and enters airways.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.</td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td rowspan="3">Labelling</td><td colspan="2">Pictograms</td></tr>
<tr><td>GHS08</td><td>GHS09</td></tr>
<tr><td>  </td><td>  </td></tr>
<tr><td>Signal words</td><td colspan="2">Danger</td></tr>
<tr><td>Hazard statements</td><td colspan="2">H304: May be fatal if swallowed and enters airways.
H410: Very toxic to aquatic life with long lasting effects.</td></tr>
<tr><td>Precautionary statements</td><td colspan="2">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.
P260: Do not breathe mist/vapours/spray.
P262: Do not get in eyes, on skin, or on clothing.
P273: Avoid release to the environment.
P301+P310: IF SWALLOWED: Immediately call a poison center or doctor/physician.
P331: Do NOT induce vomiting.
P391: Collect spillage.
P405: Store locked up.
P501: Dispose of contents/container in accordance with local/regional/national/international regulations.</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td>Note</td><td colspan="2">EUH066: Repeated exposure may cause skin dryness or cracking.
EUH208: Contains permethrin. May produce an allergic reaction.

According to Article 35 Regulation (EC) No 1272/2008 products which are supplied to the general public shall have a child-resistant fastening and shall bear a tactile warning of danger.</td></tr>
</table>

2.1.4 Authorised uses

2.1.4.1 Use description Use #1

Use # 1 – Wood boring beetles - non-professional user – brushing – indoor/outdoor

Product Type	8
Where relevant, an exact description of the authorised use	---
Target organism (including development stage)	Scientific name: Wood boring beetles Common name: Wood boring beetles Development stage: larvae
Field of use	Application of the product (i.e. brushing): Indoor/outdoor Preservation of wood for use in Use Class 1. Preventive and curative use for small scale surfaces and objects (up to max. 3 m²).
Application methods	Brushing
Application rates and frequency	Preventive use: 1 coat 120-150 mL/m² (95–119 g/m^2), equivalent to approx. 7–8 m²/L Curative use: 2 coats, yield in a total of 300 mL/m² (238 g/m^2), equivalent to 3 m²/L
Category of users	Non-professional
Pack sizes and packaging material	0.75 L – 1 L - 2.5 L - 4 L – 5 L tin can (tin plate)

2.1.4.2 Use-specific instructions for use

Mix well before use. Preventive treatment: Treat the wood with the recommended application rate (1 coat). Curative treatment: Treat the wood with the recommended application rate (2 coats).

2.1.4.3 Use-specific risk mitigation measures

Apply the product only to small indoor surfaces or objects. Treat max. 3 m². Curative treatment of load-bearing or stiffening wooden components and larger wooden objects is only allowed to be performed by qualified specialist companies. 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.

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

---

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

---

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

---

2.1.4.7 Use description Use #2

Use # 2 – Wood boring beetles - professional and industrial user – brushing, dipping – indoor/outdoor

Product Type	8
Where relevant, an exact description of the authorised use	---
Target organism (including development stage)	Scientific name: Wood boring beetles Common name: Wood boring beetles Development stage: larvae
Field of use	Application of the product (i.e. brushing/dipping): Indoor/outdoor Preservation of wood for use in Use Class 1 (preventive and curative). Preventive and curative use for all parts in wood statically loaded in dry interior rooms.
Application method(s)	Brushing, dipping (manual/automated/fully automated)
Application rate(s) and frequency	Preventive use: 1 coat 120- 150 mL/m² (95–119 g/m^2), equivalent to approx. 7–8 m²/L Curative use: 2 coats, yield in a total of 300 mL/m² (238 g/m^2), equivalent to 3 m^2/L
Categories of users	Professional, industrial
Pack sizes and packaging material	Professional: 0.75 L – 1 L - 2.5 L - 4 L – 5 L – 6 L – 20 L – 25 L tin can (tin plate) Industrial: 20 L – 25 L tin can (tin plate)

2.1.4.8 Use-specific instructions for use

Mix well before use.

Preventive treatment: Treat the wood with the recommended application rate (1 coat).

Curative treatment: Treat the wood with the recommended application rate (2 coats).

2.1.4.9 Use-specific risk mitigation measures

Brushing:

N-78: Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

Dipping (manual/automated/fully automated):

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-9: Wear a protective coverall (at least type 6, EN 13034) which is impermeable for the biocidal product (coverall 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.

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

---

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

---

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

---

2.1.4.13 Use description Use #3

Use # 3 – Wood boring beetles - professional user – injection, borehole impregnation – indoor

Product Type	8
Where relevant, an exact description of the authorised use	---
Target organism (including development stage)	Scientific name: Wood boring beetles Common name: Wood boring beetles Development stage: larvae
Field of use	Application of the product (i.e. injection/borehole impregnation): Indoor Preservation of wood for use in Use Class 1 (curative). The product can be used for all parts in wood statically loaded in dry interior rooms.
Application method(s)	Injection, borehole impregnation
Application rate(s) and frequency	Curative use: 12.5 L/m^3 (9.9 kg/m^3)
Categories of users	Professional
Pack sizes and packaging material	Professional: 0.75 L – 1 L - 2.5 L - 4 L – 5 L – 6 L – 20 L – 25 L tin can (tin plate)

2.1.4.14 Use-specific instructions for use

Mix well before use. Apply for curative treatment with the recommended application rate.

2.1.4.15 Use-specific risk mitigation measures

Borehole impregnation: N-78: Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Injection: 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-9: Wear a protective coverall (at least type type 6, EN 13034) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information).

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

---

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

---

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

---

2.1.4.19 Use description Use #4

Use # 4 – Wood boring beetles - professional user – combination of injection/borehole impregnation with brushing – indoor

Product Type	8
Where relevant, an exact description of the authorised use	---
Target organism (including development stage)	Scientific name: Wood boring beetles Common name: Wood boring beetles Development stage: larvae
Field of use	Application of the product (i.e. combination of injection/ borehole impregnation with brushing): Indoor Preservation of wood for use in Use Class 1 (curative). The product can be used for all parts in wood statically loaded in dry interior rooms.
Application method(s)	Combination of injection/borehole impregnation with brushing
Application rate(s) and frequency	Curative use: Combine Injection, borehole impregnation: 10 L/m^3 (8.0 kg/m^3) with Brushing: 1 coat 120-150 mL/m^2 (95–119 g/m^2), equivalent to approx. 7–8 m^2/L
Categories of users	Professional
Pack sizes and packaging material	Professional: 0.75 L – 1 L - 2.5 L - 4 L – 5 L – 6 L – 20 L – 25 L tin can (tin plate)

2.1.4.20 Use-specific instructions for use

Mix well before use. Curative treatment only. Apply by injection / borehole impregnation. Consequently, apply one coat by surface treatment with the recommended application rate. The combination is feasible e.g. if it is not possible to treat the surface of the wood from all sides (example: timber framing, base purlins or beam layers).

2.1.4.21 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-9: Wear a protective coverall (at least type type 6, EN 13034) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information).

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

---

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

---

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

---

2.1.5 General directions for use

2.1.5.1 Instructions for use

Comply with the instructions for use.

The wood to be treated must be dry and free from dust and grease. Do not apply to wood with a humidity rate of over 18%. Strip old, badly adhering coats completely as these could prevent the product from penetrating into the wood.

N-246, modified: During product application 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-304 (modified): Clean treated equipment with an appropriate solvent after application.
N-242 Do not rinse used equipment with water. Reuse or dispose of in a safe way.

After application, wash hands and face thoroughly with water and soap.

Drying time: approx. 1 day under normal conditions (20°C/65% rel. humidity), according to the type of wood, the quantity applied and the atmospheric conditions. High air humidity and/or low temperatures may increase drying times.

Product residues must not be released to soil, ground- and surface water or any kind of sewer.

N-37 (modified): Do not discharge the biocidal product nor its residues or painting sludge into the sewage system or the environment.

Over-painting: in normal conditions the product can be over-painted after about 3 days with any common finishing product, as required.

Do not apply e.g. for apiaries, greenhouses and saunas.

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-29, modified: Ensure adequate ventilation during and after the application, until treated surfaces have dried.

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

N-335: Keep cats away from treated surfaces. Due to their particular sensitivity to permethrin, the product can cause severe adverse reactions in cats.

No animals or bystanders should be present during the application.

N-37, modified: Do not discharge the biocidal product nor the cleaning solution of the biocidal product into the sewage system or the environment.

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: Do NOT induce vomiting. If symptoms: Immediately call

112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water and soap. 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 the 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: 2 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.

2.1.6 Other information

According to Article 35 Regulation (EC) No 1272/2008 products which are supplied to the general public shall have a child-resistant fastening and shall bear a tactile warning of danger.

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)
Tin can	0.75 L	Tin plate	Lever lid, tin plate	Non-professional, Professionals	Yes
Tin can	1 L	Tin plate	Lever lid, tin plate	Non-professional, Professionals	Yes
Tin can	2.5 L	Tin plate	Lever lid, tin plate	Non-professional, Professionals	Yes
Tin can	4 L	Tin plate	Lever lid, tin plate	Non-professional, Professionals	Yes
Tin can	5 L	Tin plate	Lever lid, tin plate	Non-professional, Professionals	Yes
Tin can	6 L	Tin plate	Lever lid + clamping ring, tin plate	Professionals	Yes
Tin can	20 L	Tin plate	Lever lid + clamping ring, tin plate	Professionals, Industry	Yes
Tin can	25 L	Tin plate	Lever lid + clamping ring, tin plate	Professionals, Industry	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please cf. to annex 3.1. for the list of studies.
All data related to the biocidal product are contained in the IUCLID dossier.

2.1.8.2 Access to documentation

A letter of access for the biocidal product satisfying the requirements set out in Annex II for the active substance contained in the biocidal product is available.

2.2 Assessment of the biocidal product

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

Please confer 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	visual analysis	100% undiluted product Batch no: 327200025	liquid	Anonymous 2016a
Colour at 20°C and 101.3 kPa	visual analysis	100% undiluted product Batch no: 327200025	Clear colourless liquid	Anonymous 2016a
Odour at 20°C and 101.3 kPa	olfactory analysis	100% undiluted product Batch no: 327200025	typical odour of naphta (Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics)	Anonymous 2016a
Acidity / alkalinity	CIPAC MT 75.3 CIPAC MT 31	100% undiluted product and 1% dilution Batch no: 327200025	The pH measurement of the test item, as it is and of a sample solution at 1 % (w/v) proved to be not applicable. Presumably due to the high content of hydrocarbons in the mixture. Acidity and alkalinity determination is therefore also not applicable.	Anonymous 2016a
Relative density / bulk density	OECD 109	100% undiluted product Batch no: 327200025	0.793 at 20°C	Anonymous 2016b Anonymous 2019b

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **accelerated storage**	CIPAC MT 46.3	100% undiluted product Batch no: 327200025	The test item was stored at 30°C for 18 weeks in original tin plate containers: Appearance of the test item: No variation from the beginning Appearance of the packaging: No variation from the beginning Weight loss 1.66%(w/w) Relative density (20°C) T0: 0.793 T18w: 0.794 Content of a.s. T0: 0.249%(w/w) T18w: 0.258%(w/w) (103.6% of T0)	Anonymous 2016b
Storage stability test – **long term storage at ambient temperature**	GIFAP monograph no. 17	100% undiluted product Batch no: 327200025	The biocidal product was stored in original 0.75 L tin plate packaging at 25°C for 24 months. a.s. content T0: 0.251% T6m: 0.252% T12m: 0.251% T18m: 0.253% T24m: 0.258% Rel. Density	Anonymous 2019c

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T0: 0.793 T6m: 0.795 T12m: 0.795 T18m: 0.794 T24m: 0.793 Weight loss T6m: 1.19% T12m: 1.69% T18m: 2.59% T24m: 3.41% (a.s. content 102.8% of T0) T0-T24m: No differences in the packaging and in the appearance of the liquid could be observed.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	100% undiluted product Batch no: 327200025	The test item LIGNEX DEFEND was stored at 0°C for 7 days. No modification of the appearance of the test item was observed. No separated matter of any nature has been spotted after the experimental process.	Anonymous 2016a
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	---	N.A.	Study waived: Considering the packaging type, the product is not expected to be exposed to light before application. The active substance contained in the product	---

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			does not absorb wavelengths above 290 nm, which indicates that the molecule is 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 Batch no: 327200025	The effect of temperature was investigated in both the accelerated and low temperature stability study. The test item was stable for seven days at 0°C and for 18 weeks at 30°C.	Anonymous 2016a Anonymous 2016b
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	---	100% undiluted product Batch no: 327200025	The long term storage test shows no signs of reactivity towards the tin plate container.	Anonymous 2019c
Wettability	---	N.A.	Study waived: The data are required for solid preparations which are to be dispersed in water. The biocidal product is a ready to use liquid formulation.	---
Suspensibility, spontaneity and dispersion stability	---	N.A.	Study waived: The data are required for wettable powders, water dispersible granules, water dispersible	---

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			powders or for formulations forming suspensions on dilutions with water. The biocidal product is a ready to use liquid formulation without water.	
Wet sieve analysis and dry sieve test	---	N.A.	Study waived: The data are required for wettable powders, suspension concentrates, water dispersible granules, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules, water soluble powders or for dustable powders and granules. The biocidal product is a ready to use liquid formulation and no suspension.	---
Emulsifiability, re-emulsifiability and emulsion stability	---	N.A.	Study waived: The data are required for emulsions. The biocidal product is a ready to use liquid formulation and no emulsion.	---
Disintegration time	---	N.A.	Study waived: The data are required for	---

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			tablets. The biocidal product is a ready to use liquid formulation and no tablet.	
Particle size distribution, content of dust/fines, attrition, friability	---	N.A.	Study waived: The data are required for powders and granules. The biocidal product is a ready to use liquid formulation and no powder or granule.	---
Persistent foaming	---	N.A.	Study waived: The data are required for products applied in water for use. The biocidal product is a ready to use liquid formulation.	---
Flowability/Pourability/Dustability	---	N.A.	Study waived: The data are required for granular materials, suspension concentrates, capsule suspensions, suspoemulsions or products applied as dust. The biocidal product is a ready to use liquid formulation and no suspension or emulsion.	---
Burning rate — smoke generators	---	N.A.	Study waived: The biocidal product is not a smoke generator.	---

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Burning completeness — smoke generators	---	N.A.	Study waived: The biocidal product is not a smoke generator.	---
Composition of smoke — smoke generators	---	N.A.	Study waived: The biocidal product is not a smoke generator.	---
Spraying pattern — aerosols	---	N.A.	Study waived: The data are required for aerosols. The biocidal product is not marketed as aerosol.	---
Physical compatibility	---	N.A.	The product is not intended to be used with other products.	---
Chemical compatibility	---	N.A.	The product is not intended to be used with other products.	---
Degree of dissolution and dilution stability	---	N.A.	Study waived: The data are required for water soluble bags, tablets and water soluble preparations. The biocidal product is a ready to use liquid formulation without water.	---
Surface tension	OECD 115	100% undiluted product Batch no: 327307	25.4 mN/m at 25°C	Anonymous 2019a
Viscosity	OECD 114 (rotational viscometer)	100% undiluted product Batch no: 327200025	20°C: 1.5 mPa*s 40°C: 1.2 mPa*s. Kinematic viscosity at 40°C: $1.5*10^{-6}$ m^2/s	Anonymous 2017

Conclusion on the physical, chemical and technical properties of the product
The ready to use biocidal product consists of 0.25%(w/w) of the active substance permethrin. The biocidal product is a clear, colourless liquid with a typical naphtha odour. The relative density was measured at 20°C and is 0.793. The kinematic viscosity is below the threshold and therefore the surface tension is determined at 25°C: 25.4 mN/m. The biocidal product is non-corrosive and stable for 2 years in its original tin packaging. For the storage tests tin cans with the smallest available volume of 0.75 liter were used. In small containers the surface-to-volume ratio plus the ratio of potentially leaky lid area to volume is most unfavorable. The relative density was originally measured according to CIPAC MT 3. Later on results according to OECD 109 were obtained by using the density of water at 4°C (Anonymous 2019b). Both methods are identical and differ only in the reference water temperature (20°C for CIPAC MT 3 and 4°C for OECD 109).

