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

Product identifier in R4BP	Anti-Insekt
Product type(s):	08 (Holzschutzmittel)
Active ingredient(s):	Permethrin
Case No. in R4BP	BC-ER023987-15
Asset No. in R4BP	DE-0015797-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/08.00016 710-05-08-00016-00-00-00-0000
Date	15.10.2019

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1 Conclusion

The ready-to-use biocidal product is intended for the preventive treatment of timber in Use Class 1 (indoor, no wetting) and for the curative treatment of timber indoor and outdoor (in protected areas, under roof, not exposed to weathering; corresponds to Use Classes 1 and 2). The mode of application includes spraying by professionals.

The ready-to-use biocidal product is intended for the preventive treatment of timber, wooden furniture and smaller wooden items in Use Class 1 (indoor, no wetting) and for the curative treatment of timber indoor, including wooden furniture and smaller wooden items, and outdoor (in protected areas, under roof, not exposed to weathering; corresponds to Use Classes 1 and 2). The mode of application includes brushing by professionals and non-professionals.

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] are fulfilled.

Please find detailed information on the uses appropriate for authorisation in chapter 2.4.
General directions for use of the product are summarised in chapter 2.5.

Physical hazards and respective characteristics
Physical-chemical hazard(s) were not identified (please find more information in chapter 3.4).

Risk assessment for human health
A human health risk assessment has been carried out for professional use of the product for all intended uses.

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable risk to professional users. Regarding professional users health protection, there are no objections against the intended uses if the directions for use are followed.

Risk Assessment for the Environment
A risk assessment for the environment was carried out for the intended uses. Because of the use conditions of the product and the wood, treated with the product, as well as the directions for use, no significant emissions of the biocidal product to the environment are expected. Therefore, no

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.

unacceptable risks for the environment are expected for the intended uses of Anti-Insekt if the directions for use are followed.

There are indications that 4-tert-butylphenol contained in the anti-skinning agent of the product may have endocrine disrupting properties. It is currently under evaluation by DE and will be included in the SVHC candidate list soon. However, based on the information available to the RefMS at the moment, it is not possible to conclude whether this co-formulant should be considered to have ED properties or not. This is further assessed in the frame of the REACH Regulation. In case the co-formulant is finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Anti-Insekt

2.1.2 Manufacturer(s) of the product

Name of manufacturer	Remmers GmbH
Address of manufacturer	Bernhard-Remmers-Strasse 13 49624 Löningen Germany
Location of manufacturing sites	Bernhard-Remmers-Strasse 13 49624 Löningen Germany

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

Active substance	Permethrin
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz 1 50569 Köln Germany
Location of manufacturing sites	Kennedyplatz 1 50569 Köln Germany

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Permethrin	3-Phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorvinyl)-2,2-dimethylcyclopropancarboxylat Cis-Trans-ratio is 25:75.	Active substance	52645-53-1	258-067-9	0.2502
Dipropylene glycol methyl ether	1-(3-methoxypropoxy)propan-1-ol	Co-solvent	34590-94-8	252-104-2	6.0
[redacted]	Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics	Solvent	-	-	93.431

- Information on the full composition is provided in the confidential annex (see chapter **Fehler! V erweisquelle konnte nicht gefunden werden.**).

- 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 ☒

- According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

2.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one 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 ☐ (The technical equivalence of the active substance from the new source was established by ECHA, see asset number EU-1234567-0000)

2.2.3 Information on the substance(s) of concern

The following substances of concern were identified:
(2-Methoxymethylethoxy)propanol (CAS Nr.: 34590-94-8)
Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics“ (CAS No.: -; EC No: -)

2.2.4 Candidate(s) for substitution

No candidate for substitution was identified.

2.2.5 Type of formulation

Ready-to-use solvent-based formulation

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[2]

The classification for the biocidal product Anti-Insekt is based on the classification of the active, and on information on other components of the product (CLP classifications and Safety Data Sheets). Besides the active substance Permethrin and the substance of concern (2-Methoxymethylethoxy)propanol, the other components do not affect the classification of the biocidal product.

- The current harmonised classification of the active substance **permethrin** is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):[3]

Acute Tox. 4	H302: Harmful if swallowed.
Skin Sens. 1	H317: May cause an allergic skin reaction.
Acute Tox. 4	H332: Harmful if inhaled.
Aquatic Acute 1	H400: Very toxic to aquatic life
Aquatic Chronic 1	H410: Very toxic to aquatic life with long-lasting effects

- The current classification of the substance of concern for HH Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics is based on the SDS submitted by the applicant and the corresponding ECHA registration report:

Aspiration hazard 1	H304: May be fatal if swallowed and enters airways

- The worst-case classification for the environment in the current notifications of the substance of concern **(2-Methoxymethylethoxy)propanol** is:[4]

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2 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

3 See: http://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/105223

Aquatic Chronic 2 H410: Toxic to aquatic life with long-lasting effects

A harmonized classification does not exist for this substance. However, in the end, the inclusion of this substance in the CLP-Assessment will not change the classification of the biocidal product

Taking the information into account, a classification of the biocidal product **Anti-Insekt** pursuant to the Regulation (EC) 1272/2008 is required, which results in:

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

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.4.

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**	
Aspiration hazard 1	H304 – May be fatal if swallowed and enters airways	
Aquatic Acute 1	H400 – Very toxic to aquatic life.	
Aquatic Chronic 1	H410 – Very toxic to aquatic life with long lasting effects.	
Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS08	
	GHS09	
Signal word	-	Danger
Hazard statements	H304	May be fatal if swallowed and enters airways.
	H410	Very toxic to aquatic life with long lasting effects.
Supplemental hazard information	EUH066	Repeated exposure may cause skin dryness or cracking.
Supplemental label elements	EUH208	Contains permethrin. May produce an allergic reaction.
Precautionary statements	P101	If medical advice is needed, have product container or label at hand.
	P102	Keep out of reach of children.

4 See: https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/6538

	P260	Do not breathe dust/fume/gas/mist/vapours/spray.
	P262*	Do not get in eyes, on skin, or on clothing.
	P301 + P310 + P331	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Do NOT induce vomiting.
	P273	Avoid release to the environment.
	P391	Collect spillage.
	P405	Store locked up.
	P501	Dispose of content/ container as hazardous waste.
Note		

*included in accordance with Reg. (EC) No. 1272/2008, Annex VI, 1.1.3.1, Note P

According to Article 35 Regulation (EC) No 1272/2008 the packaging – which is supplied to the general public and contains a substance or mixture which meets the requirements in section 3.1.1 of Annex II - shall have a **child-resistant fastening**.
According to Article 35 Regulation (EC) No 1272/2008 the packaging – which is supplied to the general public and contains a substance or mixture which meets the requirements in section 3.2.1 of Annex II - shall bear a **tactile warning of danger**.

For labelling according to Article 69 of Regulation 528/2012, in particular precautionary and risk mitigation measures (RMM), please refer to chapter 2.4.

Labelling has to be in accordance with article 69 of Regulation (EU) No. 528/2012 and with Regulation (EU) No. 1272/2008.
It is within the responsibility of the authorisation holder to comply with the legal provisions for classification and labelling.

2.4 Use(s) appropriate for authorisation[5]

2.4.1 Use 1 appropriate for authorisation – Spraying (Professional user)

Product Type(s)	08
Where relevant, an exact description of the use	The ready-to-use biocidal product is intended for the preventive treatment of timber in Use Class 1 (indoors, no wetting) and for the curative treatment of timber outdoors (in protected areas, under roof, not exposed to weathering) and indoors (corresponds to Use Classes 1 and 2). The mode of application includes spraying by professionals.

5 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

Target organism(s) (including development stage)	*Hylotrupes bajulus L*.; House longhorn beetle, Larvae. *Anobium punctatum* De Geer, Common furniture beetle, Larvae.
Field(s) of use	Indoor, Outdoor
Application method(s)	Spraying The mode of application includes spraying by professionals. The product is applied to wood structures outdoors (in protected areas, under roof, not exposed to weathering) and indoors for curative treatment (corresponds to Use Classes 1 and 2). For preventive treatment, it is used only in Use Class 1 (indoors, no wetting).
Application rate(s) and frequency	Curative treatment: 300 – 350 mL/m^2; Preventive treatment: 200 – 250 mL/m^2 2 to 3 spaying applications
Category(ies) of users	Professional
Pack sizes and packaging material	container, tinplate 0.75, 5, 10 L

2.4.1.1 Use-specific instructions for use

See chapter 2.5

2.4.1.2 Use-specific risk mitigation measures

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

2.4.2 Use 2 appropriate for authorisation –Brushing (non-professional and professional user)

Product Type(s)	08
Where relevant, an exact description of the use	The ready-to-use biocidal product is intended for the preventive treatment of timber including wooden furniture and smaller wooden items in Use Class 1 (indoors, no wetting) and for the curative treatment of timber outdoors (in protected areas, under roof, not exposed to weathering) and indoors (corresponds to Use Classes 1 and 2). The mode of application includes brushing by professionals and non-professionals.
Target organism(s) (including development stage)	*Hylotrupes bajulus* L.; House longhorn beetle, Larvae. *Anobium punctatum* De Geer, Common furniture beetle, Larvae.
Field(s) of use	Indoor, Outdoor
Application method(s)	Brushing The mode of application includes brushing by professionals and non-professionals. The product is applied to wood structures indoors and outdoors (in protected areas, under roof, not exposed to weathering) as well as wooden furniture and smaller wooden items indoors for curative treatment (corresponds to Use Classes 1 and 2). For preventive treatment, it is used only in Use Class 1 (indoors, no wetting).
Application rate(s) and frequency	Curative treatment: 300 – 350 mL/m2; Preventive treatment: 200 – 250 mL/m^2(only professionals) Professionals: 2 to 3 brushing applications Non-professionals: 2 brushing applications
Category(ies) of users	Professional General public (non-professional)
Pack sizes and packaging material	container, tinplate 0.25, 0.75, 5, 10 L 0.25 L only for non-professional use 0.75, 5, 10 L only for professional use

2.4.2.1 Use-specific instructions for use

See chapter 2.5 For non-professional use: Do not apply to large interior surface (in maximum 3 m^2). Indoor use only for furniture or other small wooden subjects.

2.4.2.2 Use-specific risk mitigation measures

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

2.5 General directions for use

2.5.1 Instructions for use

1) Application should only take place in compliance with the definition of Use Classes 1 and 2. (general) *2)* Application solutions must be collected and reused or disposed of as hazardous waste. They

must not be released to soil, ground- and surface water or any kind of sewer. Discharge to wastewater by cleaning of equipment is not allowed. (general)

2.5.2 Risk mitigation measures

1) The product must only be applied on wood which is not in direct contact with food or feedstuff for animals.
2) Use only outdoors or in a well-ventilated area.
3) Keep children and pets away from treated surfaces until dried.
4) Avoid prolonged contact of cats to treated surfaces.

RMMs for professional users

This product contains hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics (CAS-No.: -), for which a German Occupational Exposure Level (OEL) according to the German Technical Rules for Hazardous Substances (TRGS 900) is in force.

In order to keep the German OEL for this compound, the following measure shall be applied:

- Provide adequate ventilation (industrial ventilation or cross ventilation by keeping windows and doors open).

The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures:

- Wear protective chemical resistant gloves (EN 374) during product handling phase (glove material to be specified by the authorisation holder within the product information).
- For subsequent manual processing of treated wood, chemical resistant gloves (EN 374) must be worn.

Use specific RMMs for spray treatment:

- A protective coverall (at least type 3 or 4, EN 14605), which is impermeable for the biocidal product, shall be worn (coverall material to be specified by the authorisation holder within the product information).

  Under unfavourable conditions, e.g. when large open surfaces are treated or in very small rooms, the air concentration of hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics may exceed the short-term OEL and require the use of additional RPE. The Type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).

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

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

„IF IN EYES: Immediately flush eyes with plenty of clean water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing with eyelids open with water or eye wash liquid for several minutes.

IF ON SKIN (or hair): Wash the affected area thoroughly with plenty of soap and water. Get medical attention if symptoms occur.

IF INHALED: If affected, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Call a POISON CENTER or doctor/physician if you feel unwell.

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
Do NOT induce vomiting.

2.5.4 Instructions for safe disposal of the product and its packaging

1) Disposal of product and of packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

24 month

2.5.6 Other information

1) The treated timber should only be used in compliance with the definition of Use Classes 1 and 2 (general).