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	---	N.A.	Study waived: In the biocidal product there are no chemical groups present which are liable to undergo a rapid exothermic reaction. Hence, the study does not need to be conducted.	---
Flammable gases	---	N.A.	Study waived: The study does not need to be conducted because the substance is a liquid.	---
Flammable aerosols	---	N.A.	Study waived: The study does not need to be conducted because the substance is a liquid.	---
Oxidising gases	---	N.A.	Study waived: The study does not need to be conducted because the substance is a liquid.	---
Gases under pressure	---	N.A.	Study waived: The study does not need to be conducted because the substance is a liquid.	---
Flammable liquids	EC Method A.9 (ISO3679: closed cup method)	100% undiluted product Batch no: 327200025	The test item is not flammable. The test item does not ignite and turns off the test flame at 59°C.	Anonymous 2016d
Flammable solids	---	N.A.	Study waived:	---

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The study does not need to be conducted because the substance is a liquid.	
Self-reactive substances and mixtures	---	N.A.	Study waived: In the biocidal product there are no chemical groups present which are liable to undergo a rapid exothermic or self-reactive reactions. Hence, the study does not need to be conducted.	---
Pyrophoric liquids	---	N.A.	Study waived: Experience in manufacture and handling shows that the biocidal product is stable at room temperature for prolonged periods of time.	---
Pyrophoric solids	---	N.A.	Study waived: The study does not need to be conducted because the biocidal product is a liquid.	---
Self-heating substances and mixtures	---	N.A.	Study waived: This endpoint applies to solids. Hence, the study does not need to be conducted because the biocidal product is a liquid.	---
Substances and mixtures which in contact with water emit flammable gases	---	N.A.	Study waived: There are no metals or metalloids present in the biocidal product. Hence, the study does not need to be conducted.	---
Oxidising liquids	---	N.A.	Study waived: The biocidal product contains oxygen and halogens which are only bonded to hydrogen and carbon atoms. Hence, the study does not need to be conducted.	---
Oxidising solids	---	N.A.	Study waived: The study does not need to be conducted because the substance is a liquid.	---
Organic peroxides	---	N.A.	Study waived: The study does not need to be conducted because there are no organic peroxides present in the biocidal product.	---

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td>Corrosive to metals</td><td>UN Manual of Tests and Criteria: Part III, 37.4:UN test C.1</td><td>100% undiluted product

Batch no: 327200025</td><td>The biocidal product is not classified as corrosive to metals.
The test duration was 7 days at 55°C. Neither uniform nor localised corrosion was observed.

<table>
<tr><th>steel</th><th>T0 weight [g]</th><th>T7 weight [g]</th><th>Weight loss [%]</th></tr>
<tr><td>Gas phase</td><td>15.4652</td><td>15.4643</td><td>0.006</td></tr>
<tr><td>Half way immersed</td><td>15.4720</td><td>15.4722</td><td>-0.001</td></tr>
<tr><td>Fully immersed</td><td>15.3975</td><td>15.3951</td><td>0.016</td></tr>
<tr><th>Al</th><th>T0 weight [g]</th><th>T7 weight [g]</th><th>Weight loss [%]</th></tr>
<tr><td>Gas phase</td><td>5.4006</td><td>5.4006</td><td>0</td></tr>
<tr><td>Half way immersed</td><td>5.3804</td><td>5.3805</td><td>-0.002</td></tr>
<tr><td>Fully immersed</td><td>5.4025</td><td>5.4026</td><td>-0.002</td></tr>
</table></td><td>Anonymous 2016c</td></tr>
<tr><td>Auto-ignition temperatures of products (liquids and gases)</td><td>EC method A.15</td><td>100% undiluted product
Batch no: 327200025</td><td>252°C at 101.3 kPa</td><td>Anonymous 2016d</td></tr>
<tr><td>Relative self-ignition temperature for solids</td><td>---</td><td>N.A.</td><td>Study waived:
The study does not need to be conducted because the substance is a liquid.</td><td>---</td></tr>
<tr><td>Dust explosion hazard</td><td>---</td><td>N.A</td><td>Study waived:
The study does not need to be conducted because the substance is a liquid.</td><td>---</td></tr>
</table>

Conclusion on the physical hazards and respective characteristics of the product
The biocidal product does not show any physical hazards and is therefore neither explosive, self-reactive, flammable, oxidising nor corrosive to metals.

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**	**Accuracy Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance (permethrin)	HPLC-UV 220nm	5 different concentration levels: 0.02-0.06 mg/mL	Linearity was tested in 5 points 0.02-0.06 mg/mL of the concentration of the a.s. in the sample. The method proved to be linear. R^2=0.9994	Specificity was tested against the blank (solvent only) and the placebo (mixture without a.s.). The method proved to be specific.	99.0-101.0 %	99.9 %	0.33 %	N.A.	Anonymous 2016m

Analytical methods for monitoring
For the active substance, there are monitoring methods available. For more information, please refer to the CAR.

Analytical methods for soil
For the active substance, there is a monitoring method for soil available. For more information, please refer to the CAR.

Analytical methods for air
For the active substance, there is a monitoring method for air available. For more information, please refer to the CAR.

Analytical methods for water
For the active substance, there is a monitoring method for water available. For more information, please refer to the CAR.

Analytical methods for animal and human body fluids and tissues
There are no toxicologically relevant components present in the biocidal product. For more information on the active substance, please refer to the CAR

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

The biocidal product is for non-crop use. Analytical methods for residues in food of plant and animal origin are not deemed necessary. For more information on the active substance, please refer to the CAR.

Conclusion on the methods for detection and identification of the product
The analytical method for the active substance in the biocidal product proved to be specific, linear, accurate and precise and was successfully validated. Initially, the LOQ of the method was not determined and the conducting test facility could not provide the LOQ when requested by the eCA. Monitoring methods are available for the active substance. For more information, please refer to the CAR. The substance Naphtha (petroleum), hydrotreated heavy (Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics) is identified as substance of concern (SoC). No analytical method to determine the concentration of the SoC in the biocidal product is necessary according to ECHA 2020b. Therein, it is stated that no analytical method is necessary if the SoC cannot be formed during storage and therefore the concentration remains unchanged.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The PT 8 product is for the treatment of the wood subject to attack by the old house borer (*Hylotrupes bajulus*) and common furniture beetle (*Anobium punctatum* de Geer), offering at the same time preventive protection and curative action, depending on the Use. The product is intended for UC 1 as indoor or outdoor application (depending on the Use) against wood boring beetles. Please refer to section 2.1.4 for an exact description of the field of use(s).

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

Organisms to be controlled: larvae of wood boring beetles, in particular the common furniture beetle (*Anobium punctatum)* and the old house borer (*Hylotrupes bajulus)*.
The product can be used for small scale surfaces and objects (Use 1) and for all parts in wood statically loaded in dry interior rooms (Uses 2–4).

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 (from CAR of permethrin).

2.2.5.3 Mode of action, including time delay

It 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 (from CAR of permethrin).

2.2.5.4 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	Scotch pine, sap wood.	*Hylotrupes bajulus L* Recently hatched larvae	EN 46 (CEN 1988-11-01) Version 46-1 EN 73 (CEN 1988-11-01)	Preservative treatment: Brushing, 1 application. Concentration tested: 100% (w/w) Preservative retention: 120-150 mL/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. Note: For validity, 70% of larvae in	Anonymus 2016f

						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.	
Insecticide	Indoor	Scotch pine, sap wood.	*Hylotrupes bajulus L* Recently hatched larvae	EN 1390 (CEN 1994-12-16) (Determination of the eradicant action against Hylotrupes bajulus (Linnaeus) Larvae - Laboratory Method)	Curative treatment: Brushing, 2 applications. Concentration tested: 100% (w/w). Solution retention: 300 mL/m^2. Test duration: 12 weeks.	The product proved to be effective against the tested target organism, according to EN 14128 criteria.	Anonymus 2016h

Insecticide	Indoor	Scotch pine, sap wood.	*Anobium punctatum De Geer* Larvae	EN 48 (Determination of the eradicant action against larvae of Anobium punctatum (De Geer) (laboratory method))	Curative treatment: Brushing, 2 applications. Concentration tested: 100% (w/w) Preservative retention: 300 mL/m^2 Test duration: 8 weeks.	The product proved to be effective against the tested target organism, according to EN 14128 criteria.	Anonymus 2016e
Insecticide	Indoor	Scotch pine, sap wood.	*Anobium punctatum De Geer* Larvae	EN 49-1, EN 73 (CEN 1988-11-01)	Determination of the protective effectiveness against *Anobium punctatum* according to EN/49/1 after evaporating ageing procedure	The product demonstrated to have protective effectiveness against *Anobium punctatum* according to EN 49/1 after evaporative ageing procedure	Anonymus 2016g

Conclusion on the efficacy of the product
4 efficacy studies are presented to prove that the product eradicates the larvae of the target organisms and shows preventive protection at the same time. The product proved to be preventive against the tested target organism *Anobium punctatum* (de Geer) by egg-laying and larval survival according to EN 49 part 1 (2016) after evaporation ageing procedure according to EN73 (2014). The product proved to be preventive against the tested target organism (recently hatched larvae of *Hylotrupes bajulus* L.) according to EN 46-1 (2009) after evaporative aging procedure according to EN 73 (2014). The product proved to be effective against the tested target organism *Anobium punctatum* (de Geer) according to EN 48 (2005). The product proved to be effective against larvae of *Hylotrupes bajulus* L. according to EN 1390.

Justification for wood boring beetle claim:
It has to be emphasized that at the time of the dossier submission (May 2016), the Guideline in force was the "Transitional Guidance on the Biocidal Products Regulation Transitional Guidance on Efficacy Assessment for Product Type 8 Wood Preservatives" (March 2015a), and it was different to the current version. In that section, it stated: a) 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. For this reason, the *Lyctus brunneus* target was not tested.
In the current ECHA Guideline (April 2018) it is stated that "All relevant beetle species (*Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus*) should be tested except if data (relevant and robust literature data where the materials and methods are detailed; certification data on a case by case basis) are provided which demonstrate that one of the targets is the less sensitive or that the product has an equivalent activity against all beetle species (refer to EN599- 1:2014, section 5.2.3)" There are literature data showing that the toxicity of permethrin to *Hylotrupes bajulus* and *Lyctus brunneus* is at a comparable level, whereas *Anobium punctatum* is a much more tolerant beetle species and the toxicity of the active ingredient is correspondingly lower. Please find enclosed summaries about permethrin efficacy studies in wood preservation "Permethrin: A Critical Review of an Effective Wood Preservative Insecticide" (Freeman 2007) and a Report about Lyctus spp. of the "Wood Utilisation Research Centre" (Brennan 1991). Taking into account the literature data, it can be assumed that the product displays an equal level of efficacy against *Lyctus brunneus*.
Thus, the claim against wood boring beetles was accepted by the eCA.

Concerning the studies performed via brushing application, please consider the following justification:
Referring to the provided and valid efficacy studies (see table on experimental data above), the efficacious application rates are 120-150 mL/m^2 (1 coat – preventive) and 300 mL/m^2 (2 coats – curative), which already were achieved via brushing application. The justifications given below always refer to this values.
Brushing, dipping and impregnation (by spraying, as described below), are all methods of superficial non-pressure treatment. Brushing and spraying 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/impregnation, a lower level of penetration of the product in the wood can be achieved via brushing; for this reason, it can be considered a "worst case" application

method. Please note that "low pressure spraying" cannot be authorised due to the risk assessment (see section 2.2.6.3).
Injection method (stitch procedure): stitches with a hollow needle are executed with a distance of about 15 to 30 cm, through which the wood preservative is introduced into the affected wood via a special injection device. Due to capillary action and gravity, the thin fluid is distributed throughout the entire beam or wood component. An alternative method is:
Borehole impregnation:
Analogous to stitch procedure 10 mm large holes are drilled into the affected wood with a distance of about 15 to 30 cm. They are then filled with the wood preservative (300 mL/ m²), using injectors, without pressure or under pressure, and then tightly sealed again with a wooden dowel or with an additional coverage of preservative. Due to capillary action and gravity, the thin fluid is distributed throughout the entire beam or wood component.

Rationale:
The injection method (stitch procedure; description above) has been used successfully for years in the curative treatment of wood destroying insects. The practice and also calculations according to DIN EN 14128:2020-06 show that the necessary amount of 300 mL/m² is easily absorbed from the substrate. The wood that is usually treated is already partly destroyed by the insects and therefore porous. It retains the application concentration used for the efficacy testing in any case.

The application of the preservative was carried out in accordance with the standards mentioned in the table "Experimental data on the Efficacy" by surface treatment with an application quantity of 300 mL/m^2 (curative treatment). More in-depth treatment methods that allow a direct determination of a volume-related effective application quantity cannot be implemented due to available test standards. Indirectly, this application quantity can be derived from the data of the *Hylotrupes bajulus* (L.) test. In the case of the test according to EN 1390, the distance of dead and living larvae from the nearest treated surface is recorded. From the distance of the dead larvae farthest from the nearest treated surface, the maximum effective diffusion of the wood preservative transverse to the direction of the grain can be determined (according to DIN EN 14128:2020). The maximum diffusion in the test is determined by the thickness of the test specimens (25 mm). This would result in an effective application rate of 12 L/m^3. For the product, a maximum distance under 59 dead larvae of 24 mm was determined. This results in an effective, volume-related application quantity of 12.5 L/m^3 or 9.9 kg/m^3 (Use #3), which is covered by the efficacy tests with the "worst case" application method brushing. For Use #4 (combination of borehole impregnation and brushing), which is recommended when it is not possible to treat the surface of the wood from all sides, the example timber components from DIN 68800-4 can be used for calculation. At a drilled hole diameter of 10 mm and filling twice, 10 L/m^3 or 8 kg/m^3 are injected into the beam; by one subsequently applied coat of 120-150 mL/m^2, the overall application rate is above the efficacious rate achieved via brushing in the provided efficacy studies and thus, they cover also Use #4 as a "worst case" (see below).

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 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.

The eCA accepts the rationale and the justification.

Justification underlining the none-efficacy of the co-formulants in the formulation:

Please refer to confidential Annex.

2.2.5.5 Occurrence of resistance and resistance management

Permethrin is a member of the pyrethroid family, which is well known to lead to potential resistance development. (Insecticide resistance Action Committee)
Because resistance is well known to be a potential problem, strategies to avoid resistance are normal practice. For example, the use of alternating sequences, mixtures and avoidance of frequent repeated use are standard. General advice is provided by IRAC (Voss G., 1988). The principles of strategies for preventing and managing the development of resistance are similar for permethrin as they are for other synthetic pyrethroids:

- Where possible, application treatments should be recommended to be combined with non-chemical measures.
- Products should always be used in accordance with label recommendations.
- Applications should always be made against the most susceptible stages in the pest life cycle.
- Where an extended period of control is required, treatments should be alternated with products with different modes of action.
- Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.
- In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing the same class of chemistry should cease.

However, as reported in the CAR of the active substance (PT 8) "There are no reported cases of development of resistance involving the use of permethrin in wood preservation". Even in this product development of resistance is not expected. Resistance is usually associated with continued application and resistance is formed between applications such that subsequent applications are less efficacious. Wood preservatives are usually applied only once. Also, for other kinds of wood preservation with permethrin-containing products, cases of resistances are not reported or known up to the time being.

2.2.5.6 Known limitations

The wood to be treated must be dry (wood humidity below 18%) and free from dust and grease. Old, badly adhering coats could prevent the product from penetrating into the wood, so they must be removed completely.

After application of the product, the drying time is approx. 1 day under normal conditions (20°C/65% rel. humidity), according to the type of wood, the quantity applied and the atmospheric conditions. High air humidity and/or low temperatures may increase drying times.

2.2.5.7 Evaluation of the label claims

The efficacy tests presented fully support the label claims.
The product proved to be effective against the tested target organism *Anobium punctatum* (de Geer) by egg-laying and larval survival according to EN 49 part 1 (2016) after evaporation ageing procedure according to EN73 (2014).

The product proved to be preventive against the tested target organism (recently hatched larvae of *Hylotrupes bajulus* L.) according to EN 46-1 (2009) after evaporative aging procedure according to EN 73 (2014).
The product proved to be effective against the tested target organism *Anobium punctatum* (de Geer) according to EN 48 (2005).
The product proved to be effective against larvae of *Hylotrupes bajulus* L. according to EN 1390.

See below the claim matrix. The codes (A.10 etc.) are based on the "Guidance on the BPR: Volume II Parts B+C Version 3 April 2018":

Categories	Matrix Wording	code for product
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, Curative treatment - Use class 1	D.40, D.50; E.10
Method of applications and rate	Application: brushing. Application rate: 120-150 mL/m² (preventive); 300 mL/m² (curative)	F.10
Target organisms	*Hylotrupes bajulus* L. (old house borer, larvae), *Anobium punctatum* De Geer (common furniture beetle, larvae).	G.31, G.32

Categories	Matrix Wording	code for product
Use 2		
User Category	Professional, Industrial	A.20, 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, Curative treatment - Use class 1	D.40, D.50; E.10

Method of applications and rate	Application: brushing, dipping Application rate: 120-150 mL/m² (preventive); 300 mL/m² (curative)	F.10, F.14,
Target organisms	*Hylotrupes bajulus* L. (old house borer, larvae), *Anobium punctatum* De Geer (common furniture beetle, larvae).	G.31, G.32

Categories	Matrix Wording	code for product
Use 3		
User Category	Professional	A.20, 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	Curative treatment - Use class 1	D.50; E.10
Method of applications and rate	Application: injection, borehole impregnation Application rate: 12.5L/m^3	F.20, F.70
Target organisms	*Hylotrupes bajulus* L. (old house borer, larvae), *Anobium punctatum* De Geer (common furniture beetle, larvae).	G.31, G.32

Categories	Matrix Wording	code for product
Use 4		
User Category	Professional	A.20, 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	Curative treatment - Use class 1	D.50; E.10
Method of applications and rate	Application: Combination of brushing with injection, borehole impregnation Combined Application rate: 10 L/m^3, 120–150 mL/m^2 (coat)	F.10, F.20, F.70

Target organisms	*Hylotrupes bajulus* L. (old house borer, larvae), *Anobium punctatum* De Geer (common furniture beetle, larvae).	G.31, G.32

2.2.5.8 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). For the human health effect assessment of LIGNEX DEFEND product data on the 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 was topically applied on two tissues replicates for 3 minutes at room temperature and 60 minutes at 30°C, 5% CO_2.	Three-dimensional Reconstituted 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.	On the basis of the results, interpreted according to OECD 431, the test item LIGNEX DEFEND is considered NOT CORROSIVE to skin.	Test report did not include a demonstration of proficiency and an acceptance range based on historical data.	Anonymous 2016m
OECD Guideline 439 (In Vitro Skin Irritation: Reconstituted Human Epidermis Test Method), GLP: yes, Klimisch 2	The test item was topically applied on three tissues replicates for 60 minutes at 37°C±1°C. Post-treatment incubation for 42 hours at 37°C±1°C.	Three-dimensional Reconstituted 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.	On the basis of the results, interpreted according to OECD 439 the test item LIGNEX DEFEND is considered NOT IRRITANT for the skin.	Test report did not include a demonstration of proficiency and an acceptance range based on historical data.	Anonymous 2016n

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The biocidal product LIGNEX DEFEND 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. EUH066 "Repeated exposure may cause skin dryness or cracking." is required based on SoC. 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 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%	According to the evaluation criteria the test item LIGNEX DEFEND is classified into UN GHS No Category.	Test report did not include a demonstration of proficiency.	Anonymous 2016o
OECD Guideline 492 (Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals	50 µL of the test substance were applied on triplicate tissues for 30 minutes at 37°C±1°C.	50 µL of the test substance, 50 µL of methyl acetate used as positive control and 50 µL of ultrapure water used as negative control	On the basis of the results, interpreted according to OECD 492 the test item LIGNEX DEFEND is considered NOT IRRITANT.	Test report did not include a demonstration of proficiency and an acceptance range based on historical data.	Anonymous 2016p

not requiring classification and labelling for eye irritation or serious eye damage), GLP: yes, Klimisch 2					

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The biocidal product LIGNEX DEFEND 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 LIGNEX DEFEND 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.

Data waiving	
Information requirement	Not a core data requirement.
Justification	Valid data on each of the components in the product is available and no synergistic effects between any of the co-formulants or active substance are expected. This allows classification of the mixture according to CLP Regulation 1272/2008.

Skin sensitization

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intra dermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 429 (Skin Sensitisation: **LOCAL LYMPH NODE ASSAY),** GLP**: YES,** Klimisch **1** GLP, reliability 1	Species/strain: healthy CBA/CaOlaHsd mice Sex: female (nulliparous and non-pregnant) Number of animals: 5 mice / group (3 test groups and 1 negative control group)	Test Item: LIGNEX DEFEND Vehicle: AOO (4:1 (v/v) acetone / olive oil) Test item concentrations: 25%, 50% (each diluted with AOO 4:1, v/v) and 100% (undiluted test item) Topical Application, performed once daily over three consecutive days	Stimulation index (SI) of each group: Negative control (AOO): 1.0 (DPM/Node[1]: 973.1) 25%: 1.3 (DPM/Node[1]: 1249.3) 50%: 1.3 (DPM/Node[1]: 1271.7) 100%: 2.7 (DPM/Node[1]: 2662.4) The EC3 value (derived by linear interpolation) could not be calculated as the stimulation indices of all concentrations were below 3. Result negative.	None.	Anonymous 2016q

[1] disintegrations per minute per node

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	The biocidal product LIGNEX DEFEND does not cause skin sensitization.
Justification for the value/conclusion	Experimental data.

	The active substance permethrin is at a concentration in the biocidal product triggering classification with EUH208 according to CLP Regulation 1272/2008 Annex II.
Classification of the product according to CLP and DSD	Not classified. EUH208: Contains permethrin. May produce an allergic reaction.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitization	
Value/conclusion	The biocidal product LIGNEX DEFEND 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.

Data waiving	
Information requirement	Respiratory sensitization (IUCLID data point 8.3.2)
Justification	Valid data on each of the components in the product is available and no synergistic effects between any of the co-formulants or active substance are expected. This allows classification of the mixture according to CLP Regulation 1272/2008.

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 420 (Acute Oral Toxicity- Fixed Dose Method), GLP: yes, Klimisch 1	Rat; Sprague-Dawley; Female; Nr. of animal per sex per dose: 5	Oral gavage; Vehicle: cotton seed oil; Dose: 2000 mg/kg bw	No clinical signs have been observed during the observation period. A slight meteorism in the large intestine in one mouse was detected. Necropsy of the other mice did not show any abnormalities.	LD50 >2000 mg/kg bw	None	Anonymous 2016r

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 LIGNEX DEFEND is not acutely toxic via inhalation.
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 by dermal route

Value used in Risk Assessment – Acute dermal toxicity	
Value	The biocidal product LIGNEX DEFEND 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

If no dermal absorption studies exist with the specific formulation of the biocidal product, either a default value from the *Guidance on dermal absorption* (EFSA, 2017) is applied for a first worst-case exposure estimate or read across with data from the CAR of the active substance or other product formulations similar to the biocidal product to be authorised is performed.

There are no dermal absorption studies available with the specific formulation of LIGNEX DEFEND. 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 70% for organic solvent-based formulations should be applied as a default for permethrin according to Guidance on dermal absorption (EFSA, 2017).

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Permethrin
Value(s)	70%
Justification for the selected value(s)	Default value for organic solvent-based formulation 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

Not applicable.

Other

Not applicable.

2.2.6.2 Exposure assessment

During application of LIGNEX DEFEND exposure may occur by inhalation and dermal routes. Additionally, post-application exposure can occur while handling treated wood, and washing the brush/cleaning the spray equipment. Primary oral exposure is not considered to be relevant for adult users.
Secondary exposure is possible for professional users and non-professional users, when treated wood is being sanded/sawed.
Additionally secondary exposure is possible for general public (toddlers) due to playing on treated wood structures and due to mouthing of timber off-cuts. Inhalation exposure due to volatilised residues is considered negligible due to the low vapour pressure of active substance permethrin.

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. However, such investigations are not available for LIGNEX DEFEND.

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]	Automated and fully automated dipping (application)	Primary exposure, chronic: Dermal exposure during application by automated/fully automated dipping.	Industrials
[2a]	Brush treatment (application)	Primary exposure, chronic: Dermal and inhalation exposure during application by brushing.	Industrials and Professionals
[2b]	Washing out of a brush (post-application)	Primary exposure, chronic: Dermal exposure during the post-application phase.	Industrials and Professionals
[3a]	Manual Dipping (application)	Primary exposure, chronic: Dermal exposure during mixing and loading and application by manual dipping.	Industrials and Professionals
[3b]	Manual Dipping (Mixing and loading/post-application)	Primary exposure, acute and chronic: Dermal exposure during mixing and loading (daily) the post-application phase.	Industrials and Professionals
[4a]	Professional spray treatment (Mixing and loading and application)	Primary exposure, chronic: Dermal and inhalation exposure during application by low pressure spraying.	Industrials and Professionals
[4b]	Cleaning of spray equipment (post-application)	Primary exposure, chronic: Dermal exposure during post-application via cleaning of spray equipment.	Industrials and Professionals
[5]	Borehole	Primary exposure, chronic:	Professionals

	pressure impregnation	Dermal and inhalation exposure during application by injection (pressure impregnation).	
[6]	Borehole impregnation	Primary exposure, chronic: Dermal exposure during application by borehole impregnation (pressure less).	Professionals
[7]	Sanding/sawing of treated wood	Secondary exposure, chronic: Sanding / processing of treated wood post	Professionals
[8a]	Brush treatment (application)	Primary exposure, acute: Dermal and inhalation exposure during application by brushing.	Non-professionals
[8b]	Washing out of a brush (post-application)	Primary exposure, acute: Dermal exposure during the post-application phase (i.e. washing out of a brush).	Non-professionals
[9]	Sanding/sawing of treated wood	Secondary exposure, acute: Sanding / processing of treated wood post	Non-professionals
[10]	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
[11]	Dermal contact to treated surfaces	Secondary exposure, chronic: Toddler is playing outdoors on a playground structure made of treated wood	General public
[12]	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] – Primary exposure during application by automated/fully automated dipping

Description of Scenario [1] Automated and fully automated dipping		
Primary dermal and inhalation exposure occurs when the biocidal product LIGNEX DEFEND is applied in an industrial scale via (fully) 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", solvent-based products), which represents the closest possible equivalent exposure model. Indicative inhalation exposure values for the model were found in HEEG opinion 18 (EC, 2013). According to HEEG Opinion no. 9 (EC, 2010b), 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. Remark: According to HEEG opinion 18 inhalation exposure is considered to be negligible for fully automated dipping processes. Additionally HEEG opinion 18 states that if all steps are fully automated only one cycle has to be assumed. Nevertheless: as this estimation covers as a worst case fully automated as well as automated dipping processes, inhalation exposure for solvent-based products and 4 cycles are taken into account. Tier 2: 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. 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). Nevertheless: Taking into account the small pack sizes (20 L-25 L tin cans of the biocidal product are used in industrial/professional settings) a manual mixing and loading step is assumed. Please see combined scenario for industrials as well as scenario 3b.		
	Parameters	**Value**
Tier 1	Active substance content in the product	0.25%
	Body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/h
	Exposure duration[2, 6]	4 cycles/day 60 min/cycle
	Indicative hand exposure[2] (Inside used gloves; solvent-based product)	260 mg b.p./cycle
	Indicative body exposure[2] (solvent-based product)	158 mg b.p./cycle

	Indicative inhalation exposure[3]	0.6 mg/m³
	Dermal absorption	70%
	Inhalative absorption[4]	100%
Tier 2	Coated coverall[5]	90% protection (10% penetration)

[1] ECHA 2017a, HEAdhoc recommendation no 14, Appendix A
[2] ECHA 2020, HEAdhoc recommendation no 6, scenario 19
[5] EC 2013, HEEG opinion 18, page 5
[4] ECHA 2017b, page 194
[5] EC 2010b, HEEG opinion 9, page 3
[6] EC 2009, HEEG opinion 8, page 2

Calculations for Scenario [1]

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

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

Summary table: systemic exposure for industrial automated (and fully automated) dipping [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [1] adult	Tier 1 / gloves	**Permethrin**	0.0001	0.0488	n.a.[1]	**0.0489**
Scenario [1] adult	Tier 2 / gloves and coated coverall	**Permethrin**	See above (Tier 1)	0.0322	n.a.[1]	**0.0323**

[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.