2.6 Packaging

Table 3

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Container	0.25 L	Tinplate	Tinplate	Non-professional	Yes
Container	0.75, 5, 10 L	Tinplate	Tinplate	Professional	Yes

3 Assessment of the product

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

3.1.1 Intended use 1 – Addition to the Spraying

Product Type(s)	08
Where relevant, an exact description of the use	The ready-to-use biocidal product is intended for the preventive treatment of timber in Use Class 1 (indoors, no wetting) and for the curative treatment of timber outdoors (in protected areas, under roof, not exposed to weathering) and indoors (corresponds to Use Classes 1 and 2). The mode of application includes spraying by professionals.
Target organism(s) (including development stage)	*Hylotrupes bajulus* L.; House longhorn beetle, Larvae. *Anobium punctatum* De Geer, Common furniture beetle, Larvae.
Field(s) of use	Indoor, Outdoor
Application method(s)	Spraying The mode of application includes spraying by professionals. The product is applied to wood structures outdoors (in protected areas, under roof, not exposed to weathering) and indoors for curative treatment (corresponds to Use Classes 1 and 2). For preventive treatment, it is used only in Use Class 1 (indoors, no wetting).
Application rate(s) and frequency	Curative treatment: 300 – 350 mL/m^2; Preventive treatment: 200 – 250 mL/m^2 2 to 3 spraying applications
Category(ies) of users	Professional
Pack sizes and packaging material	container, tinplate 0.75, 5, 10 L

3.1.2 Intended use 2 – Addition to the Brushing

Product Type(s)	08
Where relevant, an exact description of the use	The ready-to-use biocidal product is intended for the preventive treatment of timber including wooden furniture and smaller wooden items in Use Class 1 (indoors, no wetting) and for the curative treatment of timber outdoors (in protected areas, under roof, not exposed to weathering) and indoors (corresponds to Use Classes 1 and 2). The mode of application includes brushing by professionals and non-professionals.
Target organism(s) (including development stage)	*Hylotrupes bajulus* L.; House longhorn beetle, Larvae. *Anobium punctatum* De Geer, Common furniture beetle, Larvae.

Field(s) of use	Indoor, Outdoor
Application method(s)	Brushing The mode of application includes brushing by professionals and non-professionals. The product is applied to wood structures indoors and outdoors (in protected areas, under roof, not exposed to weathering) as well as wooden furniture and smaller wooden items indoors for curative treatment (corresponds to Use Classes 1 and 2). For preventive treatment, it is used only in Use Class 1 (indoors, no wetting).
Application rate(s) and frequency	Curative treatment: 300 – 350 mL/m2; Preventive treatment: 200 – 250 mL/m^2(only professionals)
Category(ies) of users	Professional General public (non-professional)
Pack sizes and packaging material	container, tinplate 0.25, 0.75, 5, 10 L 0.25 L only for non-professional use 0.75, 5, 10 L only for professional use

3.2 *Intended* use(s) as applied for by the applicant

Use	PT	Where relevant, an exact description of the use	Target organism(s) (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category(ies) of users	Pack sizes and packaging material

1	08	The ready-to-use biocidal product is intended for the preventive treatment of timber in Use Class 1 (indoor, no wetting) and for the curative treatment of timber outdoor (in protected areas, under roof, not exposed to weathering) and indoor (corresponds to Use Classes 1 and 2). The mode of application includes spraying by professionals.	Hylotrupes bajulus L.; House longhorn beetle, Larvae. Anobium punctatum De Geer, Common furniture beetle, Larvae.	Indoor, Outdoor	Spraying The mode of application includes spraying by professionals. The product is applied to wood structures outdoor (in protected areas, under roof, not exposed to weathering) and indoor for curative treatment (corresponds to Use Classes 1 and 2). For preventive treatment, it is used only in Use Class 1 (indoor, no wetting).	Curative treatment: 300 – 350 mL/m2; Preventive treatment: 200 – 250 mL/m2 2 to 3 spaying applications	Professional	container, tinplate 0.75, 5, 10 L

2	08	The ready-to-use biocidal product is intended for the preventive treatment of timber including wooden furniture and smaller wooden items in Use Class 1 (indoor, no wetting) and for the curative treatment of timber outdoor (in protected areas, under roof, not exposed to weathering) and indoor (corresponds to Use Classes 1 and 2). The mode of application includes brushing by professionals and non-professionals.	*Hylotrupes bajulus* L.; House longhorn beetle, Larvae. *Anobium punctatum* De Geer, Common furniture beetle, Larvae.	Indoor, Outdoor	Brushing The mode of application includes brushing by professionals and non-professionals. The product is applied to wood structures indoor and outdoor (in protected areas, under roof, not exposed to weathering) as well as wooden furniture and smaller wooden items indoor for curative treatment (corresponds to Use Classes 1 and 2). For preventive treatment, it is used only in Use Class 1 (indoor, no wetting).	B Curative treatment: 300 – 350 mL/m2; Preventive treatment: 200 – 250 mL/m^2(only professionals)	Professional	container, tinplate 0.25, 0.75, 5, 10 L 0.25 L only for non-professional use 0.75, 5, 10 L only for professional use

2	08	The ready-to-use biocidal product is intended for the preventive treatment of timber including wooden furniture and smaller wooden items in Use Class 1 (indoor, no wetting) and for the curative treatment of timber outdoor (in protected areas, under roof, not exposed to weathering) and indoor (corresponds to Use Classes 1 and 2). The mode of application includes brushing by professionals and non-professionals.	*Hylotrupes bajulus* L.; House longhorn beetle, Larvae. *Anobium punctatum* De Geer, Common furniture beetle, Larvae.	Indoor, Outdoor	Brushing The mode of application includes brushing by professionals and non-professionals. The product is applied to wood structures indoor and outdoor (in protected areas, under roof, not exposed to weathering) as well as wooden furniture and smaller wooden items indoor for curative treatment (corresponds to Use Classes 1 and 2). For preventive treatment, it is used only in Use Class 1 (indoor, no wetting).	B Curative treatment: 300 – 350 mL/m2; Preventive treatment: 200 – 250 mL/m^2(only professionals)	General public (non-professional)	container, tinplate 0.25, 0.75, 5, 10 L 0.25 L only for non-professional use 0.75, 5, 10 L only for professional use

<u>Intended</u> use name(s)

1. Spraying Professional

2. Brushing Professional
3. Brushing General public (non-professional)

3.3 Physical, chemical and technical properties

Table 4: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	Batch no. 22.09.2015, AS-content: 0.237 %	liquid	Affolter, O., 2016, report no. 16011104N978
Colour at 20 °C and 101.3 kPa	Visual inspection	Batch no. 22.09.2015, AS-content: 0.237 %	pearl white (RAL 1013)	Affolter, O., 2016, report no. 16011104N978
Odour at 20 °C and 101.3 kPa	Olfactory inspection	Batch no. 22.09.2015, AS-content: 0.237 %	Strong typical solvent odour	Affolter, O., 2016, report no. 16011104N978
Acidity / alkalinity	CIPAC MT 75	Batch no. 0030304633	pH: 6.18 to 6.43 at 24.8 °C (three measurements)	Henke, W., 2016, report no. 16011104N907
Relative density / bulk density	OECD guideline 109 (EU Method A.3) pycnometer method	Batch no. 0030304633	δ=0.7946 ± 0.0003 g/cm^3 at 20°C	Henke, W., 2016, report no. 16011104N912
Storage stability test – **accelerated storage**	CIPAC MT 46	Batch no. 22.09.2015, AS-content: 0.235 %	54 °C for 2 weeks AS before storage: 0.237% AS after storage: 0.243%	Affolter, O., 2016, report no. 16011104N978
Storage stability test – **long term storage at ambient temperature**	GIFAP Monograph No. 17	Batch no. 22.09.2015, AS-content: 0.235 %	Storage at 20±2°C for 6 month. AS before storage: 0.237% AS after storage: 0.255%	Affolter, O., 2018, report no. 16011104N001

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			(107.5%). Physical state, colour, odour, viscosity and pH-value do not diverge significantly after 6 month storage. After 12 months: AS after storage: 0.239% (100.7%). Physical state, colour, odour, viscosity and pH-value do not diverge significantly after 6 month storage. After 24 months: AS after storage: 0.256% (108.1%). Physical state, colour, odour, viscosity and pH-value do not diverge significantly after 6 month storage.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **low temperature stability test for liquids**	Waiving		Waiver acceptable based on label claim “protect from frost”.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waiving		The BP is stored and transported in light-proof packaging and not exposed to light.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waiving		Waiver acceptable based on label claim “keep in original container, tightly closed, in a dry and frost free place”.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The resistance of the packaging material (tinplate) to the long-term influence of the biozide product is given.	Dangerous Goods Database http://www.dgg.bam.de/en/
Wettability	Waiving		Not applicable	
Suspensibility, spontaneity and dispersion stability	Waiving		Not applicable	
Wet sieve analysis and dry	Waiving		Not applicable	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
sieve test				
Emulsifiability, re-emulsifiability and emulsion stability	Waiving		Not applicable	
Disintegration time	Waiving		Not applicable	
Particle size distribution, content of dust/fines, attrition, friability	Waiving		Not applicable	
Persistent foaming	Waiving		Not applicable	
Flowability/Pourability/Dust ability	Waiving		Not applicable	
Burning rate — smoke generators	Waiving		Not applicable	
Burning completeness — smoke generators	Waiving		Not applicable	
Composition of smoke — smoke generators	Waiving		Not applicable	
Spraying pattern — aerosols	Waiving		Not applicable	
Physical compatibility	Waiving		Not applicable	
Chemical compatibility	Waiving		Not applicable	
Degree of dissolution and dilution stability	Waiving		Not applicable	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Surface tension	OECD guideline 115	Batch no. 0030304633	72.65 ± 0.05 mN/m at 19.9°C	Hesse, M., 2016, report No. 16011104N960
Viscosity	OECD guideline 114 falling ball viscosimeter	Batch no. 0030304633	dynamic viscosity n = 1.388 mPa * s at 20°C; n = 0.982 mPa * s at 40°C kinematic viscosity n = 1.75 mm^2 / s at 20°C; n = 1.24 mm^2 / s at 40°C	Henke, W., 2016; report no. 16011104N984

Table 5

Conclusion on the physical, chemical and technical properties
The data provided by the applicant was acceptable. The product is pearl white liquid with a solvent odour. The pH is 6.18 to 6.43 at 24.8 °C, so that measurement of acidity/ alkalinity is not required. The density is 0.7946 g/cm3 at 20°C due to the high amount of solvent used in the product. The surface tension is 72.65 ± 0.05 mN/m at 19.9°C and the viscosity is 1.388 mPa * s at 20°C respectively, 0.982 mPa * s at 40°C. Shelf-life: 24 months Biocidal product has to be stored cool (below 30°C), dry and protected from frost in closed, original containers.

3.4 Physical hazards and respective characteristics

Table 6: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	study scientifically not necessary			Waiver: The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties.	IUCLID[6]
Flammable gases	study scientifically unjustified			Waiver	IUCLID[7]
Flammable aerosols	study scientifically unjustified			Waiver	IUCLID[7]
Oxidising gases	study scientifically unjustified			Waiver	IUCLID[7]

6 Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Gases under pressure	study scientifically unjustified			Waiver	IUCLID[7]
Flammable liquids	EN ISO 13736 EN ISO 1516	Anti-Insekt, Art.-No. 2059	Flash point: 63.5 °C Test temperature: 60°C Ignition: no	Not classified based on GHS/CLP criteria	Pieper, M., 2017, Untersuchungs-bericht Auftrags-Nr.: 17-1238 Version: 02
Flammable solids	study scientifically unjustified			Waiver	IUCLID[7]
Self-reactive substances and mixtures	study scientifically not necessary			Waiver: The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.	IUCLID[7]
Pyrophoric	study			Waiver: The study does not need to be conducted	IUCLID[7]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
liquids	scientifically not necessary			because the substance is known to be stable in contact with air at room temperature for prolonged periods of time (days) and hence, the classification procedure does not need to be applied.	
Pyrophoric solids	study scientifically unjustified			Waiver	IUCLID[7]
Self-heating substances and mixtures	study scientifically unjustified			Waiver	IUCLID[7]
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary			Waiver: The study does not need to be conducted because the experience in production or handling shows that the substance does not react with water, e.g. the substance is manufactured with water or washed with water.	IUCLID[7]
Oxidising liquids	study			Waiver: The study does not need to be conducted	IUCLID[7]

[7] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
	scientifically not necessary			because there are no chemical groups present in the molecule which are associated with oxidising properties and hence, the classification procedure does not need to be applied.	
Oxidising solids	study scientifically unjustified			Waiver	IUCLID[7]
Organic peroxides	study scientifically not necessary			Waiver: The study does not need to be conducted because the product does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	IUCLID[7]
Corrosive to metals	study scientifically not necessary			Waiver: The biocidal product is not corrosive, since it (as an organic liquid) does not contain halogens, acidic or basic functional groups and the pH value of the undiluted product is not very acidic or basic (6.18 to 6.43 at 24.8 °C, i.e. within pH 4-10 range).	IUCLID[7]
Auto-ignition temperature (liquids and gases)	DIN 51794	Batch no. 0030304633	Auto-ignition temperature: 225 °C		Henke, W., 2016, Determination of the auto ignition temperature of Anti Insekt,

[7] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
					study no. 16011104N962
Relative self-ignition temperature for solids	study scientifically unjustified			Waiver	IUCLID[7]
Dust explosion hazard	study scientifically unjustified			Waiver	IUCLID[7]

Table 7

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. Experimental data on flash point (63.5 °C) and auto-ignition temperature (225 °C) were provided for the product. Anti-Insekt is not expected to have any explosive or oxidising properties. Based on experience in production and handling it can be concluded that the product is not pyrophoric, does not evolve flammable gases in contact with water and is not considered as being corrosive to metals. Conclusions on classification and labelling: The physical and chemical properties of the biocidal product do not fulfil the criteria for a classification according to Regulation (EC) No 1272/2008 and therefore, no labelling is required for physical-chemical hazards.