Combined scenarios - industrials

Summary table: combined systemic exposure from industrial use					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**Dermal**	**oral**	**total**
Scenarios [1 + 3b], Tier 2/1	**Permethrin**	0.0001	0.0334	n.a.[1]	**0.0335**

[1]n.a. not assessed

Professional exposure

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

Scenario [2a] – Primary exposure during application by brushing

Description of Scenario [2a] Brush application by professionals/industrial use
The biocidal product LIGNEX DEFEND may be applied by professionals/industrials 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, version 4 scenario no. 23 for 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 2a: 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. Tier 2b: Due to a potential combination of surface treatment (brushing, spraying) with borehole pressure impregnation in case of curative treatment, a protection factor of 90%

for body exposure when wearing coated coveralls was added This estimation covers industrial as well as professional use.		
	Parameters	**Value**
Tier 1	Concentration of substance in product	0.25%
	Body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/h
	Exposure duration[2]	240 min
	Indicative value hands[2]	0.5417 mg/m²
	Indicative value body[2]	0.2382 mg/m²
	Indicative value inhalation (non-volatile compounds)[2]	0.0016 mg/m^2 treated surface
	Inhalative absorption[3]	100%
	Dermal absorption of permethrin	70%
Tier 2a	Protective gloves[4]	90% protection (10% penetration)
Tier 2b	Coated coverall[5]	90% protection (10% penetration)
[1] ECHA 2017, HEAdhoc recommendation no 14, Appendix A [2] ECHA 2020, HEAdhoc recommendation no 6, scenario 23 [3] ECHA, 2017b, page 194 [4] EC 2010b, HEEG opinion 9, page 4 [5] EC 2010b, HEEG opinion 9, page 3		

Calculations for Scenario [2a]

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

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

Remark: as indicative values are normalized to 1% active substance the values for "concentration of substance in product" have to be used unitless ("0.25" for permethrin").

Summary table: Professional/industrial brushing [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [2a] adult	Tier 1 / no PPE	**Permethrin**	0.0002	0.0719	n.a.[1]	**0.0721**
	Tier 2a / protective gloves	**Permethrin**	See above (Tier 1)	0.0269	n.a.[1]	**0.0272**
	Tier 2b / protective gloves and coated coverall	**Permethrin**	See above (Tier 1)	0.0072	n.a.[1]	**0.0074**

[1]n.a. not assessed

Scenario [2b] – Washing out of a brush (primary exposure, post-application phase)

Description of Scenario [2b] Washing out of a brush

Professional and industrial users have to wash out the brush after usage. As the biocidal product LIGNEX DEFEND is solvent-based, therefore dermal exposure during cleaning (i.e. washing out) of a brush in the post-application phase is calculated.
Remark: Water-based paints are considered to be washed out of the brush under a running tap.

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	Active substance content in the product	0.25%
	Product density	0.793 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	70%
[1] ECHA 2017, HEAdhoc recommendation no 14, Appendix A [2] EC 2010a, HEEG Opinion 11		

Calculations for Scenario [2b]
Please see HEEG 11 "General Exposure Calculator For Washing Out Of Brushes" for detailed calculations. All output tables are provided in Annex 3.2.

Summary table: Professional/industrial brushing [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [2b] adult	Tier 1 /no PPE	**Permethrin**	n.a.[1]	0.0030	n.a.[1]	**0.0030**

[1]n.a. not assessed

Combined scenario - professionals

Cleaning of brushes is likely to occur on the day of application, therefore combined scenario has been assessed:

Summary table: combined systemic exposure from professional/industrial brushing					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [2a + 2b], Tier 2a/1,	**Permethrin**	0.0002	0.0299	n.a.[1]	**0.0301**

[1]n.a. not assessed

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

Description of Scenario [3a] Manual dipping		
Primary dermal and inhalation exposure occurs when the biocidal product LIGNEX DEFEND is applied by industrials/professionals 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 industrials/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 no. 9 (EC, 2010b), it is assumed that operators wear coated coveralls when handling wet wood preservatives. The indicative value for hand exposure is an 'inside glove' value. Tier 2: 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. Loading of LIGNEX DEFEND 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). Nevertheless: Taking into account the small pack sizes (20 L-25 L tin cans of the biocidal product are used in industrial/professional settings) a manual mixing and loading step is assumed. This is in line with the information provided by the applicant. Please see also scenario 3b. Furthermore, this scenario covers professional and industrial application.		
	Parameters	**Value**
Tier 1	Active substance content in the product	0.25%
	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	70%
Tier 2	Coated coverall[4]	90% protection (10% penetration)

[1] ECHA 2017, HEAdhoc recommendation no 14, Appendix A
[2] ECHA 2020, HEAdhoc recommendation no 6, scenario 22, page 22
[3] ECHA 2017b, page 194
[4] EC 2010b, 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/industrial manual dipping [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [3a] adult	Tier 1 / gloves	**Permethrin**	0.0000	0.1782	n.a.[1]	**0.1782**
Scenario [3a] adult	Tier 2 / gloves and coated coverall	**Permethrin**	See above (Tier 1)	0.0381	n.a.[1]	**0.0381**

[1]n.a. not assessed

Scenario [3b] – Primary exposure during manual mixing and loading as well as in the post-application phase (manual draining and reloading)

Description of Scenario [3b] Manual mixing and loading, draining and reloading after manual dipping		
Primary dermal exposure occurs during manual mixing and loading and 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 mixing and loading (1 loading/day; HEAdhoc no. 6, page 20) and 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 3a and scenario 1 respectively. According to the model, dermal exposure (hands) is foreseen, while inhalation exposure to aerosols is not considered to be relevant. For acute exposure: as a worst case 3 loadings per day are assumed (1 loading for mixing and loading, 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, resulting in 1.44 loadings/day (1 loading/day M&L + 0.44 loadings/day post-application phase). For industrial combined exposure: Due to the small pack sizes one manual mixing and loading step is calculated. Please see scenario 1 as well as combined scenario for industrials. Post application steps are already included in scenario 1. Taking into account the product density of 793 mg/mL a value of 396.8 mg/loading is used (793 mg/mL * 0.5 mL/loading). The indicative value for hand exposure (0.5 mL b.p./loading) is without protective gloves. In order to be in line with scenario 3a 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	0.25%
	Body weight[1]	60 kg
	Indicative exposure[2] (without gloves)	0.5 mL b.p/loading referring to 396.8 mg/loading
	Product density	0.793 g/m
	Number of loadings per day[2] (chronic)	1.44 loadings/day
	Number of loadings per day[2] (acute)	3 loadings/day

	Number of loadings per day[2] (calculated for combined exposure)	1 loading/day
	Dermal absorption	70%
	Protective gloves[3]	90% protection (10% penetration)

[1] ECHA 2017, HEAdhoc recommendation no 14, Appendix A
[2] ECHA 2020, HEAdhoc recommendation no 6, scenario 22, page 20 - 24
[3] EC 2010b, 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/industrial manual dipping – pre- and post-application phase [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [3b] Adult - chronic	Tier 1 / gloves	**Permethrin**	n.a.[1]	0.0017	n.a.[1]	**0.0017**
Scenario [3b] Adult - acute	Tier 1 / gloves	**Permethrin**	n.a.[1]	0.0035	n.a.[1]	**0.0035**
Scenario [3b] Adult – chronic	Tier 1 / gloves	**Permethrin**	n.a.[1]	0.0012[2]	n.a.[1]	**0.0012**[2]

[1]n.a. not assessed
[2]calculated for combined industrial exposure.

Combined scenario – professionals

Pre-application, application and post-application working tasks are likely to occur on the day of application, therefore combined scenario has been assessed:

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 acute], Tier 2/1,	**Permethrin**	0.0000	0.0381	n.a.[1]	**0.0416**

[1]n.a. not assessed

Scenario [4a] – Primary exposure during application by spray treatment

Description of Scenario [4a] Low pressure spray		
Primary dermal and inhalation exposure occurs when the biocidal product LIGNEX DEFEND is applied by industrials/professionals via low-pressure spraying (hand-held device, 1-3 bar). This scenario is based on the scenario available in HEAdhoc recommendation no. 6, version 4 scenario no. 3 for the assessment of professional coarse spraying of hard surfaces ("Spraying Model 1"). As a worst case potential hand exposure values without protective gloves are used for tier 1. Exposure time is 120 minutes, as agreed during the HEAdhoc-1-2016 meeting. According to the information provided in ECHA, 2015b (p. 204) mixing and loading is included. Although the model is originally for indoor and outdoor insecticide use, in ECHA 2015b it is stated that *"the model may also apply to other operations involving application via hand-held compression sprayers".* This complies with the information provided by the applicant. Tier 2: Indicative hand exposure values inside (as provided in spraying model 1) were used for refinement. Additionally a protection factor of 95% was used as a reasonable and conservative default value to convert the potential to actual body exposure when wearing impermeable coveralls, according to HEEG Opinion 9. Due to the classification of the biocidal product an RPE has to be worn. Therefore an RPE with a protection factor of 10 was taken into account.		
	Parameters	**Value**
Tier 1	Concentration of substance in product	0.25%
	Body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/h
	Exposure duration[2]	120 min
	Potential hand exposure[2] (without gloves)	181 mg b.p/min

	Indicative value body[2]	92 mg b.p/min
	Indicative value inhalation (non-volatile compounds)[2]	104 mg/m^3
	Inhalative absorption[3]	100%
	Dermal absorption	70%
Tier 2	Indicative hand exposure[2] (inside gloves)	10.7 mg b.p./min
	Clothing penetration (impermeable coverall)[4]	95% protection (5% penetration)
	RPE[5]	Protection factor 10

[1] ECHA 2017, HEAdhoc recommendation no 14, Appendix A
[2] ECHA 2020, HEAdhoc recommendation no 6, scenario 3
[3] ECHA 2017b, page 194
[4] EC 2010b, HEEG opinion 9, page 3
[5] ECHA 2015b, p. 154, Table A

Calculations for Scenario [4a]

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

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

Summary table: systemic exposure for professional/industrial low pressure spraying[mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [4a] adult	Tier 1 / no PPE	**Permethrin**	0.0108	0.9555	n.a.[1]	**0.9663**
Scenario [4a] adult	Tier 2 / gloves, impermeable coverall and RPE	**Permethrin**	0.0011	0.0534	n.a.[1]	**0.0546**

[1]n.a. not assessed

Scenario [4b] – Primary exposure during cleaning of spray equipment

Description of Scenario [4b] Cleaning of spray equipment		
Post-application dermal exposure occurs when the spray equipment is cleaned by industrials/professionals after spray application of LIGNEX DEFEND (see scenario 4a). No inhalation exposure is assumed during this scenario according to HEAdhoc recommendation no. 4. This scenario is based on information provided in HEAdhoc recommendation no. 4. It is considered to provide the most appropriate available input values for this task. The cleaning process is performed at the end of each working day and a maximum duration is expected to be 20 min. Tier 2: As professionals are expected to wear appropriate gloves and to be in line with scenario 4a a protection factor of 90% for potential hand exposure was taken into account. Furthermore professionals are expected to still wear the impermeable coverall, therefore a protection factor of 95% for body exposure was taken into account.		
	Parameters	**Value**
Tier 1	Concentration of substance in product	0.25%
	Body weight[1]	60 kg
	Exposure duration[2]	20 min/day
	Product density	0.793 g/ml (=0.793 mg/µl)
	Indicative value hands[2] (without gloves)	35.87 µL/min → 28.44 mg/min
	Indicative value body[2]	19.28 µL/min → 15.29 mg/min
	Dermal absorption	70%
Tier 2	Protective gloves[3]	90% protection (10% penetration)
	Clothing penetration (impermeable coverall)[4]	95% protection (5% penetration)
[1] ECHA 2017, HEAdhoc recommendation no 14, Appendix A [2] ECHA 2020, HEAdhoc recommendation no 4 [3] EC 2010b, HEEG opinion 9, page 4 [4] EC 2010b, HEEG opinion 9, page 3		

Calculations for Scenario [4b]

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

Summary table: systemic exposure for cleaning of spray equipment [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [4b] adult	Tier 1 / no PPE	**Permethrin**	n.a.[1]	0.0255	n.a.[1]	**0.0255**
Scenario [4b] adult	Tier 2 / gloves	**Permethrin**	n.a.[1]	0.0021	n.a.[1]	**0.0021**

[1]n.a. not assessed

Combined scenario – professionals

Spraying and cleaning of spray equipment are expected to happen on the same day, therefore combined scenario has been assessed:

Summary table: combined systemic exposure from professional/industrial spraying and cleaning of spray equipment					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [4a + 4b], Tier 2/2,	**Permethrin**	0.0011	0.0555	n.a.[1]	**0.0566**

[1]n.a. not assessed

Scenario [5] – Primary exposure during application by borehole pressure impregnation (injection)

Description of Scenario [5] Professional borehole pressure impregnation		
Primary dermal and inhalation exposure occurs when the biocidal product LIGNEX DEFEND is applied by professionals via borehole pressure impregnation. This scenario is based on the scenario available in HEAdhoc recommendation no. 6, version 4 scenario no. 26 for the assessment of professional using a PT 8 ("Subsoil treatment Model 2"). Indicative body exposure values for the model are to be found in Biocides Human Health Exposure Methodology (ECHA, 2015b, p. 203). In the model the biocidal product is applied to the drills using a wood injector (pressure impregnation). Mixing and Loading is included into the model and hand exposure is actual exposure inside gloves. 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.		
	Parameters	**Value**
Tier 1	Concentration of active substance in product	0.25%
	Body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/h
	Exposure duration[2]	80 min
	Indicative hand exposure[2] (inside gloves)	8.0 mg b.p/min
	Indicative body exposure[3]	25.8 mg b.p/min
	Indicative inhalation exposure[2]	0.57 mg/m^3
	Inhalative absorption[4]	100%
	Dermal absorption rate of substance	70%
Tier 2a	Coated coverall[5]	90% protection (10% penetration)
[1] ECHA 2017, HEAdhoc recommendation no 14, Appendix A [2] ECHA 2020, HEAdhoc recommendation no 6, scenario 26 [3] ECHA 2015b, p. 203 [4] ECHA 2017b, page 194 [5] EC 2010b, HEEG opinion 9, page 3		