[7] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

3.5 Methods for detection and identification

Table 8

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**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	GC-FID	Is given, no relevant interferences were observed	R^2 = 0.99885, range: 30mg/L – 250 mg/L	Addition of 0, 150µL. 300µL, 450 µL Permethrin stock solution to BP test item. Each sample was measured twice.	96.3% - 99.8%	97.5%	1%	29.4 mg/L	Affolter, O., 2016, report no. 16011104N926

Table 9

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	permethrin	0.09 mg/kg	$PNEC_{soil}$ CAR Doc IIA combined; (PT08+PT18), 11/2013, 4.2.3.5
Drinking water	permethrin	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	permethrin	0.47 ng/L	$PNEC_{water}$ based on NOEC *Daphnia magna*: 4.7 ng/L, AF: 10 CAR Doc IIA combined; (PT08+PT18), 11/2013, 4.2.1.6
Air	permethrin	15 µg/m³	medium+long-term AEL: 0.05 mg/kg bw/d; AR (PT08), 02/2014, LoEP, AR (PT18), 04/2014, LOEP,
Animal and human body fluids and tissues	no relevant residues expected		Waiver, CAR PT8 Tagros DocIIIA, 4.2.d; 12/2012
Food of plant origin	no relevant residues expected		Waiver; CAR PT8 Bayer/Sumitomo DocIIIA, 4.3; 12/2012 CAR PT8 Tagros DocIIIA, 4.3; 12/2012
Food of animal origin	no relevant residues expected		Waiver; CAR PT8 Bayer/Sumitomo DocIIIA, 4.3; 12/2012 CAR PT8 Tagros DocIIIA, 4.3;

			12/2012

Table 10

Analytical methods for surface water –accepted for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	LC MS/MS Synergi 2µ Polar RP column; ESI+ m/z 408→183 m/z 408→ 355	confirmation included by second transition	0.04 – 10 ng/mL R^2=0.9995	m/z 408 →183 0.05 µg/L / 10 0.5 µg/L / 10 m/z 408 →355 0.05 µg/L / 10 0.5 µg/L / 10	99 – 105 % 92 – 95 % 91 – 104 % 90 – 101 %	102 % 93 % 98 % 95 %	2.0 % 1.8 % 4.2 % 3.3 %	0.05 µg/L validated for surface water, but LOQ >> MRL based on PNEC water Method is acceptable for drinking water.	Krebber & Braune, 2008 CAR PT8 Bayer/ Sumitomo DocIIIA, 4.2 (5); 12/2012

Table 11

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	LC MS/MS Synergi 2µ Polar RP column; ESI+ m/z 408→183 m/z 408→ 355	confirmation included by second transition	1 – 100 ng/mL R^2=0.9992 – 0.9999	m/z 408→183 silt loam 0.005 mg/kg / 5 0.05 mg/kg / 5 sandy loam 0.005 mg/kg / 5 0.05 mg/kg / 5 m/z 408→355 silt loam 0.005 mg/kg / 5 0.05 mg/kg / 5 sandy loam 0.005 mg/kg / 5	 89 – 105 % 100 – 103 % 82 – 98 % 92 – 95 % 91 – 108 % 99 – 102 % 83 – 98 %	 95 % 101 % 88 % 93 % 96 % 101 % 89 %	 6.4 % 1.3 % 7.3 % 1.6 % 7.1 % 1.3 % 7.0 %	Permethrin	LC MS/MS Synergi 2µ Polar RP column; ESI+ m/z 408→183 m/z 408→ 355

				0.05 mg/kg / 5	91 – 94 %	93 %	1.5 %		

Table 12:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	LC MS/MS; ESI+ m/z 408→183 m/z 408→ 355	confirmation included by second transition	5 – 500 ng/mL R^2 > 0.997	m/z 408→183 ambient air 5 µg/m³/ 5 48 µg/m³/ 5 warm humid air 4.8 µg/m³/ 5 49 µg/m³/ 5 m/z 408→355 ambient air 5 µg/m³/ 5 48 µg/m³/ 5 warm humid air 4.8 µg/m³/ 5	Not given in DocIIIA	 87 % 90 % 92 % 91 % 88 % 90 % 91 %	 5 % 4 % 4 % 3 % 6 % 4 % 2 %	5 µg/m³	Bacher, 2008 CAR PT8 Bayer/Sumitomo DocIIIA, 4.2 (4); 12/2012

				49 µg/m³/ 5		90 %	4 %		
Permethrin	GC-ECD, DB-5 column	confirmation included by GC-MS m/z 127, 163, 183, but no validation data presented in CAR	0.05 – 10 mg/L R=1.0	0.1 µg/m³/ 5 1 µg/m³/ 5		72 % 74 %	1.9 % 3.4 %	0.1 µg/m³	Sathiyanarayanan, 2006CAR PT8 Tagros DocIIIA, 4.2.b; 12/2012
SoC Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics (CAS-No.: -)	GC-MS/ GC-FID					91		LOQ: 10 mg/m^3	D. Breuer A. Eisenhardt 2009 IFA Arbeitsmappe 7735: Kohlenwasserstoffgemische – RCP, 43/2009

Table 13

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving for determining the concentration of the AS in the BP. 1. 5.2.1. Soil: No data waiving. 2. 5.2.2. Air: No data waiving. 3. 5.2.3. Water (including drinking water) and sediment: No data waiving. 4. 5.2.4 Body fluids and tissues: Data waving was accepted. 5. 5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant[7] Data waving was accepted.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 14

Conclusion on the methods for detection and identification
The methods provided regarding the active substance, residues and substance of concern were acceptable. The methods provided regarding the residues of the active substance were acceptable. Please note: The method for determination of permethrin in surface water is not sufficient for monitoring the limit of 0.47 ng/L based on PNEC water. But the presented method was accepted in CAR.

[7] Not necessary if neither the active substance nor the material treated with it come into contact with food- producing animals, food of plant and animal origin or feeding stuffs

3.6 Efficacy against target organisms

3.6.1 Function and field of use

The applicant's claim for the wood preservative "Anti-Insekt" is preventive in use class 1 and curative against wood boring beetles in use class 1 and 2. Application of the product is carried out by professionals through surface treatments (spraying and brushing). Application of the product is carried out by non-professionals only through brushing.

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

Target organisms to be controlled by "Anti-Insekt" are larvae of wood boring beetles, namely *Hylotrupes bajulus* (*H. bajulus*) and *Anobium punctatum* (*A. punctatum*). "Anti-Insekt" is a preventive and curative wood preservative thus preventing and killing an ongoing infestation by wood boring beetle larvae inside the wood.

3.6.3 Effects on target organisms, including unacceptable suffering

Wood boring beetle larvae are killed after contact with treated wood. Death is caused without suffering.

3.6.4 Mode of action, including time delay

As a pyrethroid, Permethrin acts as a neurotoxin, targeting the potassium and sodium channel recovery in the nervous system. With regards to the curative function in accordance with EN 14128:2003 "Anti-Insekt" is considered fast acting (12 weeks) for *H. bajulus*, and fast acting (8 weeks) also for *A. punctatum*.

3.6.5 Efficacy data

For proof of efficacy the applicant submitted four laboratory key studies in accordance with European efficacy assessment standards. All studies were carried out with "Anti-Insekt", which means the test products were identical to the BP.

Preventive efficacy against wood boring beetles

Concerning the applicant's claim for preventive effectiveness against wood boring beetle larvae of *H. bajulus* a test with "Anti-Insekt" according to EN 46-1 (2009) in combination with evaporative ageing prior to the biological test according to EN 73 (2014) was performed. Mortality of larvae after 4 weeks testing period was 100 %. The untreated control demonstrated a mortality of 3.3 %. The test was valid. The average application rate applied by brushing was 198.7 ml/m² (158.2 g/m^2). The lowest effective application rate of a single test specimen (replication) was 198.0 ml/m² (157.3 g/m^2). Thus, the application rate applied for preventive treatment against *H. bajulus* of 200 to 250 ml/m^2 was demonstrated.

Concerning the applicant's claim for preventive effectiveness against wood boring beetle larvae of *A. punctatum* a test with "Anti-Insekt" according to EN 49-1 (2005) in combination with evaporative ageing prior to the biological test according to EN 73 (2014) was performed. Mortality of larvae after 26 weeks testing period was 100 %. The untreated control demonstrated sufficient survival of larvae. The test was valid. The average application rate applied by brushing was 199.2 ml/m² (158,6 g/m^2). The lowest effective application rate of a single test specimen (replication) was 199.0 ml/m² (158.5 g/m^2). Thus, the application rate applied for preventive treatment against *A. puncatum* of 200 to 250 ml/m^2 was demonstrated.

Preventive use in use class 2, which the applicant had intended, cannot be authorised due to the requirement to demonstrate fungicidal activity for any preventive biocidal products in use class 2 and higher (see Guidance on the Biocidal Products Regulation - Volume II Efficacy - Assessment and Evaluation (Parts B&C), section 5.5.8.2.2.3). Fungicidal activity was not demonstrated and is not expected for "Anti-Insekt", as the product contains just the insecticidal active substance permethrin.

Curative efficacy against wood boring beetles

A sufficient curative effect of "Anti-Insekt" against larvae of *H. bajulus* is supported by an experimental study according to EN 1390:2006. With a mean application rate of the ready to use product "Anti-Insekt" of 299.5 ml/m² (238.0 g/m²) the achieved mean mortality was 93 %. Application was carried out by brushing and is equally acceptable for spraying. According to EN 14128:2003 an achieved mean mortality equal to or greater than 80 % in 12 weeks is regarded as sufficient effective for a fast acting curative wood preservative against *H. bajulus*. The lowest effective application rate of a single test specimen (replication) was 299.0 ml/m² (237.6 g/m^2). The curative action of "Anti-Insekt" against *H. bajulus* has thus been demonstrated for the proposed average retention rate of 300 to 350 ml/m².

A sufficient curative effect of "Anti-Insekt" against larvae of *A. punctatum* is supported by an experimental study according to EN 48:2005. With a mean application rate of the ready to use product "Anti-Insekt" of 299.6 ml/m² (238.1 g/m²) on pine the achieved mean mortality was 98 %. With a mean application rate of the ready to use product "Anti-Insekt" of 299.8 ml/m² (238.2 g/m²) on beech the achieved mortality was 100 %. Application was carried out by brushing and is equally acceptable for

spraying. According to EN 14128:2003 an achieved mean mortality equal to or greater than 80 % in 8 weeks is regarded as sufficient effective for a fast acting curative wood preservative against *A. puncatum*. The lowest effective application rate of a single test specimen (replication) on pine and beech was 299.5 ml/m² (238.0 g/m²). The curative action of “Anti-Insekt” against *H. bajulus* has thus been demonstrated for the proposed average retention rate of 300 to 350 ml/m².

The application for curative treatment by borehole injection has been withdrawn by the applicant.

Table 15

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, wood preservative	Preventive treatment of wood in use class 1	Anti-Insect	*H. bajulus*	EN 46-1 EN 73	Minimum: 198.0 ml/m² 4 weeks Average: 198.7 ml/m² 4 weeks	100 % mortality	Fennert and Kolling 2016. Determination of the preventive action against recently hatched larvae of *H. bajulus* (L.) according to EN 46-1 (2009) after evaporative ageing procedure according to EN 73 (2014).
Insecticide, wood preservative	Curative treatment of wood in use class 1	Anti-Insekt	*H. bajulus*	EN 1390	Minimum: 299.0 ml/m² 12 weeks Average: 299.5 ml/m² 12 weeks	93 % mortality	Fennert and Kolling 2015. Determination of the eradicant action against larvae of *H. bajulus* (L.) according to

							EN 1390 (2006).
Insecticide, wood preservative	Curative treatment of wood in use class 1	Anti-Insekt	*A. punctatum*	EN 48	Minimum: 299.5 ml/m² 8 weeks Average: 299.6 ml/m² 8 weeks (*Pinus sylvestris*), Minimum: 299.8 ml/m² 8 weeks Average: 299.6 ml/m² 8 weeks (*Fagus sylvatica*)	98 % mortality (*Pinus sylvestris*), 100 % mortality (*Fagus sylvatica*)	Fennert and Kolling 2016. Determination of the eradicant action against larvae of *A. punctatum* De Geer according to EN 48 (2005)
Insecticide, wood preservative	Preventive treatment of wood in use class 1	Anti-Insect	*A. punctatum*	EN 49-1 EN 73	Minimum: 199.0 ml/m² 26 weeks Average: 199.2 ml/m² 26 weeks	100 % mortality	Fennert and Kolling 2016. Determination of the protective effectiveness against Anobium punctatum (de Geer) by egg-laying and larval survival according to EN 49 part 1 (2005) after evaporative ageing procedure according to EN 73 (2014)

3.6.6 Occurrence of resistance and resistance management

Resistance of target organisms to “Anti-Insekt” is unlikely to occur. With the envisioned amount of product application of 300 ml/m² for curative measures a minimum of 90 % of all wood boring beetle larvae will be killed. Surviving beetles may reproduce but their progeny will be killed completely because of the preventive effects on egg-larvae in the next generation. In total 100 % mortality will be achieved at least in the F_1-generation. With the amount of 200 to 250 ml/m² for preventive treatment all larvae of wood boring beetles (*H. bajulus* and *A. punctatum*) were killed. With no survivals, resistance by inheritance is unlikely.