Calculations for Scenario [5]

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

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

Summary table: systemic exposure for professional borehole pressure impregnation [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [5] adult	Tier 1 / gloves	**Permethrin**	0.0000	0.0789	n.a.[1]	**0.0789**
Scenario [5] adult	Tier 2 / gloves and coated coverall	**Permethrin**	See above (Tier 1)	0.0247	n.a.[1]	**0.0247**

[1]n.a. not assessed

Scenario [6] – Primary exposure during application by borehole impregnation (pressure less)

Description of Scenario [6] Borehole impregnation		
Primary dermal exposure occurs when the biocidal product LIGNEX DEFEND is applied by professionals via pressure less borehole impregnation. Only dermal exposure is considered relevant for non-volatile compounds. The assessment of vapour is negligible, since the a.s. is not volatile. In this application the wood preservatives is funnelled into boreholes several drillings are applied. This scenario is based on the scenario available in HEAdhoc recommendation no. 6, version 4, scenario no. 25 for the assessment of professional using a PT 8 ("Mixing and loading Model 4"). The model considers application and mixing and loading. Tier 2: Although tier 1 already showed acceptable exposure risk, professionals are expected to wear appropriate gloves during application of biocidal products. Therefore a protection factor of 90% was used according to HEEG Opinion 9.		
	Parameters	**Value**
Tier 1	Concentration of active substance in product	0.25%
	Body weight[1]	60 kg
	Dermal absorption rate of substance	70%
	Number of assumed loadings[2]	100 boreholes/day
	Indicative hand exposure values[2]	10 mg/loading
Tier 2	Protective gloves[3]	90% protection (10% penetration)
[1] ECHA 2017, HEAdhoc recommendation no 14, Appendix A [2] ECHA 2020, HEAdhoc recommendation no 6, scenario 25 [3] EC 2010b, HEEG opinion 9, page 4		

Calculations for Scenario [6]

$$Potential\ hands\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = Indicative\ exposure\ value\ \left[\frac{mg}{loading}\right] \times \frac{dermal\ abs.\,[\%]}{100} \times \frac{conc.substance\ in\ product\ [\%]}{100} \times \frac{gloves\ penetration\ [\%]}{100} \times number\ of\ loadings\ \left[\frac{1}{day}\right] \times \frac{1}{body\ weight\ [kg]}$$

Summary table: systemic exposure for professional borehole pressure less impregnation [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [6] adult	Tier 1 / no PPE	**Permethrin**	negligible	0.0292	n.a.[1]	**0.0292**
Scenario [6] adult	Tier 2 / gloves	**Permethrin**	negligible	0.0029	n.a.[1]	**0.0029**

[1]n.a. not assessed

Scenario [7] – Secondary exposure during professional sanding of treated wood posts

Description of Scenario [7] Professional sawing/sanding of treated wood
Secondary exposure occurs during sanding or sawing of treated wood. The application rate is given with 238 g biocidal product per square meter (300 mL/m² x 0.793 g/mL), representing a worst case (maximum amount for curative treatment). 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: Permethrin: 238 g/m^2 x 0.25% = 0.595 g/m^2 → 0.0595 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 as well as 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.

	Parameters	**Value**
Tier 1	Application rate of product	238 g/m^2
	Concentration of active substance in product	0.25%
	Amount of active substance on surface	0.0595 mg/cm^2
	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 substance	70%
	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, 2015b
[2] EC 2002c, Part 3, p. 37
[3] ECHA 2017, HEAdhoc recommendation no 14, Appendix A
[4] ECHA 2021, Technical Agreement for Biocides, page 21
[5] ECHA 2017b, page 194
[6] ECHA 2015c, HEAdhoc recommendation No 5
[7] ECHA 2015b, page 171, Table

Calculations for Scenario [7]

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

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

Summary table: systemic exposure for professional sawing/sanding of treated wood [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [7] adult	Tier 1 /no PPE	**Permethrin**	0.0001	0.1138	n.a.[1]	**0.1140**
Scenario [7] adult	Tier 2 /no PPE	**Permethrin**	See above (Tier 1)	0.0034	n.a.[1]	**0.0035**

[1]n.a. not assessed

Calculations for Scenario [2a; 2b; 3a; 3b; 4; 5; 6; 7]

Please see Annex 3.2 for detailed calculations.

Further information and considerations on scenario [2a; 2b; 3a; 3b; 4; 5; 6; 7]

Please see detailed description of respective scenario.

Combined scenario - professionals

Due to the potential combination of superficial treatments with borehole impregnation methods following combined uses were considered.

Summary table: combined systemic exposure from professional brushing and professional borehole pressure impregnation					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [2a + 2b + 5], Tier 2b/1/2,	**Permethrin**	0.0002	0.0351	n.a.[1]	**0.0353**

[1]n.a. not assessed

Non-professional exposure

Scenario [8a] - Primary exposure during application by brush treatment

Description of Scenario [8a] Brush application by non-professionals		
LIGNEX DEFEND biocidal product 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 indoors or 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 based on waterborne products it is considered as the best approximation of a realistic worst case. 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: 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: According to the applicant and as clearly indicated on the label provided by the applicant the maximum treatable area for indoor use is 3 m^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. Thus, for 3 m^2 an application duration of 23 min may be assumed, which was rounded up to 30 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	0.25%
	Body weight[1]	60 kg
	Inhalation rate[1]	1.25 m^3/h
	Inhalative absorption[4]	100%
	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/m^3
	Outdoor indicative exposure value body[2]	16.9 mg/min
	Outdoor indicative exposure value of hands (no gloves)[2]	5.91 mg/min
	Outdoor indicative inhalative exposure value [2]	1.63 mg/ m^3
	Exposure duration outdoor[3]	155 min
	Exposure duration indoor	30 min
	Dermal absorption	70%
[1] ECHA 2017, HEAdhoc recommendation no 14, Appendix A [2] ECHA 2015b, page 216 [3] EC 2002b, Part 2, page 78 [4] ECHA 2017b, page 194		

Calculations for Scenario [8a]

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

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

Summary table: Non-professionals brushing indoors[mg/kg bw/incident]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [8a] adult	Tier 1 /no PPE	**Permethrin**	0.0001	0.1625	n.a.[1]	**0.1626**

[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 [8a] adult	Tier 1 /no PPE	**Permethrin**	0.0002	0.1031	n.a.[1]	**0.1033**

[1]n.a. not assessed

Scenario [8b] – Primary exposure during the post-application phase (washing out of a brush)

Please refer to scenario 2b. No PPEs are considered.

Remark: Potential exposure values are acute, not chronic as in scenario 2b.

Combined scenarios

Cleaning of brushes is likely to occur on the day of application, therefore combined scenario has been assessed:

Summary table: combined systemic exposure non-professionals brushing and washing the brush					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [8a outdoor + 8b], Tier 1/1	**Permethrin**	0.0002	0.1061	n.a.[1]	**0.1063**

[1]n.a. not assessed

Summary table: combined systemic exposure non-professionals brushing and washing the brush					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [8a indoor + 8b], Tier 1/1	**Permethrin**	0.0001	0.1655	n.a.[1]	**0.1656**

Calculations for Scenario [8a; 8b]

Please see Annex 3.2 for detailed calculations.

Further information and considerations on scenario [8a; 8b]

Please see detailed description of respective scenario.

Exposure of the general public

Scenario [9] – Secondary exposure during non-professional sanding of treated wood posts

Please refer to Scenario 7, professional sawing and sanding. Scenario 7 covers non-professional sawing and sanding as no PPE is taken in account.

Remark: Potential exposure values are acute, not chronic as in Scenario 7.

Scenario [10] – Secondary exposure - toddler chewing preserved timber off-cuts

Description of Scenario [10] Mouthing of treated wood chips

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 4 x 4 x 1 cm (corresponding to 16 cm^3 and 48 cm^2) is chewed.

Tier 1: As a worst case it is assumed that whole surface of wood piece (48 cm^2) is covered evenly with wood preservative. Thereby, substances are extracted by chewing. Oral absorption is 100%. For exposure assessment curative application rate of 238 g/m^2 (300 mL/m^2 x 0.793 g/mL) were used for calculations as worst case.

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.

The amount of active substance on surface is calculated as follows:
Permethrin: 238 g/m^2 x 0.25% = 0.595 g/m^2 → 0.0595 mg/cm^2

	Parameters	**Value**
Tier 1	Application rate product	238 g/m^2
	Concentration of substance in product	0.25%
	Amount of active substance on surface	0.0595 mg/cm^2
	Size of wood chip (4 x 4 x 1 cm)[1]	16 cm^3
	Surface of wood chip[1] (4 x 4 x 2 + 4 x 1 x 4 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%

[1] EC 2002a, page 50ff; This guidance document was partly used as this scenario was not described in ECHA, 2015b.

[2] ECHA 2017, HEAdhoc recommendation no 14, Appendix A

Calculations for Scenario [10]

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

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 [10] toddler	Tier 1 /no PPE	**Permethrin**	n.a.[1]	n.a.[1]	0.0286	**0.0286**

[1]n.a. not assessed

Scenario [11] – Secondary exposure - dermal contact of toddler to treated surfaces

Description of Scenario [11] Dermal contact to treated surfaces
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 curative application rate of 238 g/m² (300 mL/m² x 0.793 g/mL) 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. The amount of active substance on surface is calculated as follows: Permethrin: 238 g/m² x 0.25% = 0.595 g/m² → 0.0595 mg/cm² Tier 1: The realistic worst case is based on the assumption that a toddler is playing daily outdoors on a playground structure made of treated wood (chronic). 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.

Tier 1	**Parameters**	**Value**
	Application rate product	238 g/m²
	Concentration of substance in product	0.25%
	Amount of active substance on surface	0.0595 mg/cm²
	Body weight toddler[1]	10 kg
	Hand surface area[1]	115.2 cm²
	Contaminated hand surface area[2]	40%
	Playing events[3]	1 / day
	Dermal absorption (not used, please see description above)	70%
	Oral absorption rates	100%
Tier 2	Transfer factor (dislodgeable residues)[4]	3%

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

Calculations for Scenario [11]

$$\frac{Dermal}{Oral}\, systemic\ exposure, tier\ 1\ \left[\frac{mg}{kg\ bw\ day}\right]$$

$$= amount\ of\ active\ substance\ on\ surface\ \left[\frac{mg}{cm^2}\right] * hand\ surface\ area\ [cm^2]$$

$$* \frac{Contamination\ hand\ surface\ area\ [\%]}{100} * \frac{Oral\ absorption\ (dermal\ absorption)\ [\%]}{100}$$

$$* Frequency\ \left[\frac{1}{day}\right] * \frac{1}{body\ weight\ [kg]}$$

Summary table: systemic exposure for general public from dermal contact to treated surfaces [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [11] toddler	Tier 1 /no PPE	**Permethrin**	n.a.[1]	**-**[2]	0.2742	**0.2742**
Scenario [11] toddler	Tier 2 /no PPE	**Permethrin**	n.a.[1]	**-**[2]	0.0082	**0.0082**

[1]n.a. not assessed
[2]worst case: all exposure oral; see description of scenario [11]

Scenario [12] - Secondary exposure via inhalation of volatilised residues

Description of Scenario [12] Inhalation of volatilised residues
Inhalation of volatilised residues: toddler inhaling volatilised residues from treated timber indoors. As worst case 24h/day of inhalation exposure is assumed. This scenario also covers children and adults. According to the HEEG Opinion 13 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 m³/24 h and body weight of 10 kg) representing the worst case, is ≤1: $$0.328 \bullet \frac{MW(g/mol) \bullet VP(Pa)}{AEL_{long-term}} \leq 1$$ This is true for Permethrin (0.0055). Therefore long-term exposure to volatilised residues is negligible for adults, infants and children for this a.s. and no further calculations are performed.

Calculations for scenario [9; 10; 11; 12]

Please see Annex 3.2 for detailed calculations.

Further information and considerations on scenario [9; 10; 11; 12]

Please see detailed description of respective scenario.

Combined scenarios

Summary table: combined systemic exposure non-professional uses					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [8a outdoor + 8b + 9], Tier 1/1/2	**Permethrin**	0.0003	0.1095	n.a.[1]	**0.1098**

[1]n.a. not assessed

Summary table: combined systemic exposure non-professional uses					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [8a indoor + 8b + 9], Tier 1/1/2	**Permethrin**	0.0002	0.1689	n.a.[1]	**0.1691**

Summary table: combined systemic exposure for general public					
Scenarios combined	**Estimated uptake [mg/kg bw/day]**				
		inhalation	**dermal**	**oral**	**total**
Scenarios [10+11] toddler, Tier 1/2	**Permethrin**	n.a.[1]	-[2]	0.0368	**0.0368**

[1]n.a. not assessed
[2]cf. to explanation in scenario [11]

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 RMMs 'Do not use on wood which may come in direct contact with food, feed and livestock.' and '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 which may come in direct contact with food, feed and livestock.

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.