3.6.7 Known limitations

Not relevant

3.6.8 Evaluation of the label claims

The applicant provided technical information sheets for professional and non-professional users, respectively. On both sheets, the following claims are made:

- Product against *H. bajulus* and *A. punctatum*
- Curative treatment with 300 – 350 ml/m²
- Fast acting curative action
- Preventive efficacy against re-infestation
- To be used in interior and protected exterior areas

For professional users, additional claims are made:

- Preventive treatment with 200 – 250 ml/m²
- For brushing, low-pressure spraying or borehole impregnation

The label claims referred to the efficacy can be accepted mostly. For professional users, the applicant must add a statement that preventive use of the product is only authorised for use class 1. The application by borehole impregnation was withdrawn by the applicant and therefore must be removed from the label for professional users.

In the information sheet, professional users are requested to take note of the provisions of DIN 68800-3:2012 and DIN 68800-4:2012. DIN 68800 is a German national standard for wood protection in structural engineering. The provisions of DIN 68800 have not been considered in the assessment for

authorisation of the biocidal product "Anti-Insekt", thus the present authorisation does not include the protection of structural wood components according to DIN 68800.

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

As the product is not intended to be authorised for use with other biocidal product(s), there is no need for information at this point.

3.6.10 Data waiving and conclusion

As no data relevant for efficacy of the product have been waived, there is no need for information at this point.

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Conclusion on the efficacy
With the application rate of 200 to 250 ml/m² (preventive use, surface application via brushing or spraying) and 300 to 350 ml/m² (curative use, surface application via brushing or spraying) sufficient preventive and curative efficacy against wood boring beetle larvae (*Hylotrupes bajulus* and *Anobium punctatum*) can be assumed and the product “Anti-Insekt” can be authorised.

3.7 Risk assessment for human health

3.7.1 Assessment of effects of the active substance on human health

Table 16

Permethrin	Value	Study	Safety factor
AEL long-term	0.05 mg/kg bw/d	12-month dog study. Bayer (Kalinowski *et al*, 1982)	100
AEL medium-term	0.05 mg/kg bw/d	12-month dog study. Bayer (Kalinowski et al, 1982)	100
AEL acute	0.5 mg/kg bw	Rat 2 year oral study (acute effect) Bayer (Ishmael and Litchfield, 1988)	100

Table 17

Permethrin	Value	Reference
Inhalative absorption	100 %	Default value
Oral absorption	100 %	Assessment-Report (RMS IE (2014))
Dermal absorption	3 % **75 %**	Assessment-Report (RMS IE (2014)) Human dermal penetration study Default value to be used for the product evaluated

3.7.2 Assessment of effects of the product on human health

3.7.2.1 Skin corrosion and irritation

Table 18

Data waiving was acceptable for the following information requirements	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	A skin irritation study performed with the product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.1 “Skin corrosion or skin irritation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), “testing on the biocidal products does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected. Sufficient information on skin-irritating/skin corrosion properties of the components of the biocidal product is available. Information on synergistic effects are not available. According to Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing is considered not necessary. For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available through safety data sheets and other information for each of the individual components in the product. Information on synergistic effects is not available.

Table 19

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to the skin. May cause skin dryness and cracking. May cause paresthesia.
Justification for the value/conclusion	Evaluation and classification is based on the toxicological properties of the single components. The content of components classified for skin irritation or corrosivity is below the limits for classification. The biocidal product contains Naphtha (petroleum, hydrotreated heavy, CAS No. 64742-48-9, 89 %, w/w), which is labelled with EUH066 (Annex VI of Regulation (EC) No 1272/2008. Thus, also the biocidal product has to be labelled accordingly. Pyrethroids like the active substance permethrin can cause paresthesia.
Classification of the product according to CLP	Classification for skin irritation/corrosivity is not required. Labelling with EUH066 (Repeated exposure may cause skin dryness or cracking). Labelling for paresthesia.

3.7.2.2 Eye irritation

Table 20

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	An eye irritation study performed with the product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.2 “Eye irritation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), “testing on the biocidal products does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected. Sufficient information on eye-irritating/eye damage properties of the components of the biocidal product is available. Information on synergistic effects are not available. According to Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing is considered not necessary For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available through safety data sheets and other information for each of the individual components in the product. Information on synergistic effects is not available. Based on the results of the eye irritation studies with the active substance and information on the hazards of the single components it can be predicted that the biocidal product is not an eye irritant.

Table 21

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to the eyes.
Justification for the value/conclusion	Evaluation and classification is based on the toxicological properties of the single components. The content of components classified for eye irritation or damage is below the limits for classification.
Classification of the product according to CLP	Classification for eye irritation/damage is not required.

3.7.2.3 Respiratory tract irritation

Table 22

Data waiving	
Information requirement	Annex III of BPR, point 8.7.1, “other endpoints”
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008. The biocidal product does not contain components classified for respiratory irritation in relevant concentrations

Table 23

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the value/conclusion	Based on intrinsic properties of individual components the biocidal product is not irritating to the respiratory tract.
Classification of the product according to CLP	Classification for respiratory tract irritation is not required.

3.7.2.4 Skin sensitization

Table 24

Data waiving was acceptable for the following information requirements	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin sensitising properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.3 “Skin sensitisation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), “testing on the biocidal products does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available through safety data sheets and other information for each of the individual components in the product. Information on synergistic effects is not available.

Table 25

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitising.
Justification for the value/conclusion	The active substance is classified for skin sensitisation according to Regulation (EC) No 1272/2008: Permethrin (0.25 %): Skin Sens. 1 [1)] (H317: C ≥ 1 %; EUH208: C > 0.1 %)[2)3)]
Classification of the product according to CLP	Classification for skin sensitisation is not required. Labelling with EUH208 (Contains permethrin. May produce an allergic reaction.)

1) According to Annex VI of Regulation (EC) No 1272/2008
2) According to Regulation (EC) No 1272/2008
3) According to the active substance evaluation permethrin is not skin-sensitising. A CLH intention to remove this entry has been submitted. However, a final decision is not available. Thus, the current classification is legally binding.

3.7.2.5 Respiratory sensitization (ADS)

Table 26

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	Data on respiratory sensitisation for the biocidal product or their components are not available.

Table 27

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	8.4. Respiratory sensitisation
Justification for the value/conclusion	Data on respiratory sensitisation for the biocidal product or their components are not available.
Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

3.7.2.6 Acute toxicity

3.7.2.6.1 Acute toxicity by oral route

Table 28

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.1. By oral route
Justification	A study on acute oral toxicity of the biocidal product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 “Acute toxicity” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), “testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal product the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components. Consequently, classification of the biocidal product can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 29

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route. Causes human aspiration toxicity.
Justification for the selected value	Based on the oral LD_{50} available for the single components the oral LD_{50} of the biocidal product is estimated as > 2000 mg/kg bw. Additional information on non-active substances: Naphtha, petroleum, hydrotreated heavy (ShellSol D60; 93 %, w/w) Asp. 1 [1)], (concentration limit for Asp. 1: ≥ 10 %; kinematic viscosity (40 °C) ≤ 20.5 mm^2/s) [2)]
Classification of the product according to CLP	Classification for acute oral toxicity is not required. Asp. 1; H304 (May be fatal if swallowed and enters airways.)

[1)] According to Annex VI of Regulation (EC) No 1272/2008

[2)] According to Regulation (EC) No 1272/2008. The dynamic viscosity and the density of the biocidal product are: 0.982 mPa x s (40 °C) and 0.7946 g/cm^3 (20 °C), respectively. In accordance to Regulation (EC) No 1272/2008 Annex I, section 3.10.1.6.2 a dynamic viscosity of 1.2 mm^2 / s is calculated.

3.7.2.6.2 Acute toxicity by inhalation

Table 30

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	A study on acute inhalation toxicity of the biocidal product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 “Acute toxicity” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), “testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal product the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components. Consequently, classification of the biocidal product can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 31

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route.
Justification for the selected value	Based on the inhalation LC_{50} available for the single components the inhalation LC_{50} of the biocidal product is estimated as > 5 mg/L.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required.

3.7.2.6.3 Acute toxicity by dermal route

Table 32

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.3. By dermal route
Justification	A study on acute dermal toxicity of the biocidal product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 “Acute toxicity” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), “testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal product the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components. Consequently, classification of the biocidal product can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 33

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	Based on the dermal LD50 available for the single components the dermal LD50 of the biocidal product is estimated as > 2000 mg/kg bw.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

3.7.2.7 Information on dermal absorption

Table 34

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	The applicant refers to the study of Bartelt und Hubbell (1987, in vivo, human) submitted for the evaluation of the active substance. For this study only a study summary from the CAR is available. According to this summary the test formulation was 0.081 % permethrin solved mainly in propan-2-ol. It is not known if the test formulation contains other components. In contrast, the biocidal product consists of 0.25 % permethrin solved in Naphtha (petroleum), hydrotreated heavy (CAS-Nr. 64742-48-9) with some other co-formulants. Both solvents differ significantly with respect to their physico-chemico properties. Propan-2-ol is a polar organic solvent whereas Naphtha is an extremely non-polar liquid. Hence, both formulations are not comparable according to EFSA Guidance on Dermal Absorption (2012). Differences in dermal absorption are very likely.

Table 35

Value(s) used in the Risk Assessment – Dermal absorption	
Substance exposure scenario(s) (e.g. undiluted formulation or 1:100 in-use dilution, etc.)	All scenarios
Value(s)	75 %
Justification for the selected value(s)	Default, EFSA Guidance on Dermal Absorption (2012), refer also to the table above

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

Naphtha, petroleum, hydrotreated heavy (CAS-No. 64742-48-9) was identified as substance of concern. For toxicological properties of this component refer to sections 3.7.2.1 and 3.7.2.6.1.

3.7.2.9 Available toxicological data relating to a mixture

Not relevant

3.7.2.10 Other

Not relevant

3.7.2.11 Summary of effects assessment

Table 36

Endpoint	Brief description
Skin corrosion and irritation	Not classified for skin irritation or corrosion. Repeated exposure may cause skin dryness or cracking. Labelling with EU066 is required. Skin exposure may cause paresthesia.
Eye irritation	Not classified for eye irritation or damage.
Respiratory tract irritation	Not classified for respiratory tract irritation.
Skin sensitisation	Not classified for skin sensitisation. However, labelling with EUH208 for permethrin is required.
Respiratory sensitization (ADS)	Not classified for respiratory sensitisation.
Acute toxicity by oral route	Not classified for acute oral toxicity. Oral LD_{50} calculated from information on the ingredients: > 2000 mg/kg bw. Classification with Asp. 1, H304 is required due to the toxicological properties of an ingredient and its concentration in the biocidal product. .
Acute toxicity by inhalation	Not classified for acute inhalation toxicity. Inhalation LC_{50} calculated from information on the ingredients: > 5.0 mg/L.
Acute toxicity by dermal route	Not classified for acute dermal toxicity. Dermal LD_{50} calculated from information on the ingredients: > 2000 mg/kg bw.
Information on dermal absorption	In the absence of a dermal absorption study with a comparable biocidal product a default of 75 % should be used for human exposure and risk assessment.
Available toxicological data relating to non-active substance(s)	Refer to sections above.
Available toxicological data relating to a mixture	Not relevant
Other relevant information	Not available

3.7.3 Exposure assessment

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

Table 37

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	Not applicable	Yes	yes	Not applicable	Yes	yes	n.a.
Dermal	Not applicable	Yes	yes	Not applicable	Yes	yes	n.a.
Oral	Not applicable	Not applicable	no	Not applicable	Not applicable	yes	no

List of scenarios

Table 38

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Application	Primary exposure, acute - application by brushing outdoor (dermal, inhalation)	Non-professionals
2.	Application	Primary exposure, acute - application by brushing indoor (dermal, inhalation)	Non-professionals
3.	Application	Primary exposure, acute - cleaning brush (dermal)	Non-professionals
4.	Post-application	Secondary exposure, acute, adult - processing (sanding/cutting) treated wood, (inhalation, dermal)	General public
5.	Post-application	Secondary exposure, acute, toddler - chewing treated wood off-cut, (oral)	General public
6.	Post-application	Secondary exposure, long-term, toddler (represents also worst case for older children and adults) - inhalation of volatilised residues indoors (inhalation)	General public
7.	Post-application	Secondary exposure, long-term, toddler - playing on treated structure and mouthing, (dermal, oral)	General public

Summary table: scenarios				
Scenario number	**Use number**	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1	1	Spray treatment	Primary exposure of workers resulting from application of the b.p. using a hand-held and powered spraying device and cleaning of equipment.	Professional
2	2	Brush treatment	Primary exposure of workers resulting from application of the b.p. using hand-held equipment such as a brush or a roller and cleaning of equipment.	Professional
3	-	Secondary exposure: Mechanical processing of treated wood	Secondary exposure of workers resulting from mechanical processing of treated wood, i.e. sawing or sanding preventively or curatively treated wood.	Professional

3.7.3.1.1 Professional exposure

Anti-Insekt is a solvent-based liquid wood preservative. It is applied by spraying or brushing for the curative or preventive treatment of wooden structures.