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

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/day]**
			Permethrin
[1]	*Industrials*	*Tier 1 / gloves*	**0.0489**
		Tier 2 / gloves, coated overall	**0.0323**
[1+3b]	*Industrials*	*Tier 2/1 gloves / coated overall*	**0.0335**
[2a]	*Professionals/Industrials*	*Tier 1 / no PPE*	**0.0721**
		Tier 2 a / protective gloves	**0.0272**
		Tier 2b / protective gloves and coated coverall	**0.0074**
[2b]	*Professionals/Industrials*	*Tier 1 / no PPE*	**0.0030**
[2a+2b]	*Professionals/Industrials*	*Tier 2a / 1 gloves / no PPEs*	**0.0301**
[3a]	*Professionals/Industrials*	*Tier 1 / gloves*	**0.1782**
		Tier 2 / gloves and coated coveralls	**0.0381**
[3b] chronic	*Professionals/Industrials*	*Tier 1 / gloves*	**0.0017**
[3b] acute	*Professionals/Industrials*	*Tier 1 / gloves*	**0.0035**
[3a+3b acute]	*Professionals/Industrials*	*Tier 2 / 1 gloves and coated coveralls / gloves*	**0.0416**
[4a]	*Professionals/Industrials*	*Tier 1 / no PPE*	**0.9663**
		Tier 2 / gloves, impermeable coverall and RPE	**0.0546**
[4b]	*Professionals/Industrials*	*Tier 1 / no PPE*	**0.0255**
[4b]	*Professionals/Industrials*	Tier 2 / gloves	**0.0021**
[4a+4b]	*Professionals/Industrials*	*Tier 2 / 2 gloves, impermeable coverall / RPE and gloves*	**0.0566**
[5]	*Professionals*	Tier 1 / gloves	**0.0789**
		Tier 2 / gloves and coated coverall	**0.0247**
[6]	*Professionals*	Tier 1 / no PPE	**0.0292**
		Tier 2 / gloves	**0.0029**

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/day]**
			Permethrin
[7]	*Professionals*	Tier 1 /no PPE	**0.1140**
		Tier 2 /no PPE	**0.0035**
[2a+2b+5]	*Professionals*	Tier 2b / 1 / 2 protective gloves and coated coverall / no PPE / gloves and coated coverall	**0.0353**
[8a]	*Non-professionals*	Tier 1 /no PPE - indoor	**0.1626**
		Tier 1 /no PPE - outdoor	**0.1033**
[8b]	*Non-professionals*	Please see scenario [2b]	**---**
[8a outdoor+8b]	*Non-professionals*	Tier 1/1 no PPE	**0.1063**
[8a indoor+8b]	*Non-professionals*	Tier 1/1 no PPE	**0.1656**
[9]	*Non-professionals*	Please see scenario [7]	**---**
[10]	*General public*	Tier 1 /no PPE	**0.0286**
[11]	*General public*	Tier 1 /no PPE	**0.2742**
		Tier 2 /no PPE	**0.0082**
[12]	*General public*	Tier 1 → exposure negligible	**n.r.**
[8a outdoor+8b+9]	*Non-professionals*	Tier 1 / 1 / 2 no PPE	**0.1098**
[8a indoor+8b+9]	*Non-professionals*	Tier 1 / 1 / 2 no PPE	**0.1691**
[10+11]	*General public*	Tier 1 / 2 no PPE	**0.0368**

2.2.6.3 Risk characterization for human health

Reference values to be used in Risk Characterisation (from CAR of permethrin, Ireland 2014)

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
$AEL_{short\text{-}term}$	Rat 2 year oral study (acute effect)	59.46 mg/kg bw/day	100	No[2]	0.5 mg/kg bw/day
$AEL_{medium\text{-}term}$	12-month dog study	5 mg/kg bw/day	100	No[2]	0.05 mg/kg bw/day
$AEL_{long\text{-}term}$	12-month dog study	5 mg/kg bw/day	100	No[2]	0.05 mg/kg bw/day
ARfD	90-day inhalation rat	59.46 mg/kg bw/day	100	No[2]	0.5 mg/kg bw/day
ADI	Chronic rat study	5 mg/kg bw/day	100	No[2]	0.05 mg/kg bw/day

[1] Inter/Intra species variation.

[2] According to the respective CAR: Permethrin: Extensive and rapid. Only between 3 and 6% of the administered dose is being recovered unmetabolised in faeces. The Guidance on BPR: Volume III Parts B+C (ECHA, 2017b) states that "… when oral absorption rate exceeds 80%, the default value of 100% should be applied for the derivation of AELs and internal exposure levels." Consequently, oral absorption is assumed to be 100%.

Maximum residue limits or equivalent

MRLs are not relevant for this biocidal product as the product 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, 2017) 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 LIGNEX DEFEND is not classified as irritating/corrosive or as sensitising a risk assessment for these local effects is not required.

The SoC Naphtha (petroleum), hydrotreated heavy (Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics) is classified for Asp. Tox. 1 and EUH066. According to the Guidance on BPR: Volume III Parts B+C (ECHA, 2017b) "Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products" both hazard classifications are assigned to Band A. According to the guidance document it is considered sufficient to apply appropriate P-phrases associated with the concerned H-phrase. Additionally, when the proposed RMMs 'Ensure adequate ventilation during and after the application, until treated surfaces have dried.' and for non-professional users 'Apply the product only to small indoor surfaces and objects. Treat max. 3 m².' are implemented, the intended uses do not lead to concern for the users.

The biocidal product 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. Furthermore, the use instruction 'After application, wash hands and face thoroughly with water and soap.' added by the applicant, additionally prevents prolonged, unintentional dermal contact to the biocidal product after application.

Risk for industrial users

Systemic effects

Task/ Scenario	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] automated dipping	1 / gloves	5	0.05[1]	0.0489	97.80	Yes
	2 / gloves and coated coverall	5	0.05[1]	0.0323	64.60	Yes
Scenario [3b] Draining and reloading after dipping – chronic[2]	1 / gloves	5	0.05[1]	0.0012	2.40	Yes

[1] $AEL_{long\ term}$

[2] calculated for combined industrial exposure (combination with scenario 1 automated dipping)

Combined scenarios

Task/ Scenario	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 + 3b]	2/1	5	0.05[1]	0.0355	67.00	Yes

[1] $AEL_{long\ term}$

The occupational risk assessment for the biocidal product takes into account systemic effect of the active substance permethrin. Exposure of industrial users to biocidal products generally takes place via the inhalation and/or dermal route. The basis for the risk characterization of biocidal products are internal reference values (AELs). The quantitative risk characterization for professional users takes into account the $AEL_{long\text{-}term}$ of permethrin (0.05 mg/kg bw/d) as reference value.
A risk for industrial users referring to the active substance permethrin resulting from the use of the biocidal product is unlikely if the risk characterization for each scenario results in

an estimated uptake of the a.s. of less than 100% of the $AEL_{long\text{-}term}$. Industrial users are expected to follow a minimum of instructions.
Scenario 1 "automated dipping" would already result in an acceptable risk in tier 1. Exposure during loading operations of biocidal product in industrial/professional settings is expected to be very low. Therefore, exposure during fully-automated transfer/pumping is expected to be negligible. Nevertheless, taking into account the small pack sizes (20 L-25 L tin cans of the biocidal product are assumed to be used in industrial/professional settings) a manual Mixing and Loading step is assumed as represented by scenario 3b. The combination of both scenarios results in an acceptable risk when gloves and a coated coverall (tier 2) as PPEs are used for scenario 1 "automated dipping". Therefore, protective gloves and coated coverall as PPE should be used to obtain safe use for application via automated dipping.

The risk assessment for other scenarios concerning industrial users is covered by the risk assessment of the same scenarios for professional users as presented in the section bellow. For details refer to this section.

Risk for professional users

Systemic effects

Task/ Scenario	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 [2a] Brushing	1 / no PPE	5	0.05[1]	0.0721	144.20	No
	2a / protective gloves	5	0.05[1]	0.0272	54.40	Yes
	2b / protective gloves and coated coverall	5	0.05[1]	0.0074	14.80	Yes
Scenario [2b] Washing brush	1 / no PPE	5	0.05[1]	0.0030	6.00	Yes
Scenario [3a] Manual dipping	1 / gloves	5	0.05[1]	0.1782	356.40	No
	2 / gloves and coated coverall	5	0.05[1]	0.0381	76.20	Yes
Scenario [3b] Draining and reloading after dipping – chronic	1 / gloves	5	0.05[1]	0.0017	3.40	Yes

Scenario [4a] low pressure spraying	1 / no PPE	5	0.05[1]	0.9663	1932.60	No
	2 / gloves, impermeable coverall and RPE	5	0.05[1]	0.0546	109.20	No
Scenario [4b] cleaning of spray equipment	1 / no PPE	5	0.05[1]	0.0255	51.00	Yes
	2 / gloves	5	0.05[1]	0.0021	4.20	Yes
Scenario [5] Borehole pressure impregnation	1 / gloves	5	0.05[1]	0.0789	157.80	No
	2 / gloves and coated coverall	5	0.05[1]	0.0247	49.40	Yes
Scenario [6] Pressureless borehole impregnation	1 / no PPE	5	0.05[1]	0.0292	58.80	Yes
	2 / protective gloves	5	0.05[1]	0.0029	5.80	Yes
Scenario [7] Sanding/sawing	1 / no PPE	5	0.05[1]	0.1140	228.00	No
	2 / no PPE	5	0.05[1]	0.0035	7.00	Yes

[1] $AEL_{long\ term}$

Combined scenarios

Task/ Scenario	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 [2a + 2b]	2a/1	5	0.05[1]	0.0301	60.20	Yes
Scenarios [3a + 3b]	2/1	5	0.05[1]	0.0416	83.20	Yes
Scenarios [4a + 4b]	2/1	5	0.05[1]	0.0566	113.20	No
Scenarios [2a + 2b + 5]	2b/1/2	5	0.05[1]	0.0353	70.60	Yes

[1] $AEL_{long\ term}$

Conclusion

Acceptable risk levels for application via brushing are obtained when PPE are prescribed as demonstrated by scenario 2a. Protective gloves should be used to obtain safe use. Dermal exposure during cleaning (i.e. washing out) of a brush is expected, as the biocidal product

is non-water based. Therefore, a combination of scenarios 2a "brushing" and 2b "washing brusher" was calculated.
For scenario 3a "manual dipping" an acceptable risk is obtained in tier 2 by applying protective gloves and coated coverall. The same is true for the combination of "manual dipping" (scenario 3a) with scenario 3b (Mixing and loading, draining and reloading after dipping). An acceptable risk is obtained when gloves and a coated coverall (tier 2) as PPEs are used for scenario 3a "manual dipping".
For application of the biocidal product via borehole pressure impregnation (scenario 5) acceptable risk levels are obtained when protective gloves and coated coverall are used.
A safe use for application via pressureless borehole impregnation (scenario 6) is obtained when protective gloves are prescribed. Although tier 1 already showed acceptable exposure, professionals are expected to wear appropriate gloves during application of biocidal products.
The secondary exposure to professional workers during sanding/sawing of treated wood is assessed in scenario 7. The calculation of the risk through secondary exposure to wood preserved with the biocidal product shows an acceptable risk for workers during sanding of treated wood without PPE.

The application method low-pressure spraying (scenario 4a) did not result in acceptable risk levels in tier 1. Even the use of protective gloves and impermeable coverall in tier 2 do not reduce the risk to an acceptable level. Therefore, the combination of scenario 4a with 4b (cleaning of the spray equipment) also did not result acceptable risk levels. Since the dermal route is the major exposure route for permethrin in the calculated scenario the implementation of PPE for spray application only results in a minor reduction of the estimated uptake of the active substance. Initially a default dermal absorption value of 75% was proposed by the applicant. This value was updated in a later stage of the authorisation process to the default value of 70% for organic solvent-based formulation according to the current EFSA guideline (EFSA, 2017). The dermal absorption of 70% is a very conservative value, but in the absence of further information regarding dermal absorption no additional refinements are possible. Therefore, the application of the biocidal product via low-pressure spraying is not authorised.

Due to the combination of superficial treatments (application via brushing) with borehole impregnation methods as described in Use #4 a combined scenario (2a + 2b + 5) was calculated and the risk assessed. Borehole pressure impregnation represents the worst case as compared to pressureless borehole impregnation a higher exposure is expected. The combination of borehole treatment with brushing was acceptable when protective gloves and coated coverall are prescribed during application of the biocidal product.

Risk for non-professional users

Systemic effects

Task/ Scenario	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 [8a] Brushing outdoor	1 / no PPE	59.46	0.5[1]	0.1033	20.66	Yes

Scenario [8a] Brushing indoor	1 / no PPE	59.46	0.5[1]	0.1626	32.52	Yes
Scenario [8b] Washing brush	1 / no PPE	59.46	0.5[1]	0.0030	0.60	Yes
Scenario [9] Sanding/sawing	1 / no PPE	59.46	0.5[1]	0.1140	22.80	Yes
	2 / no PPE	59.46	0.5[1]	0.0035	0.70	Yes

[1] $AEL_{short\ term}$

Combined scenarios

Task/ Scenario	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 [8a outdoor + 8b + 9] adult	1/1/2	59.46	0.5[1]	0.1098	21.96	Yes
Scenarios [8a indoor + 8b + 9] adult	1/1/2	59.46	0.5[1]	0.1691	33.82	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 assessment calculations for all scenarios for this type of user. For non-professional use no PPEs are foreseen.

The biocidal product is used for the preservation of wood via brushing in Use Class 1, which is only used in interiors. For potential outdoor treatment of wood used in Use Class 1 with the biocidal product prior to its use in interiors, scenario 8a outdoor has been calculated resulting in acceptable risk levels.

According to the applicant the maximum treatable area is 3 m². Under this condition acceptable risk levels for indoor application of the biocidal product via brushing by non-professionals are obtained. Furthermore, the corresponding advice 'Apply the product only to small indoor surfaces and objects. Treat max. 3 m². Curative treatment of load-bearing or stiffening wooden components and larger wooden objects is only allowed to be performed by qualified specialist companies.' has to be added to the instructions for use.

In addition the secondary exposure to non-professional users (scenario 9 "sanding/sawing of treated wood") is assessed. The calculation of the risk through secondary exposure to wood preserved with the biocidal product did not lead to an unacceptable risk for non-professional users during sanding and handling of treated wood.

Furthermore, scenarios 8a indoor or 8a outdoor were combined with scenarios 8b and 9 depicting a combined scenario where a non-professional user applies the biocidal product via brushing, washes out the brush and sands or saws treated wood on the same day. The combination of these scenarios did not lead to an unacceptable risk for non-professional users.

Risk for the general public

The general public can be secondarily exposed to the biocidal product via the oral, dermal and inhalation routes.
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. For further details refer to scenario 12 in section 2.2.6.2.

Systemic effects

Task/ Scenario	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 [10] Toddler chewing wood	1 / no PPE	59.46	0.5[1]	0.0286	5.72	Yes
Scenario [11] Dermal contact to treated surfaces	1 / no PPE	5	0.05[2]	0.2742	548.40	No
	2 / no PPE	5	0.05[2]	0.0082	16.40	Yes

[1] $AEL_{short\ term}$ [2] $AEL_{long\ term}$

Conclusion
For mouthing exposure it was assumed that a toddler picks up and chews a wood off-cut (scenario 10). 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 10 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 11). It is important to mention, that this scenario has several limitations. Wood treated with the biocidal product is used for Use class 1 and thus should not be used for the construction of outdoor playground structures. Therefore, the scenario is highly conservative and has only little significance since a possible risk will be overestimated. Even though the scenario is not very realistic, it is considered as worst case because of lack of a more realistic scenario for this specific Use class. It is also important to clarify, that this scenario depicts a worst case but not a realistic worst case. The exposure assessment for toddlers also represents a worst case for the general public as they are a sensitive sub population. In tier 1 of the scenario it is assumed that all of the contamination of the toddler's hand is ingested during mouthing behavior for the active substance. For tier 2 a transfer coefficient for dislogable residues of 2% was considered. For scenario 11 an acceptable risk at tier 2 was calculated.