Anti-Insekt is a ready-to-use wood preservative containing the active substance (a.s.) permethrin (CAS-No 52645-53-1, 0.269%). The biocidal product also contains the substance of concern (SoC) hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics (CAS-No.: -).

For professional use, the biocidal product is marketed in different package sizes: container, tinplate 0.75, 5, 10 L.

The exposure to the a.s./ SoC. is assessed separately for the different application techniques and will thus be described in individual subsections of the current section. It is usually based on the harmonised document “Biocides Human Health Exposure methodology (BHHEM, October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated where relevant with the corresponding parts from HEEG/HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007.

In Chapter 4.3.1the details of the exposure calculations to the a.s./ SoC for the professional user are laid out.

The inhalation exposure to the SoC hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics, resulting from the different application techniques is assessed using the consumer exposure model ConsExpo or the Advanced REACH Tool (ART), respectively, which are applicable to assess the volatile substance.

- **Scenario 1: Spray treatment**

Table 39

Description of Scenario [n]

Description

A harmonised approach for exposure assessment of spray treatment is described in the *Biocides Human Health Exposure Methodology document* (October 2015, version 1). The assessment laid out in this PAR follows this approach.

Anti-Insekt is a ready-to-use wood preservative which is sprayed with hand-held and powered equipment.

Dermal exposure

Exposure to skin is considered to occur during all phases of handling.

During the application process, exposure via skin seems likely, mainly due to the deposition of the generated droplets on the work clothing and the hands of the operator. The application method of manual spraying is assessed using "Spraying model 2" (*Biocides Human Health Exposure Methodology document,* October 2015, version 1) and the applicant also propounds this model to assess the described exposure situation. The model is based on measurement data collected during spraying with hand-held spraying device and medium spraying pressure (4-7 bar) and provides data of potential body and actual hand exposure (measurements of hand exposure inside gloves). The model covers spray application indoors and outdoors, in overhead and downward direction. It relates to application of remedial biocides to structural timber and masonry in industrial, recreational and residential settings. It already contains the loading phase. Therefore, a separate calculation for this phase has not been performed.

In addition, exposure of hands during cleaning of the equipment has to be considered, although it represents a minor part of the total dermal exposure. This post-application phase is assessed using the model presented in the "*Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure: Cleaning of spray equipment in antifouling use (PT 21)*". However, the assessor assumes that a thorough cleaning for 20 minutes as considered in the above mentioned document for PT 21 is not needed in case of solvent wood preservative solutions; instead, a figure of 10 min seems to be appropriate here.

Exposure by inhalation

Exposure to aerosols occurs during the application phase (spraying) and is calculated for the a.s. permethrin using the values from "Spraying model 2". In addition, inhalation exposure to vapours of the SoC hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics was calculated using the advanced REACH Tool (ART). The modelled scenario included the 80 min application phase and a 400 min nonexposure period. However, in order to estimate the short-term exposure level (STEL), the exposure occurring during the 80 min phase of the actual application was assessed separately.

Summary of exposure assessment

The results of the calculation for potential / actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 42 (for risk characterisation, see 3.7.4). Details of the exposure calculations for the professional user are laid out in annex 4.3.1.

In Tier 2, a refined exposure assessment is performed due to the identified risk in Tier 1. Since the dermal exposure to the a.s. permethrin is most relevant, the following safety measures are taken into account for Tier 2: protective gloves and protective coverall (type 3/4, impermeable). To reduce the exposure of vapours of the volatile SoC hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics, with regard to the German OEL, improved ventilation was included in Tier 2. However, even with improved ventilation, exceedance of the short-term exposure level established by the German TRGS-900 was found to be likely. Thus, RPE was included in Tier 2 in order to keep the German short-term OEL during the application phase.

	Parameters	Value

Tier 1	conc. a.s. permethrin	0.269%
	conc. SoC hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics	93.431%
	density of product	0.7946 g/cm³
	Amount of b.p. used	37.35 kg [1)]
	Air exchange rate (used for calculation of exposure to vapours of the SoC with ART)[2)]	0.3 /h
Tier 2	Air exchange (Improved ventilation: cross ventilation)	3 /h
	APF for RPE (Half mask+gas filter/P2-Particelfilter)	10
	Chemical protective gloves, protection factor	90%
	Chemical protective coverall (Type 3 or 4, impermeable), protection factor	95%

1) Biocides Human Health Exposure Methodology, Version 1, Oct. 2015, Chapter 3.1.1-PT 8 (p. 50) indicates a median quantity of 47 L of product used spraying job, which equals the indicated amount at the given density.
2) The RMS assumes an air exchange rate of 0.5 /h for natural ventilation (Tier 1) and 5 /h for improved industrial ventilation or cross ventilation by keeping windows and doors open (Tier 2), respectively. However, these values cannot be selected in ART. Therefore, air exchange rates of 0.3 /h and 3 /h were used.

Calculations for Scenario 1

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 42 For details of the calculation of dermal and inhalation exposure, please refer to Chapter 4.3.1 of this PAR. For risk characterisation, see chapter 3.7.4.

- **Scenario 2: Brush treatment**

Table 40

Description of Scenario 3: Brush treatment

Description

A harmonised approach for exposure assessment of brush treatments is described in the *Biocides Human Health Exposure Methodology document* (October 2015, version 1). The assessment laid out in this PAR follows this approach.

Anti-Insekt is a ready-to-use wood preservative which is applied using hand-held equipment such as brush or roller for brush application.

Dermal exposure

Exposure to skin is considered to occur during all phases of handling.

For the application phase, no appropriate exposure model for professional brushing is available, therefore the dermal exposure is assessed using the BfR “Summary Report - Human Exposure to Wood Preservatives” which is recommended by the harmonised document “Biocides Human Health Exposure Methodology (October 2015, version 1)”. The application process significantly contributes to the total dermal exposure.

Additionally, exposure of hands during cleaning of the brush is considered, although it represents a minor part of the total dermal exposure. As a worst case assumption this post-application phase is calculated on the basis of a Human Exposure Expert Group opinion (HEEG, endorsed TM III 2010) dealing with washing paint out of a brush.

Exposure by inhalation

Exposure to aerosols is only expected for the application phase and for the a.s. permethrin, it was calculated using indicative values of the German BfR-study. This is in line with the harmonised document “*Biocides Human Health Exposure Methodology”* (October 2015, version 1). In this study, inhalation exposure has been detected, but exposure to aerosols was not mentioned in detail. On this account, it is assumed that the values given by this study might overestimate the exposure by inhalation. The short-term exposure level (STEL) was extracted from the time dependent air concentrations simulated in ConsExpo 4.1. It is the average over the 15 min interval with the highest air concentration.

In addition, inhalation exposure to vapour has to be calculated for the volatile SoC hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics using ConsExpo 4.1. In contrast to the non-volatile a.s. permethrin, the exposure to aerosols of the volatile compound is assessed to be negligible in relation to the exposure to vapour.

Summary of exposure assessment

The results of the calculation for potential / actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 42 (for risk characterisation, see 3.7.4). Details of the exposure calculations for the professional user are laid out in annex 4.3.1.

In Tier 2, a refined exposure assessment is performed due to the identified risk in Tier 1. Since the dermal exposure to the a.s. permethrin is most relevant, protective gloves as a risk reduction measure are taken into account for Tier 2. To reduce the exposure to vapours of the volatile SoC hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics, with regard to the German OEL, an improved ventilation was included in Tier 2.

	Parameters	Value
Tier 1	conc. a.s. permethrin	0.269%
	conc. SoC hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics	93.431%

	density of product	0.7946 g/cm³
	Amount of b.p. used	8.79 kg
	Air exchange rate (used for calculation of exposure to vapours of the SoC with ConsExpo)	0.5 /h
	Duration of stay in the treated area (used for calculation of exposure to vapours of the SoC with ConsExpo)	480 min
Tier 2	Air exchange (Improved ventilation: cross ventilation)	5 /h
	Chemical protective gloves, protection factor	90%

Calculations for Scenario 2

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 42 . For details of the calculation of dermal and inhalation exposure, please refer to Chapter 4.3.1 of this PAR. For risk characterisation, see chapter 3.7.4.

- **Scenario 3: Mechanical processing of treated wood**

Table 41

Description of Scenario 4: Mechanical processing of treated wood		
Description Secondary exposure due to mechanical processing of treated wood produced by application via spraying or brushing cannot be excluded. Therefore, the inhalation exposure to wood dust and dermal exposure during handling of treated wood and resulting from transfer of wood preservative to the skin are estimated here. Inhalation exposure for mechanical processing of treated wood is assessed taking the limit value for the wood dust concentration of 2 mg/m³ into account - according to the German Hazardous Substances Ordinance "Gefahrstoffverordnung" and the Technical Rules for Hazardous Substances (TRGS 553). For calculation of the concentration of the a.s. within the wood dust, it is assumed that the applied application liquid is distributed within a thin layer at the wood surface. Sanding, as a worst case, releases wood dust created entirely from this layer. The density of the wood is taken from the Technical Agreements for Biocides (TAB, 2016, version 1). Since the a.s. is not chemically fixed to the wood it cannot be ruled out that the substance can be released when the surface is wet, for instance. Therefore, it is reasonable that during the mechanical processing of treated wood dermal exposure could occur due to transfer of wood preservative to the hand. For exposure assessment, it is assumed that 20 % of both palms are exposed. *Summary of exposure assessment* The results of the calculation for potential / actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 42 (for risk characterisation, see 3.7.4). Details of the exposure calculations for the professional user are laid out in annex 4.3.1. In Tier 2, a refined exposure assessment is performed due to the identified risk in Tier 1. Since the dermal exposure to the a.s. permethrin is most relevant, protective gloves as a risk mitigation measure are taken into account for Tier 2.		
	Parameters	Value
Tier 1	conc. a.s. permethrin	0.269%
	density of the b.p.	0.7946 g/cm³
	application amount b.p.	350 mL/m²
	application amount b.p.	278 g/m²
	conc b.p. in treated wood surface	139.055 kg/m³
Tier 2	Chemical protective gloves, protection factor	90%

Calculations for Scenario 3

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 42. For details of the calculation of dermal and inhalation exposure, please refer to Chapter 4.3.1 of this PAR. For risk characterisation, see chapter 3.7.4.

- **Summary of professional exposure**

The scenarios described here include all phases of application (mixing and loading, application and post-application). Therefore, the values in the following table are combined exposure values of all phases.

Table 42

Exposure scenario	**Tier/PPE**	**a.s. 1 permethrin**		**SoC 1 hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics**
		Estimated external inhalation exposure	**Estimated external dermal exposure [mg/day]**	**Estimated external inhalation exposure [mg/m³]**
Scenario 1 Spray treatment	Tier 1: • No protection	3.41x10^{-2} mg/m^3	85.82	8 h TWA: 630 STEL: 3700
	Tier 2: • Protective gloves (EN 374)[1)] • Protective coverall[2)] • Improved ventilation[3)] RPE providing an APF of 10[4)]	3.41x10^{-3} mg/m^3	3.33	8 h TWA: 15 STEL: 89
Scenario 2 Brush treatment	Tier 1: • No protection	1.36x10^{-2} mg/day	5.55	8 h TWA: 677 STEL: : 1094
	Tier 2: • Protective gloves[1)] (EN 374) • Improved ventilation [3)]	1.36x10^{-2} mg/day	2.00	8 h TWA: 121 STEL: : 166
Scenario 3 Secondary exposure of workers resulting from mechanical processing of treated wood	Tier 1: • No protection	1.87x10^{-3} mg/m³	6.13	n.a.
	Tier 2: • Protective gloves (EN 374)	1.87x10^{-3} mg/m³	0.61	n.a.

1) EN 374
2) Type 3/4, EN 14605
3) Cross ventilation providing an air exchange rate of 3 /h (ART) or 5/h (ConsExpo).
4) Helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2

3.7.3.1.2 Non-professional exposure

- **Scenario [1]**

Table 43

Description of Scenario [1]		
Primary acute exposure by application, brushing, outdoor, non-professional user, dermal and inhalation exposure The biocidal product is for non-professional use and will be applied outdoors by brushing. According to the label provided by the applicant the biocidal product is also applied on the inner surface of window frames and doors. Since windows and doors has to be disassembled or at least opened before application this use can also considered as outdoor use and no separate exposure scenario has to be assessed. Exposure assessment is based on exposure data summarised in the Biocides Human Health Exposure Methodology, 2015 and the TNsG on Human Exposure (2002): Brushing sheds and fences, outdoor (direct from can). (Ann. Occup. Hyg. 44: 421-426, 2000). The exposure duration of 150 min is also based on these documents.		
	Parameters	Value
Tier 1	Dermal exposure hands, indicative value (Biocides Human Health Exposure Methodology, 2015)	5.91 mg BP/min
	Dermal exposure body, indicative value (Biocides Human Health Exposure Methodology, 2015)	16.9 mg BP/min
	Inhalation exposure, indicative value (Biocides Human Health Exposure Methodology, 2015)	1.63 mg BP/m^3
	Concentration a.s. (tech.) in the b.p.	0.25 % (w/w)
	Exposure duration (TNsG on Human Exposure, 2002; Ann. Occup. Hyg. 44: 421-426, 2000)	150 min
	Dermal absorption (Default, EFSA Guidance on Dermal Absoprtion, 2012)	75 %
	Inhalation absorption (default for all active substances, CAR)	100 %
	Inhalation rate, adult (HEEG opinion No. 17, short-term exposure)	1.25 m^3/h
	Body weight, adult (HEEG opinion No. 17)	60 kg
	No protection by gloves or clothing	

Calculations for Scenario [1]

Systemic exposure

$Exposure_{dermal}$ = (dermal exposure hands + dermal exposure body) x concentration a.s. x exposure duration x dermal absorption / body weight adult

$Exposure_{inhalation}$ = inhalation exposure x concentration a.s. x exposure duration x inhalation rate x inhalation absorption / body weight adult

$Exposure_{dermal}$ = (5.91 mg BP/min + 16.9 mg BP/min) x 0.25 % x 150 min x 75 % / 60 kg
= 0.1069 mg/kg bw

$Exposure_{inhalation}$ = 1.63 mg/m³ x 0.25 % x 150 min x 1.25 m³ / 60 min x 100 % / 60 kg
= 0.0002 mg/kg bw

Total systemic exposure = 0.1071 mg a.s./kg bw

- **Scenario [2]**

Table 44

Description of Scenario [2]		
Application, Primary exposure, acute, application by brushing indoor (dermal, inhalation) For the scenario brushing indoors the Consumer product painting model 1 TNsG on Human Exposure (2002) part 2, p. 202, Rough wooden joists and the underside of floor boards, overhead indoors, with water based product (includes decanting) as proposed in the Biocides Human Health Exposure Methodology document (2015) is used. According to the applicant and as clearly indicated on the label provided by the applicant the maximum surface for indoor treatment is 3 m². Since the biocidal product is particularly for use on wooden furniture and similar small objects this is considered realistic. 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/m². Thus, for 3 m³ an application duration of 23 min can be calculated (rounded up to 30 min). Although this value was determined for outdoor treatment it is also considered applicable for indoor application.		
	Parameters	Value
Tier 1	Dermal exposure hands, indicative value (Biocides Human Health Exposure Methodology, 2015)	150 mg BP/min
	Dermal exposure body, indicative value (Biocides Human Health Exposure Methodology, 2015)	35.7 mg BP/min
	Inhalation exposure, indicative value (Biocides Human Health Exposure Methodology, 2015)	3.1 mg BP/m³
	Concentration a.s. (tech.) in the b.p.	0.25 % (w/w)
	Exposure duration (Ann. Occup. Hyg. 44: 421-426, 2000), maximum surface for indoor treatment: 3 m², see also section *Further information and considerations on scenario [2]*	30 min
	Dermal absorption (default, EFSA Guidance on Dermal Absorption, 2012)	75 %
	Inhalation absorption (default)	100 %
	Inhalation rate, adult (HEEG opinion No. 17, 2013, short-term exposure)	1.25 m³/h
	Body weight, adult (HEEG opinion No. 17, 2013)	60 kg
	No protection by gloves or clothing	

Calculations for Scenario [2]

$Exposure_{dermal}$ = (dermal exposure hands + dermal exposure body) x concentration a.s. x exposure duration x dermal absorption / body weight adult
= (150 mg BP/min + 35.7 mg BP/min) x 0.25 % x 30 min x 75 % /60 kg
= 0.1740 mg/kg bw

$Exposure_{inhalation}$ = inhalation exposure x concentration a.s. x exposure duration x inhalation rate x inhalation absorption / body weight adult
= 3.1 mg/m^3 x 0.1 % x 30 min x 1.25 m^3 / 60 min x 100 % / 60 kg
= 0.0001 mg/kg bw

Total systemic exposure = 0.1741 mg a.s./kg bw

- **Scenario [3]**

Table 45

Description of Scenario [3]		
Primary acute exposure by cleaning the brush, non-professional user, dermal exposure Dermal exposure by cleaning of the used brush is assessed according to the HEEG opinion No. 11 Exposure model Primary exposure scenario - washing out of a brush which has been used to apply a paint (2010) using the attached Excel sheet (section 4.3.2).		
	Parameters	Value
Tier 1	Volume of paint remaining on brush after painting (1/8 of 200 ml = 25 ml, HEEG opinion No. 11, 2010)	25 mL
	Concentration a.s. (tech.) in the b.p.	0.25 % (w/w)
	Density biocidal product	0.7946 g/cm^3
	Penetration factor gloves (no gloves)	100 %
	Dermal absorption permethrin (refer to chapter37.7.2.7 Information on dermal absorption)	75 %
	Frequency of washing (HEEG opinion No. 11, 2010)	3
	Body weight, adult (HEEG opinion No. 17, 2013)	60 kg

Calculations for Scenario [3]

For detailed exposure calculations refer to the corresponding extract from the excel sheet (as presented in the HEEG opinion No. 11, 2011) in chapter 4.3.2

Systemic exposure

$Exposure_{dermal}$ = **0.00327 mg/kg bw**

Table 46

Summary table: systemic exposure from non-professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake [mg/kg bw]	Estimated dermal uptake [mg/kg bw]	Estimated oral uptake [mg/kg bw]	Estimated total uptake [mg/kg bw]
Scenario [1]; Application by brushing, outdoor, dermal and inhalation exposure	1	0.0002	0.1069	-	0.1071
Scenario [2] Application by brushing, indoor, dermal and inhaltion exposure	1	0.0001	0.1740	-	0.1741
Scenario [3]; Cleaning the brush, dermal exposure	1	-	0.00327	-	0.00327

- **Combined scenarios**

Table 47

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**Estimated inhalation uptake [mg/kg bw]**	**Estimated dermal uptake [mg/kg bw]**	**Estimated oral uptake [mg/kg bw]**	**Estimated total uptake [mg/kg bw]**
Scenarios [1+3]	0.0002	0.1069 0.0033	-	0.1104
Scenarios [2+3]	0.0001	0.1740 0.0033	-	0.1774

3.7.3.1.3 Secondary exposure of the general public

- **Scenario [4]**

Table 48

Description of Scenario [4]		
Secondary acute exposure, adult - sanding treated wood, inhalation and dermal exposure The exposure estimates of the general public to the active substance of this biocidal product in treated wood by sanding is based on the recommendations of the TNsG on Human Exposure (2002). Some parameters have been adapted due to more recent guidance. It is assumed that an adult sands a wooden post with a dimension of 4 cm x 4 cm x 250 cm. The long sides of the post are treated with biocidal product (4000 cm^2). It is assumed that the biocidal product is evenly distributed in the 1-cm outer layer. The corresponding wood volume is 3000 cm^3. Hence the concentration of the active substances in the wood can be calculated from the application rate, the density, the treated surface and the volume of wood with biocidal product. The transfer coefficient and the percentage of the hand getting in contact have not been adopted from the TNsG on Human Exposure (2002) but amended in accordance to the HEAdhoc recommendation No. 5 Non-professional use of antifouling paints: exposure assessment for a toddler (2015). Although these parameters are for exposure of toddlers to antifouling paints it is expected that they also represent a worst case for adults getting in contact to wood preservatives..		
	Parameters	Value
Tier 1	Application rate (applicant)	350 mL/m^2 = 278.11 g/m^2 assuming a density of 0.7946 g/cm^2
	Concentration a.s. (tech.) in the b.p.	0.25 % (w/w)
	Dimension of wooden post to be sanded (TNsG on Human Exposure (2002) Part 3, Page 50),	4 cm x 4 cm x 250 cm = 4000 cm^3

	Surface of wooden post treated with the biocidal product (long sides only)	4000 cm^2
	Volume of wood treated with biocidal product (biocidal product is in the 1-cm-outer-layer (TNsG on Human Exposure (2002) Part 3, Page 50)	3000 cm^3
	Concentration a.s.on/in the treated wood: Application rate x density x concentration a.s. x surface treated wood / volume treated wood [1)]	0.09270 mg a.s./cm^3
	Hand inner surface (both hands), adult (HEAdhoc Recommendation No. 14, 2017), half of both hands	410 cm^2
	Percentage of hand surface getting in contact to the biocidal product (HEAdhoc recommendation No. 5, 2015)	40 %
	Transfer coefficient, rough sawn wood, dried fluid (Biocides Human Health Exposure Methodology, 2015 and HEAdhoc recommendation No. 5, 2015)	3 %
	Dermal Absorption (default acc. to EFSA Guidance on Dermal Absorption (2012), refer also to3.7.2.7)	75 %
	Body weight, adult (HEAdhoc Recommendation No. 14, 2017)	60 kg
	Wood density (MOTA, 2013 from TM III, 2008)	0.4 g/cm^3
	Wood dust concentration in the air during sanding (EU, OEL, 2004)	5 mg/m^3
	Exposure duration (TNsG on Human Exposure (2002) part 3, page 50)	60 min
	Inhalation rate adult, long-term (HEAdhoc Recommendation No. 14, 2017)	1.25 m^3/h
	Inhalation absorption (CAR/AR, 2014)	100 %

[1)] For inhalation exposure, it is assumed that the applied amount is evenly distributed in the 1-cm-outerlayer.

Calculations for Scenario [4]

Systemic exposure

$Exposure_{dermal}$ = concentration a.s. in the treated wood x hand inner surface of both hands x percentage contaminated skin x transfer coefficient x dermal absorption / body weight adult

$Exposure_{inhalation}$ = concentration a.s. in the treated wood x aerial wood dust concentration / density wood dust x exposure duration x inhalation rate / body weight adult

$Exposure_{dermal}$ = 0.093196 mg a.s./cm^3 x 410 cm^2 x 40 % x 3 % x 75 % / 60 kg
= 0.005701 mg a.s./kg bw

$Exposure_{inhalation}$ = 0.08767 mg a.s./cm^3 x 5 mg/m^3 x 1 h x 1.25 m^3/h / (0.4 g/cm^3 x 60 kg)
= 0.000024 mg a.s./kg bw

Total systemic exposure = 0.00573 mg a.s./kg bw

- **Scenario [5]**

Table 49

Description of Scenario [5]		
Secondary acute exposure, toddler - chewing treated wood off-cut, oral exposure The exposure estimates are based on the recommendations of the TNsG on Human Exposure (2002). It is based on the assumption that a toddler mouth and chew a piece of wood of 4 cm x 4 cm x 1 cm, which can be considered as 1 cm-cut-off of a wooden post as described in scenario 3. Hence, four surfaces of 1 cm x 4 cm are treated with the biocidal product resulting in a total surface of 16 cm^2. The concentration of the active substance on the wood surface is calculated from application rate and the density. The total amount of a.s. available for extraction is calculated from the treated surface and the application rate.		
	Parameters	Value
Tier 1	Application rate (applicant)	350 mL/m^2 = 0.0350 mL/cm^2
	Density biocidal product (applicant)	0.7946 g/cm^3
	Concentration a.s. (tech.) in the b.p.	0.25 % (w/w)
	Concentration a.s. on the surface	0.06953 mg a.s./cm^2
	Dimension of the wood cut off (TNsG Human Exposure to Biocidal Products (2002) Part 3, page 50, Infant acute, Chewing wood off-cut)	4 cm x 4 cm x 1 cm = 16 cm^3
	Surface treated with the biocidal product (for calculation see above)	4 x 4 cm x 1 cm = 16 cm^2
	Total amount a.s. on/in wood (= surface treated with the biocidal product x concentration a.s. on the surface) [1)]	1.112 mg a.s.
	Extraction coefficient (TNsG Human Exposure to Biocidal Products (2002) Part 3)	10 %
	Oral absorption (CAR/AR, default)	100 %
	Body weight, toddler (HEAdhoc Recommendation No. 14, 2017))	10 kg