In all general public exposure scenarios no exceedance of the corresponding reference values of permethrin was observed and thus the biocidal product is considered safe for the general public.

The exposure assessment for the general public is based on the assumption that only contact to dried residues occur and bystanders are not present during the application. Therefore, the RMMs 'Keep children and pets (especially cats) away from treated surfaces until dried.' and 'No animals or bystanders should be present during the application.' are required.

Risk for consumers via residues in food

When the biocidal product is applied according to the recommended uses, no food, drinking water or livestock exposure is foreseen. Therefore, no risk for consumers via residues in/on food is expected and 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

Human health risk from combined exposure to several active substances or substances of concern within a biocidal product was not assessed.

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." and "No animals or bystanders should be present during the application."
However, cats are more sensitive to pyrethroids like permethrin. Therefore, the access of cats to freshly treated objects and dried treated surfaces has to be avoided and the following RMMs have been added: "Keep children and pets (especially cats) away from treated surfaces until dried." and "N-335: Keep cats away from treated surfaces. Due to their particular sensitivity to permethrin, the product can cause severe adverse reactions in cats."

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The biocidal product is authorised for curative and preventive treatment of timber in use class 1. The mode of application for amateurs and professionals is brushing. For professionals and industrial users the modes of application are dipping, injection and borehole impregnation. Application rates are 120-150 mL/m² for preventive treatment (1 coat) and 300 mL/m² for remedial treatment (2 coats).
The risk assessment for the biocidal product LIGNEX DEFEND is based on the assessment report of the active substance permethrin (Ireland, 2014) and short-term toxicity studies of the biocidal product (see "Summary table-Further Ecotoxicological studies") provided by the applicant. For permethrin in PT 8 and PT 18 a new effect study on additional terrestrial non-target organisms (*Folsomia candida*) was provided (Ireland, 2017). The outcome of the MS e-consultation provided a clear majority opinion to use the new proposed $PNEC_{Soil}$. The new PNEC for soil is 0.175 mg/kg wwt.

The following PNECs were used for the environmental risk assessment:

Summary table on calculated PNEC values for the active ingredient		
Compartment	**Permethrin**	**Unit**
STP	0.00495	mg/L
Freshwater	0.00047	µg/L
Sediment	0.217	µg/kg$_{wwt}$
Soil	0.175	mg/kg$_{wwt}$
Oral, bird	≥16.7	mg/kg food
Oral, small mammal	120	mg/kg food

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 is based on the classification of the active substance. Due to the composition of the biocidal product LIGNEX DEFEND the active substance permethrin, contained in the biocidal product in 0.25%(w/w), is the only component that needs to be considered for the environmental classification of the biocidal product.

The harmonised classification and labelling of the active substance permethrin (ATP 00) for environmental effects is Aquatic Acute 1, H400: Very toxic to aquatic life, M=1000 and Aquatic Chronic 1, H410: Very toxic to aquatic life with long lasting effects.

In the assessment report on Permethrin (Ireland, 2014) a classification of the active substance permethrin with Aquatic Acute 1, M=100; Aquatic Chronic, M=10000 is proposed.

Additionally acute toxicity studies were submitted with the biocidal product LIGNEX DEFEND (see "Summary table-Further Ecotoxicological studies"). As already shown in the toxicity tests submitted for the AR of Permethrin, the most sensitive aquatic species tested were invertebrates (Daphnia magna) with an EC_{50} (48h) of 0.777 mg/L.

Summarised, according to Reg. (EC) No 1272/2008 the biocidal product LIGNEX DEFEND has to be classified and labelled as Aquatic Acute 1, H400: Very toxic to aquatic life and Aquatic Chronic 1, H410: Very toxic to aquatic life with long lasting effects, with the pictogram GHS09, the signal word Warning 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/ Inoculum	End point	Exposure		Results	Remarks	Reference[1]
			Design	Duration	EC_{50}		
Short-term toxicity to fish OECD Guideline 203 (Fish, Acute Toxicity Test), GLP, Reliability 2	*Brachydanio Rerio*	LC50	Static, limit test at 100 mg/L of the test item for 96 hours.	96h	>100 mg/L	N.A	Anonymous, 2016i
Short-term toxicity to aquatic invertebrates, OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test), GLP, Reliability 2	*Daphnia magna*	EC50	Static, organisms have been exposed to 10.00, 4.55, 2.07, 0.94 and 0.43 mg/L test item dilutions of for a total period of 48 hours.	48h	0.777 mg/L	N.A	Anonymous, 2016j
Toxicity to aquatic algae, OECD Guideline 201 (Freshwater Alga and Cyanobacteria, Growth Inhibition Test), GLP, Reliability 2	*Pseudokirchneriella subcapitata*	Inhibition rate	Static, limit test at 100 mg/L of the test item for 72 hours.	72h	17.59%	N.A	Anonymous, 2016k

[1] Please include the reference to IUCLID.

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	All provided short-term toxicity studies are lacking a reliable analytical detection method to quantify the ingredients of the test solution. Nominal concentrations, provided by the applicant were used. However, the short term toxicity tests of the product lead to no change in the environmental classification that was based on the active substance permethrin. Therefore, the biocidal product has to be classified as Aquatic Acute 1 and Aquatic Chronic 1.
Justification for the value/conclusion	Experimental data

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

There was no new data submitted, neither for the active substances nor for the biocidal products.

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

There was no new data submitted, neither for the active substances nor for the biocidal products.

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

There was no new data submitted, neither for the active substances nor for the biocidal products.

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

There was no new data submitted, neither for the active substances nor for the biocidal products.

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

Foreseeable routes of entry into the environment are described in detail in 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)	Remarks	Reference [1]
Aerobic biodegradability, OECD 310:2014, GLP, reliability 3	*Acqueus medium*	*25±2° C*	21.74	82%	*On the basis of results obtained, interpreted according to OECD 310:2014, the test item LIGNEX DEFEND should be considered not biodegradable in aerobic conditions.*	Anonymous, 2016l

[1] Please include the reference to IUCLID.

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. Uncertainties caused by deviations from the guideline in the performance of the tests, inaccurate documentation and the lack of a reliable detection method for the active substance permethrin do not allow any conclusions to be drawn regarding the degradability of permethrin and thus of LIGNEX DEFEND. In addition, it is agreed, that permethrin fulfils the P criterion. The biodegradability of LIGNEX DEFEND is therefore determined considering the degradation behaviour of the active substance permethrin. The active substance is defined as not readily biodegradable according to OECD 301B. No clear evidence on degradation was observed in an effect study on microorganisms in sewage sludge (Ireland, 2014).
Justification for the value/conclusion	Experimental data

Leaching behaviour (ADS)

Product is for interior use only and therefore exposure to environmental compartments is not expected.

In line with statements made within the Revised Emission Scenario Document for Wood Preservatives (ESD) (OECD, 2013), no assessment of in-service losses and risks arising from timber in UC 1 needs to be made as "the potential emissions from treated wood to the outer environment are considered negligible" and as such, environmental risk is considered to be negligible for all compartments.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	distribution and dissipation in soil
Justification	Data on distribution and dissipation for the active substance permethrin in soil are available through Letter of Access. Furthermore, exposure of the environment is considered negligible for application and service life of wood in UC1.

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

Data waiving	
Information requirement	distribution and dissipation in water and sediment
Justification	Data on distribution and dissipation for the active substance permethrin in water and sediment are available through Letter of Access. Furthermore, exposure of the environment is considered negligible for application and service life of wood in UC1.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	distribution and dissipation in air
Justification	Data on distribution and dissipation for the active substance permethrin in air are available through Letter of Access. Furthermore, exposure of the environment is considered negligible for application and service life of wood in UC1.

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

The environmental exposure assessment is based on the Revised Emission Scenario Document for Wood Preservatives (OECD, 2013). Where necessary the Guidance on BPR Vol. IV, Environment, Part B&C (ECHA, 2017c) is also taken into consideration.

General information

Assessed PT	PT 8
Assessed scenarios	none
ESD(s) used	OECD "Revised Emission Scenario Document for Wood Preservatives (OECD, 2013)"
Approach	Qualitative assessment of relevant life cycle steps
Distribution in the environment	Assessed based on the Guidance on BPR Vol. IV, Environment, Part B&C (ECHA, 2017c)
Groundwater simulation	Not applicable
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use (application): Yes Storage: Yes Service life: Yes
Remarks	

Emission estimation

It is accepted in the PT 8 ESD (OECD, 2013) and the Assessment Report for permethrin that in-service leaching losses from timber protected from weather (rain and driven rain) will be negligible and thus no risks to environmental compartments will be expected.

When the product is applied in-situ, then there is potential for losses to floor but, when applied indoors (UC 1), impervious covers would prevent contamination. Alternatively, spills and drips would be wiped up and dried deposits scraped up or sanded: it is expected that all wastes are disposed of to landfill sites. No emissions during application are expected to reach environmental compartments.

The following RMM has to be noted for industrial, professional and non-professional applications taking place outside, for wood in UC 1:

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 tarpoline) and disposed of in a safe way."

In addition wood preservatives containing permethrin might be harmful to non-target species such as bats by direct exposure (e.g. curative treatment of wooden roof frameworks). Therefore, following instruction for use has to be applied:

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

As a consequence, no calculations have been undertaken in this PAR on the basis that application and in-service losses in UC 1 are negligible and risks to environmental compartments are not expected.

Fate and distribution in exposed environmental compartments

No data is available

Primary and secondary poisoning

Primary poisoning
Not required because no environmental exposure is expected.

Secondary poisoning
Not required because no environmental exposure is expected.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: No PEC for permethrin has been determined for risk characterisation in air compartment, since exposure to air is not expected due to the low vapour pressure of permethrin (2.155 x 10-6 Pa at 20°C) and its high adsorption potential. The biocidal product LIGNEX DEFEND is not considered to be of concern for the air compartment.

Sewage treatment plant (STP)

Conclusion: No PEC for permethrin has been determined for risk characterisation for the STP, since emissions from application or service life for treated wood used in use class 1 is considered negligible.

Aquatic compartment

Conclusion: No PEC for permethrin has been determined for risk characterisation for the aquatic compartment, since emissions from application or service life for treated wood used in use class 1 is considered negligible.

Terrestrial compartment

Conclusion: No PEC for permethrin has been determined for risk characterisation for the terrestrial compartment, since emissions from application or service life for treated wood used in use class 1 is considered negligible.

Groundwater

Conclusion: No PEC for permethrin has been determined for risk characterisation for groundwater, since the exposure of groundwater is considered negligible for treated wood used in use class 1.

Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments
Limited use of wood preservatives in UC 1 gives rise to negligible emissions to environmental compartments and thus no mixture toxicity assessment was performed.

Screening Step 2: Identification of relevant substances
No further mixture toxicity assessment was performed

Screening Step 3: Screen on synergistic interactions
Not available

Tiered approach

No further mixture toxicity assessment was performed

Aggregated exposure (combined for relevant emmission sources)

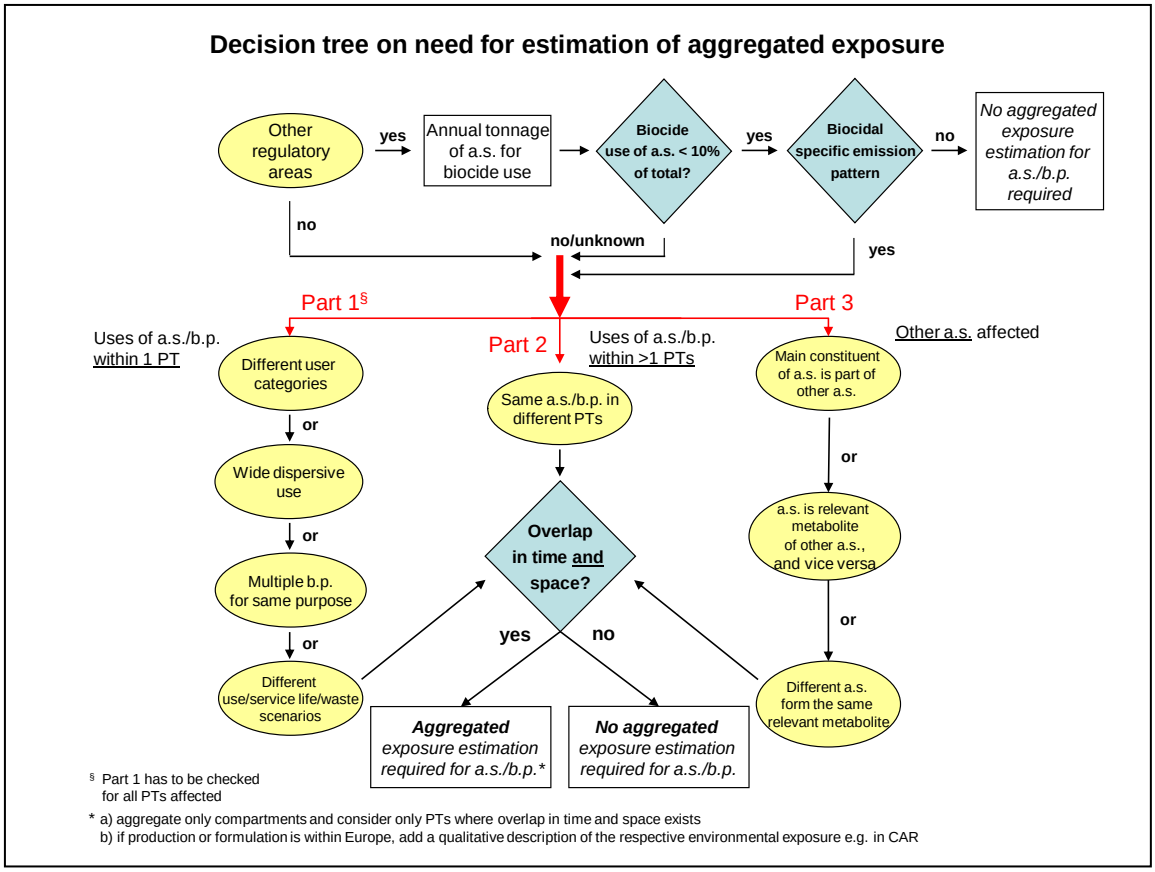


Figure 1: Decision tree on the need for estimation of aggregated exposure

As a first step it has to be evaluated whether an aggregated exposure assessment needs to be conducted or not. Since an exposure to the environment is considered negligible due to the authorised use class (UC 1), an aggregated exposure assessment has not to be performed.

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

No risk characterisation was performed for the environment.

However, the following RMM has to be applied for industrial, professional and non-professional applications taking place outside of wood in UC 1:

N-246, modified "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 tarpoline) and disposed of in a safe way."

For the industrial use of permethrin, according to the Implementing Regulation of permethrin, following RMMs have to be introduced:

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.

The authorised uses of the wood preservative LIGNEX DEFEND (containing 0.25%w/w permethrin) can be considered acceptable when applied by industrial, professional or non-professional users.

Emissions during application and in-service emissions in UC 1 are considered negligible. Therefore, no unacceptable risks for the environment are expected for the intended uses of LIGNEX DEFEND.

2.2.9 Measures to protect man, animals and the environment

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:
Suitable extinguishing agents: CO^2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Extinguishing media unsuitable for safety reasons: Water jet.

2.2.10 Assessment of a combination of biocidal products

The biocidal product LIGNEX DEFEND is not intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

Background
The biocidal product „LIGNEX DEFEND" 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). 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 „LIGNEX DEFEND", 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 authorised 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).

Authorised uses for the relevant biocidal product

The biocidal product „LIGNEX DEFEND" belongs to product type 8 and contains the active substance permethrin. The product is a ready to use solvent-based wood preservative to be used by non-professionals, professionals and industrial users for preventive and curative uses in order to control wood boring beetles (*Hylotrupes bajulus* and *Anobium punctatum*).

Product Type	8
Where relevant, an exact description of the authorised use	---
Target organism(s), development stage	Scientific name: *Hylotrupes bajulus* L. Common name: Wood boring beetles Development stage: larvae Scientific name: *Anobium punctatum* De Geer Common name: Wood boring beetles Development stage: larvae
Field of use	Application: Indoor / outdoor Preservation of wood for use in Use Class 1 (preventive and curative). The product can be used for all parts in wood statically loaded in dry interior rooms
Category(ies) of users	Non-professionals, professionals, industrial
Application method(s)	Non-professionals: Brushing Professionals: injection, borehole impregnation Professionals/industrials: Brushing, dipping (manual/automated/fully automated)

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 authorised 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 authorised in Austria under product type 8 (wood preservatives), based on a significantly lower number of biocidal product/s (families).

Currently in Austria there are only 6 biocidal products with proven efficacy against both target organisms authorised. These are listed in the following table:

Remark: In order to avoid any double usage of biocidal products to control these wood boring beetles these two target organisms are assessed as one.

Product name	**Active substance**	**Target organism**	**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
Vikane	Sulfurylfluorid	*Hylotrupes bajulus, Anobium punctatum, Lyctus brunneus, Bursaphelenchus xylophilus, Cryptotermes cavifrons, Incisitermes minor, Incisitermes snyderi, Neotermes jouteli, Kalotermes approximates, Coptotermes formosanus*	Fumigation	Trained 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
Xyladecor gegen Holzwürmer "Neu"	Cypermethrin	*Reticulitermes sp.; Hylotrupes bajulus Anobium punctatum, Anobium punctatum De Geer*	Professionals: Brushing, borehole injection Non-professionals: brushing, borehole injection Preventive and curative uses.	Non-professionals, professionals

Koratect Ib	Cypermethrin	*Hylotrupes bajulus, Anobium punctatum, Lyctus brunneus*	Brushing, borehole injection Preventive and curative uses.	Professionals
Lignum Woodworm Killer	Permethrin	*Hylotrupes bajulus L., Anobium punctatum De Geer, Lyctus brunneus, Reticulitermes spp.*	Non-professionals: brushing, low pressure spray Professionals: brushing, low pressure spray, injection Preventive and curative uses.	Non-professionals, professionals

Taking a closer look on the already authorised biocidal products against the target organisms it crystallises, that 2 of these contain – amongst others - the active substance propiconazol, which fulfills the exclusion criteria for being reprotoxic 1B. One biocidal product is authorised just for trained professionals with the laborious application method of fumigation. One product is based on permethrin itself and the two remaining biocidal products are based on cypermethrin, which is no CFS nor fulfills exclusion criteria but has the same mode of action as permethrin. In addition the current biocidal product provides a great number of application methods. Thus it becomes the only product for professionals to be authorised for automated/fully automated dipping processes.

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 authorised 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 minimize 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 authorised 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 summarized here, the Austrian Competent Authority concludes that the chemical diversity of active substances in authorised biocidal products to minimize the occurrence of resistance cannot be assured. 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 LIGNEX DEFEND will be authorised for a period not exceeding 5 years in accordance with Article 23(6) of Regulation (EU) No 528/2012.

2.2.12 ED assessment of co-formulants

The ED assessment of the biocidal product 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. There are no indications of endocrine disrupting properties, hence the product is not an endocrine disruptor. Further details on the performance of the assessment are given in the confidential annex.

3 ANNEXES

3.1 List of studies for the biocidal product

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	Reference	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
3.8, 4.2, 4.17	Anonymous	2016d	Surface Tension, Flash Point an Auto-ignition on the Sample Lignex Defend	Innovhub – Stazioni Sperimentali per l'Industria	201601340	Anonymous 2016d	Yes	No	J.F. Amonn SPA/AG
3.1, 3.2, 3.4	Anonymous	2016a	Chemical-physical Determinations and Low Temperature Stability Test on the Test Item Lignex Defend	Eurofins Biolab S.r.l.	S-2016-01235 AM	Anonymous 2016a	Yes	No	J.F. Amonn SPA/AG
3.3, 3.4	Anonymous	2016b	Accelerated Stability Study for 18 Weeks at 30°C on the Test Item Lignex Defend	Eurofins Biolab S.r.l.	2016/92 AM	Anonymous 2016b	Yes	No	J.F. Amonn SPA/AG
3.3	Anonymous	2019b	Amendment to Final Report 2016/92 AM	Eurofins Biolab S.r.l.	2016/92 AM	Anonymous 2019b	Yes	No	J.F. Amonn SPA/AG

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	Reference	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
3.4	Anonymous	2019c	Shelf Life Stability Study for 24 Months at 25°C on the Test Item Lignex Defend	Eurofins Biolab S.r.l.	RF_2016/93 AM	Anonymous 2019c	Yes	No	J.F. Amonn SPA/AG
3.8	Anonymous	2019a	Sample Determination of Surface Tension on the Sample Lignex Defend	Innovhub – Stazioni Sperimentali per l'Industria	1902800	Anonymous 2019a	Yes	No	J.F. Amonn SPA/AG
3.9	Anonymous	2017	Viscosity Determination on the Test Item Lignex Defend	Eurofins Biolab S.r.l.	S-2016-03889 AM	Anonymous 2017	Yes	No	J.F. Amonn SPA/AG
4.16	Anonymous	2016c	Corrosion Test on the Test Item Lignex Defend	Eurofins Biolab S.r.l.	S-2016-01236 AM	Anonymous 2016c	Yes	No	J.F. Amonn SPA/AG
5	Anonymous	2016m	Set up and Validation of an HPLC-UV Method for an Identification and Quantification of the active ingredient Permethrin in the Test Item Lignex Defend	Eurofins Biolab S.r.l.	S-2016-01209 AM	Anonymous 2016m	Yes	No	J.F. Amonn SPA/AG

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	Reference	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
6.7	Anonymous	2016e	**Prüfbericht 32/16/9974/04**	MPA Eberswalde	32/16/9974/04	Anonymous 2016e	No	No	J.F Amonn SPA/AG
6.7	Anonymous	2016f	**Prüfbericht 32/16/9974/01**	MPA Eberswalde	32/16/9974/01	Anonymous 2016f	No	No	J.F Amonn SPA/AG
6.7	Anonymous	2016g	**Prüfbericht 32/16/9974/03**	MPA Eberswalde	32/16/9974/03	Anonymous 2016g	No	No	J.F Amonn SPA/AG
6.7	Anonymous	2016h	**Prüfbericht 32/16/9974/02**	MPA Eberswalde	32/16/9974/02	Anonymous 2016h	No	No	J.F Amonn SPA/AG
8.1.1	Anonymous	2016m	IN VITRO SKIN CORROSION – RECONSTRUCTED HUMAN EPIDERMIS (RHE) TEST METHOD ACCORDING TO OECD N. 431 ON: "LIGNEX DEFEND"	Eurofins Biolab S.r.l.	S-2016-01239 AM	Anonymous 2016m	Yes	Yes	J.F Amonn SPA/AG

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	Reference	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
8.1.1	Anonymous	2016n	IN VITRO SKIN IRRITATION – RECONSTRUCTED HUMAN EPIDERMIS (RHE) TEST METHOD ACCORDING TO OECD N. 439 ON: "LIGNEX DEFEND"	Eurofins Biolab S.r.l.	S-2016-01238 AM	Anonymous 2016n	Yes	Yes	J.F Amonn SPA/AG
8.1.2	Anonymous	2016o	SCREENING FOR THE EYE IRRITANCY POTENTIAL USING THE BOVINE CORNEAL OPACITY AND PERMEABILITY ASSAY WITH LIGNEX DEFEND	BSL BIOSERVICE Scientific Laboratories Munich GmbH	164472	Anonymous 2016o	Yes	Yes	J.F Amonn SPA/AG
8.1.2	Anonymous	2016p	IN VITRO OCULAR IRRITATION ON "LIGNEX DEFEND": RECONSTRUCTED EPIOCULAR TISSUE MODEL TEST METHOD	Eurofins Biolab S.r.l.	S-1026-02012 AM	Anonymous 2016p	Yes	Yes	J.F Amonn SPA/AG

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	Reference	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
8.3.1	Anonymous	2016q	Test for Sensitisation (Local Lymph Node Assay - LLNA) with LIGNEX DEFEND	Eurofins Munich / BSL Munich	164473	Anonymous 2016q	Yes	Yes	J.F Amonn SPA/AG
8.5.1	Anonymous	2016r	ACUTE ORAL TOXICITY - FIXED DOSE METHOD - ON "LIGNEX DEFEND"	Eurofins Biolab S.r.l.	Report No.: S-2016-02014	Anonymous 2016r	Yes	Yes	J.F Amonn SPA/AG
9.2	Anonymous	2016i	**Acute toxicity test on aquatic organisms (Brachydanio rerio): LC50 test on "LIGNEX DEFEND"**	Eurofins Biolab S.r.l.	S-2016-01232AM	Anonymous 2016i	yes	yes	J.F Amonn SPA/AG
9.2	Anonymous	2016j	**Acute toxicity on aquatic organisms (Daphnia sp.): on "LIGNEX DEFEND"**	Eurofins Biolab S.r.l.	S-2016-01210AM	Anonymous 2016j	yes	yes	J.F Amonn SPA/AG

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	Reference	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
9.2	Anonymous	2016k	**Freshwater algae and cyanobacteria, growth inhibition test on "LIGNEX DEFEND"**	Eurofins Biolab S.r.l.	S-2016-01233AM	Anonymous 2016k	yes	yes	J.F Amonn SPA/AG
10.2	Anonymous	2016l	**Evaluation of aerobic biodegradability on "LIGNEX DEFEND"**	Eurofins Biolab S.r.l.	S-2016-01234AM	Anonymous 2016l	yes	yes	J.F Amonn SPA/AG

3.2 Output tables from exposure assessment tools

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)

Please refer to the 6.7 IUCLID section.

3.6 Confidential annex

Please confer to separate document.

3.7 Other Information

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

Brennan, G.K. (1990): Powder Post Borer (Lyctus spp.) Attack on Dry Timber – A review, (Report Wood Utilisation research center (W.A.)

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

DIN EN 14128 (2020) -06: Durability of wood and wood based products – Efficacy criteria for curative wood preservatives as determined by biological tests.

DIN 68800-4 (2020): Holzschutz – Teil 4: Bekämpfungs- und Sanierungsmaßnahmen gegen Holz zerstörende Pilze und Insekten.

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

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

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

EC 2013 HEEG: Opinion 18 *For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping*

ECHA 2013: Guidance on the Application of the CLP Criteria (Version 4.0, November 2013).

ECHA 2014: HEAdhoc Recommendation no. 4 *Cleaning of spray equipment in antifouling use (PT21)*

ECHA 2015a: Transitional Guidance on Efficacy Assessment for Product Type 8 Wood Preservatives, March 2015

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

ECHA 2015c: 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 2020a: HEAdhoc Recommendation no. 6 *Methods and models to assess exposure to biocidal products in different product types, version 4*

ECHA 2020b: Technical Agreements for Biocides – Analytical Methods and Physico-chemical Properties (APCP), February 2020

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

EFSA (2010): Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010; 8(6):1637.

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

Freeman, M.H., Obanda, D.N., Shupe, T.F. (2007): Permethrin: A Critical Review of an Effective Wood Preservative Insecticide (IRG/WP 07-30413)

Garrod, A.N.I., Guiver, R., Rimmer, D.A. 2000: *Potential Exposure of Amateurs (Consumers) through painting Wood Preservative and Antifoulant Preparations*, Ann. Occup. Hyg. 44: 421-426

Ireland 2014: SUBSTANCE EVALUATION REPORT, Permethrin, EC Number(s): 258-067-9, CAS Number(s): 52645-53-1, May 2016.

Ireland 2017: CAR Addendum, Permethrin PT8 and PT18, EC Number(s): 258-067-9, CAS Number(s): 52645-53-1, March 2017.

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

OECD (2008): Emission Scenario Document For Insecticides, Acaricides And Products To Control Other Arthropods For Household And Professional Uses. OECD Series On Emission Scenario Documents Number 18, 2008: ENV/JM/MONO(2008)14.

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

USDA (2019): Technical report of narrow range oils in crops. Available at: https://www.ams.usda.gov/sites/default/files/media/HorticulturalOilsTR_Final_01302019.pdf

Voss, G. (1988): Insecticide/acaricide resistance: Industry's efforts and plans to cope. Pesticide Science, Vol. 23 (2), p. 149 - 156

Winter, C.K. (2003): Pesticides and Herbicides – Toxicology. Encyclopedia of Food Sciences and Nutrition (2nd Edition), p. 4494-4501

LEGAL NORMS

COMMISSION IMPLEMENTING REGULATION (EU) No 1090/2014: of 16 October 2014 approving permethrin as an existing active substance for use in biocidal products for product- types 8 and 18. Available at:
ELI http://data.europa.eu/eli/reg_impl/2014/1090/oj

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