[1)] It is assumed that the whole amount applied to the surface is potentially available for oral exposure

Calculations for Scenario [5]

Systemic exposure

$Exposure_{oral}$ = Total amount a.s. in/on wood x extraction coefficient x oral absorption / body weight toddler

$Exposure_{oral}$ = 1.112 mg a.s. x 10 % x 100 % / 10 kg

0.0111 mg/kg bw

- **Scenario [6]**

Table 50

Description of Scenario [6]		
Secondary long-term exposure, adult - inhalation of volatilised residues in doors ,inhalation exposure This scenario is based on a proposal from the TNsG on Human exposure (2002) and the more specified recommendations in the HEEG opinion No. 13 “Assessment of Inhalation Exposure of Volatilised Biocide Active Substance”. The estimation of air concentrations by saturated vapour pressure is a conservative but very simple approach. Since the major use of the biocidal product will be outdoors the potential risk by inhalation exposure is limited to a small number of applications. This exposure assessment for toddlers represents also a worst case for other members of the general public.		
	Parameters	Value
Tier 1	Molecular weight a.s. (CAR/AR, 2014)	391.3 g/mol
	Vapour pressure a.s. (25 °C, CAR/AR, 2014)	2.155×10^{-6} Pa
	Gas constant (Atkins Physical Chemistry, 5th Edition)	8.31451 J/mol/K
	Temperature (assumed room temperature = 20 °C HEEG opinion No. 13, 2011)	293 K
	Saturated vapour pressure a.s. (calculated acc. to HEEG opinion No. 13, 2011)	3.46×10^{-4} mg/m^3
	Exposure duration (worst case, HEEG opinion No. 13, 2011)	24 h
	Inhalation rate, toddler (HEAdhoc Recommendation No. 14, 2017, long-term exposure)	8 m^3/24 h
	Inhalation absorption (CAR/AR 2014, default)	100 %
	Body weight, toddler (HEAdhoc Recommendation No. 14, 2017)	10 kg

Calculations for Scenario [6]

Systemic exposure

$Exposure_{inhalation}$ = saturated vapour concentration a.s. x inhalation rate x inhalation duration x inhalation absorption / body weight toddler

$Exposure_{inhalation}$ = 3.46×10^{-4} mg/m^3 x 8 m^3/d x 1 d x 100 % / 10 kg

= 0.000277 mg a.s./kg bw/d

- **Scenario [7]**

Table 51

Description of Scenario [7]		
Secondary long-term exposure, toddler - playing on treated structure and mouthing, dermal and oral exposure A first recommendation for assessment of secondary long-term exposure of a toddler playing on treated structures is provided in the TNsG on Human Exposure (2002). This exposure assessment was amended in accordance to the Recommendation No. 5 of the BPC Ad hoc Working Group on Human Exposure (HEAdhoc) “Non-professional use of antifouling paints: exposure assessment for a toddler” (2015). It is assumed that dried wood preservatives and antifoulings have similar properties in this context. This exposure assessment for toddlers represents also a worst case for other members of the general public.		
	Parameters	Value
Tier 1	Application rate (applicant)	350 mL/m^2 = 0.0350 mL/cm^2
	Density biocidal product (applicant)	0.7946 g/cm^3
	Concentration a.s. (tech.) in the b.p.	0.25 % (w/w)
	Amount a.s. available on wood surface for transfer to skin (Application rate x density x concentration a.s.)	0.06953 mg a.s./cm^2
	Hand surface (toddler, palms of both hands, HEAdhoc Recommendation No. 14, 2017)	115.2 cm^2
	Proportion of palms of hand in contact with the b.p., percentage contaminated skin (Headhoc recommendation No. 5, 2015)	40 %
	Transfer coefficient of biocidal product from dried b.p. to hand (Headhoc recommendation No. 5, 2015)	3 %
	Transfer coefficient of paint from hand to mouth for dried paint (Headhoc recommendation No. 5, 2015, based on Pest Control Fact Sheet, 2.2.7, 2006)	50 %
	Dermal absorption (default, EFSA Guidance on Dermal Absorption, 2012)	75 %
	Oral absorption (CAR/AR, 2014)	100 %
	Body weight, toddler (HEAdhoc Recommendation No. 14, 2017)	10 kg

Calculations for Scenario [7]

Systemic exposure

$Exposure_{dermal}$ = application rate b.p. x concentration a.s. in b.p. x density x hand inner surface of both hands x proportion of palms of hand in contact with the b.p. x transfer coefficient dried b.p. to hands x dermal absorption / body weight

$Exposure_{oral}$ = application rate b.p. x concentration a.s. in b.p. x density x hand inner surface of both hands x transfer coefficient x percentage contaminated skin x transfer coefficient hand to mouth x oral absorption / body weight

$Exposure_{dermal}$ = 350 mL/ m^2 x 0.7946 g/cm^3 x 0.25 % x 115.2 cm^2 x 3 % x 40 % x 75 % / 10 kg
= 0.00721mg a.s./kg bw

$Exposure_{oral}$ = 350 mL/ m^2 x 0. 7946 g/cm^3 x 0.25 % x 115.2 cm^2 x 3 % x 40 % x 50 % x 100 % / 10 kg
= 0.00481 mg a.s./kg bw

Total systemic exposure = 0.0120 mg a.s./kg bw

Table 52

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg bw[/d]**	**Estimated dermal uptake mg/kg bw[/d]**	**Estimated oral uptake mg/kg bw[/d]**	**Estimated total uptake mg/kg bw[/d]**
Scenario [4], adult, sanding treated wood	1	0.00002	0.00570	-	0.00573
Scenario [5] , toddler, chewing treated wood cut-off	1	-	-	0.0111	0.0111
Scenario [6], toddler, inhalation volatilised residues	1	0.000277	-	-	0.000277
Scenario [7], toddler, dermal contact to treated surface	1	-	0.00721	0.00481	0.0120

- **Combined scenarios**

Table 53

Summary table: combined systemic exposure of the general public

Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios [6+7]	0.000277	0.00721	0.00481	0.0123

3.7.3.2 Dietary exposure

The intended use descriptions of the permethrin-containing biocidal product for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used for the preservation of wood that does not come into direct contact with food, feedstuff or livestock animals.

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

- **Scenario [n]**

Not applicable.

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR.

3.7.3.4 Aggregated exposure

Not relevant

3.7.3.5 Summary of exposure assessment

Table 54

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1.	Non-professional users	1	0.1071 mg/kg bw
2.	Non-professional users	1	0.1741 mg/kg bw
3.	Non-professiona users	1	0.00327 mg/kg bw
4.	Bystanders (adults)	1	0.00573 mg/kg bw
5.	Bystanders (toddlers)	1	0.0111 mg/kg bw
6.	Bystanders (toddlers)	1	0.000277 mg/kg bw/d
7.	Bystanders (toddlers)	1	0.0120 mg/kg bw/d

Table 55

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1. Spray treatment	professional	Tier 2: protective gloves, coverall, RPE, improved ventilation	Acceptable
2. Brush treatment	professional	Tier 2: protective gloves, improved ventilation	Acceptable

3.7.4 Risk characterisation for human health

3.7.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) as in Table 56.

Table 56

Reference values of the active substance Permethrin					
Reference	**Study**	**NOAEL (LOAEL)**	**AF**	**Correction for oral absorption**	**Value**
$AEL_{short\text{-}term}$	Rat 2 year oral study (acute effect) Bayer (Ishmael and Litchfield, 1988)	50 mg/kg bw	100	No	0.5 mg/kg bw
$AEL_{medium\text{-}term}$	12-month dog study. Bayer (Kalinowski et al, 1982)	5 mg/kg bw	100	No	0.05 mg/kg bw/d
$AEL_{long\text{-}term}$	12-month dog study. Bayer (Kalinowski *et al*, 1982)	5 mg/kg bw	100	No	0.05 mg/kg bw/d
ARfD	Not derived				-
ADI	Not derived				-

3.7.4.2 Maximum residue limits or equivalent

No further MRLs are required.

Table 57

MRLs or other relevant reference values	**Reference**	**Relevant commodities**	**Value**
MRL (permethrin)	Reg. (EC) No 839/2008	all	0.05* or 0.1*mg/kg
MRL (permethrin)	Reg. (EC) No 37/2010	bovine edible tissues	fat 0.5 mg/kg muscle, liver, kidney, milk: 0.05 mg/kg

* MRL set at LOQ

3.7.4.3 Specific reference value for groundwater

No specific reference values for groundwater were derived.

3.7.4.4 Risk for industrial users

No industrial applications are intended.

3.7.4.5 Risk for professional users

The occupational risk assessment for the biocidal product Anti-Insekt takes into account systemic effects of the active substance permethrin as well as systemic and local effects of the substance of concern.
Exposure of professional users to biocidal products generally takes place via the inhalation and/or dermal route and is usually assessed by means of external inhalation and/or dermal exposure values. For many substances (both active substances and substances of concern) external reference values such as occupational exposure limits (OELs) are available. By contrast, internal reference values (AELs) normally exist for active substances only. Therefore, external reference values will preferably be the basis for the risk characterisation of biocidal products as chemical mixtures. In case only internal reference values are available, they will be converted to external reference values in order to allow for a comparison with external exposure values.

In the biocidal product Anti-Insekt hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics (CAS Nr.: -) is identified as substance of concern based on classification with H304 (May be fatal if swallowed and enters airways) and EUH066 (Repeated exposure may cause skin dryness or cracking) (for details see chapter 3.7.2).

Systemic effects – permethrin

The primary toxic effects of the active substance permethrin are adaptive hepatic effects in a 1 year study in dogs. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to permethrin resulting from use of the biocidal product.
As reference value the AELlong-term of 0.05 mg/kg bw/day is used.

Details of risk characterisation
Reference values

For the purpose of risk characterisation resulting from exposure of professional users to permethrin from the biocidal product Anti-Insekt, inhalation and dermal exposure to permethrin is assessed. For this, the systemic reference value AELlong-term (0.05 mg/kg bw/d) of permethrin is used. Since this systemic reference value is to be compared with external inhalation and dermal exposure concentrations of permethrin, the corresponding AELlong-term is converted to an external inhalation reference value (RVinhal) and an external dermal reference value (RVderm) according to the following equations:

RVinhal (in mg/m3) = AELlong-term of permethrin (in mg/kg bw/d) x 60 kg / 10 m3 x100 % / 100 %-inhalation absorption

RVderm (in mg/kg bw/d) = AELlong-term of permethrin (in mg/kg bw/d) / 75 %-dermal absorption x 100 %.

By this means RVinhal equivalent to 0.30 mg/m3 and RVderm equivalent to 0.07 mg/kg bw/d are calculated for permethrin.

Absorption by inhalation

As default inhalation absorption of 100 % is assumed for the active substance permethrin.

Dermal absorption rate

Valid data are not available for the biocidal product Anti-Insekt and permethrin, respectively. Therefore, the default value of 75 % for active substance concentration below 5 % (according to the EFSA Guidance on Dermal Absorption, 2012) has to be taken into consideration for risk assessment.

Calculation of risk quotients (RQ) and substance specific risk index (RI)

The risk quotient for the inhalation route (RQinhal) and dermal route (RQderm) referring to the active substance permethrin resulting from use of the biocidal product Anti-Insekt is determined according to the following equations:

RQinhal = inhalation exposure to permethrin (in mg/m3) / RVinhal of permethrin (in mg/m3).

RQderm = dermal exposure to permethrin (in mg/kg bw/d) / RVderm of permethrin (in mg/kg bw/d).

Dermal exposure to permethrin given in mg/kg bw/d is calculated from dermal exposure to permethrin given in mg/person through division by 60 kg/person.

The summation of RQinhal and RQderm for a substance within a scenario gives the corresponding substance specific risk index (RI). Table 58 gives a detailed overview of the risk assessment results referring to the active substance permethrin for the biocidal product. It is noted that for clarity reasons exposure values, risk quotients and total risk indices are rounded to two decimal places in Table 58 However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the active substance permethrin resulting from the use of the biocidal product Anti-Insekt is unlikely if the risk characterisation for each scenario yields a risk index

(RI) of less than 1. As shown in Table 58 the RI of the scenarios spray treatment, brush treatment, and secondary exposure: mechanical processing of treated wood exceed the value of 1 after TIER 1 consideration. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenarios. However when risk mitigation measures are implemented the risk characterisation results consistently yield RI of less than 1 in TIER 2.

Table 58: Overview of detailed risk assessment results referring to the active substance permethrin for the biocidal product Anti-Insekt

Scenario		inhalation external			dermal external				RI	Acceptable
		potential / actual exposure	RV_{inhal}	RQ_{inhal}	potential/actual exposure		RV_{derm}	RQ_{derm}		
		mg/m^3	mg/m^3		mg/person	mg/kg bw/d	mg/kg bw/d			
Spray treatment	Tier 1	0.03	0.30	0.11	85.82	1.43	0.07	21.46	21.57	no
	Tier 2	$3.41x10^{-3}$	0.30	0.01	3.33	0.06	0.07	0.83	0.84	yes
Brush treatment	Tier 1	$1.36x10^{-3}$	0.30	$4.53x10^{-3}$	5.55	0.09	0.07	1.39	1.39	no
	Tier 2	$1.36x10^{-3}$	0.30	$4.53x10^{-3}$	2.00	0.03	0.07	0.50	0.50	yes
Mechanical processing of treated wood	Tier 1	$1.87x10^{-3}$	0.30	$6.23x10^{-3}$	6.13	0.10	0.07	1.53	1.54	no
	Tier 2	$1.87x10^{-3}$	0.30	$6.23x10^{-3}$	0.61	0.01	0.07	0.15	0.16	yes

Tier 1: no PPE; Tier 2: protective gloves, protective coverall, improved ventilation, and RPE (‘spray treatment’); protective gloves, and improved ventilation (‘brush treatment’); protective gloves (‘Secondary exposure: Mechanical processing of treated wood’),

RVinhal: reference value for the inhalation route

RQinhal: risk quotient for the inhalation route

RVderm: reference value for the dermal route

RQderm: risk quotient for the dermal route

RI: substance specific risk index

Conclusion

Based on the risk assessment of the active substance permethrin via the inhalation and dermal route, a risk for professional users resulting from the uses (spray treatment, and brush treatment) with the biocidal product Anti-Insekt as well as from secondary exposure: mechanical processing of treated wood is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 after TIER 2 consideration. Regarding occupational safety, there are no objections against the uses as well as secondary exposure taking into account the provisions described in chapter 2.5.2 of this PAR.

Systemic effects – h**ydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics**

The primary toxic effects of the substance of concern hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics that form the constituent of the additive Solvent D60 are neurotoxicity and skin irritation.

For the purpose of risk characterisation a concentration of 93.431 % is assumed for hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics (for details see chapter 2.2.1. The risk assessment is provided below (Table 59).

The quantitative risk characterisation for professional users takes into account inhalation exposure to hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics resulting from use of the biocidal product.

As no systemic reference values for hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics are established the risk characterisation is based on the German OEL.

The OEL for hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics is determined based on the *Reciprocal Calculation-based Procedure – RCP* for hydrocarbon mixtures as stated in the Technical Rules for Hazardous Substances (TRGS) 900. Details of the calculation are provided below.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users to hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics from the biocidal product, inhalation exposure to hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics is assessed.

For this, the German OEL (250 mg/m^3, 8 h TWA) for hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics is calculated as shown below and used as external inhalation reference value (RV_{inhal}) that is directly compared with airborne concentrations of hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics.

In addition, the German short-term OEL (500 mg/m^3, 15 min STEL) must be complied with to limit the exposure peaks. Thus for assessment of exposure peaks the German short-term OEL (500 mg/m^3, 15 min) of hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics is calculated as shown below and used as external inhalation reference value that is directly compared with airborne

concentrations of exposure peaks to hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics.

Absorption by inhalation

As default inhalation absorption of 100 % is assumed for the substance of concern hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics.

Calculation of the German OEL according to the *Reciprocal Calculation-based Procedure – RCP* as stated in the TRGS900

For determination of the OEL for the substance of concern hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics as a worst case a fraction of 98 % C10-C13 aliphates (group reference value for C9-C14 aliphates of 300 mg/m³ applies) and a fraction of 2 % aromatics (group reference value for C9-C14 aromatics of 50 mg/m³ applies) is assumed:

1 / OEL (mg/m³) = fraction of C9-C14 aliphates / group reference value for C9-C14 aliphates + fraction of C9-C14 aromates / group reference value for C9-C14 aromatics

1 / OEL (mg/m³) = 0.98 / 300 mg/m³ + 0.02 / 50 mg/m³ = 1 / 3.67×10^{-3} mg/m³

OEL (mg/m³)= 1 / 3.67×10^{-3} mg/m³ = 272.72 mg/m³ → 250 mg/m³ (Rounding rule: > 100 mg/m³: round up or down to the nearest full 50)

By this means an OEL equivalent to 250 mg/m³ is calculated for hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics.

Calculation of the German short-term OEL

The short-term OEL for the substance of concern hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics is determined as follows:

Short-term OEL (mg/m³) = OEL (in mg/m³) * excursion factor

Short-term OEL (mg/m³) = 250 mg/m³ * 2

An excursion factor of 2 is applied for substances with systemic effects when no further substance specific data justifying a higher factor are available.

By this means an short-term OEL equivalent to 500 mg/m³ is calculated for hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics.

Calculation of risk quotients (RQ) and substance specific risk index (RI)

The risk quotient for inhalation route (RQ_{inhal}) referring to the substances of concern hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics resulting from use of the biocidal product Anti-Insekt is determined according to the following equations:

RI (8 h TWA) = inhalation exposure to hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics (in mg/m³) / German OEL of hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics (in mg/m³).

RI (15 min STEL) = inhalation peak exposure to hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics (in mg/m³) / German short-term OEL of hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics (in mg/m³).

In this case where only inhalation exposure to hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics is assessed for the professional user, the RQ_{inhal} is identical with the corresponding substance specific risk index (RI). Table 59 gives a detailed overview of the risk assessment results referring to the substance of concern hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics. It is noted that for clarity reasons exposure values, risk quotients and total risk indices are rounded to no or two decimal places in Table 59. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the substance of concern hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics resulting from the use of the biocidal product Anti-Insekt is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 59 the RIs of the spray treatment and brush treatment exceed the value of 1 after TIER 1 consideration after 8 h as well as short-term exposure. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenarios. However when risk mitigation measures are implemented the risk characterisation results consistently yield RIs of less than 1 in TIER 2 for the above mentioned intended uses spray treatment and brush treatment.

Table 59: Overview of detailed risk assessment results referring to the substance of concern hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics for the biocidal product Anti-Insekt

Scenario		inhalation external (8 h)			Acceptable	inhalation external (15 min)			Acceptable
		potential / actual exposure	German OEL	RI_{TWA}		potential / actual exposure	German short-term OEL	RI_{STEL}	
		mg/m³	mg/m³			mg/m³	mg/m³		
Spray treatment	Tier 1	630	250	2.52	no	3700	500	7.40	no
	Tier 2	15	250	0.06	yes	89	500	0.18	yes
Brush treatment	Tier 1	677	250	2.71	no	1094	500	2.19	no
	Tier 2	121	250	0.48	yes	166	500	0.33	yes

Tier 1: no PPE; Tier 2: protective gloves, protective coverall, improved ventilation, and RPE (‘spray treatment’); protective gloves, and improved ventilation (‘brush treatment’)

RI_{TWA}: substance specific risk index regarding TWA (time-weighted average, 8 h)

RI_{STEL}: substance specific risk index regarding STEL (short-term exposure limit, 15 min)

Conclusion

Based on the risk assessment of the substance of concern hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics via the inhalation route, a risk for professional users resulting from the intended uses (spray treatment and brush treatment) with the biocidal product Anti-Insekt is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 after TIER 2 consideration. Regarding occupational safety, there are no objections against the intended uses taking into account the provisions described in chapter 2.5.2 of this PAR.

Local effects

The local toxicity profiles of the active substance permethrin and the substance of concern hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics are considered.

The active substance permethrin contributes to the classification of the product with EUH208 (Contains permethrin. May produce an allergic reaction.). Additionally permethrin is a pyrethroid. Dermal exposure to pyrethroids is known to cause paresthesia, which is normally transient and does not persist.

The substance of concern hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics contributes to the classification of the biocidal product Anti-Insekt with H304 (May be fatal if swallowed and enters airways) and EUH066 (Repeated exposure may cause skin dryness or cracking).

Qualitative local risk characterisation

The active substance permethrin triggers the classification of the product with EUH208 (Contains permethrin. May produce an allergic reaction.), a hazard statement that is not associated with a requirement for local risk characterisation according to Appendix 3-3 chapter 4.3.2 to ECHA Guidance Vol III Part B, version 2.

The substance of concern hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics <2 % aromatics triggers the classification of the biocidal product Anti-Insekt with H304 (May be fatal if swallowed and enters airways) as well as EUH066 (Repeated exposure may cause skin dryness or cracking) and is therefore assigned in hazard classification band A according to the Guidance on substances of concern (SoC) (Annex A to ECHA Guidance Vol III Part B, version 2). This guidance states that for these SoCs appropriate risk mitigation measures in the form of the precautionary (P)-statements should be applied. It is assumed that the application of the precautionary statements associated with the concerned hazard statement H304 and EUH066 and the provisions described in chapter 2.5 are sufficient to minimise the risk for professional users.

Conclusion

Concerning the skin affecting properties of biocidal product Anti-Insekt, exposure should be minimized with protection measures. If the proposed protection measures are implemented, the intended uses (‘spray treatment’ and ‘brush treatment’) as well as secondary exposure resulting from ‘Mechanical processing of treated wood’ do not lead to concern for professional users.

Conclusion

In summary, a risk for professional users resulting from the use of the biocidal product Anti-Insekt is unlikely for the intended uses spray treatment and brush treatment as well as from secondary exposure: mechanical processing of treated wood. Risk mitigation measures described in chapter 2.5 have to be taken into account in order to ensure safe use of the biocidal product Anti-Insekt.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.7.4.6 Risk for non-professional users

Table 60: 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]; Application by brushing, out-door, dermal and inhalation exposure	1	50	0.5	0.1071	21	yes
Scenario [2] Application by brushing, in-door, dermal and inhalation exposure	1	50	0.5	0.1742	35	yes
Scenario [3]; Cleaning the brush, dermal exposure	1	50	0.5	0.0033	0.7	yes

Table 61: Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios [1+3]	1	50	0.5	0.1104	22	yes
Scenarios [2+3]	1	50	0.5	0.1775	36	yes

Local effects

The biocidal product contains the pyrethroid permethrin. Pyrethroids are known to cause paresthesia, which are normally transient and do not persist. Hence, an appropriate labelling on the packaging is required to inform susceptible persons.

The biocidal product is labelled with EUH066. Based on the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation 4.3.2.5 this labelling leads to the hazard category “low” for local effects. Hence, a quantitative assessment is not required. Due to the low application frequency further risk mitigation measures are not required regarding this effect if the biocidal product is used as intended.

Conclusion

No human health risk was identified.

Hence, the biocidal product is considered safe for non-professional application if used as intended and if all safety advices are followed.

Based on a proposal of the applicant, the exposure assessment for indoor use by non-professional users is restricted to a treated surface of 3 m^2. Hence a corresponding advice has to be added to the instructions for use

A quantitative assessment for non-professional users and the general public from exposure to the solvent naphtha (petroleum), hydrotreated heavy (CAS number: 64742-48-9) was not performed since agreed reference values for these groups do not exist. However, it is known that high concentrations of this compound are unpleasant and may lead to drowsiness. Thus, the biocidal product should only be used in well-ventilated areas. A corresponding labelling is required.

3.7.4.7 Risk for the general public

Table 62: 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 [4], adult, sanding treated wood	1	50	0.5	0.00573	1.1	Scenario [4], adult, sanding treated wood
Scenario [5] , toddler, chewing treated wood	1	50	0.5	0.0111	2.2	Scenario [5] , toddler, chewing treated wood

cut-off						cut-off
Scenario [6], toddler, inhalation volatilised residues	1	5	0.05	0.000277	0.6	Scenario [6], toddler, inhalation volatilised residues
Scenario [7], toddler, dermal contact to treated surface	1	5	0.05	0.0120	24	Scenario [7], toddler, dermal contact to treated surface

Table 63: Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios [6+7]	1	5	0.05	0.0123	25	yes

- **Local effects**

[The biocidal product contains the pyrethroid permethrin. Pyrethroids are known to cause paresthesia, which are normally transient and do not persist. Hence, an appropriate labelling on the packaging is required to inform susceptible persons.

The biocidal product is labelled with EUH066. Based on the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation 4.3.2.5 this labelling leads to the hazard category “low” for local effects. Hence, a quantitative assessment is not required. Due to the low application frequency and the fact that the solvent, which triggers this labelling evaporates rapidly further risk mitigation measures for the general public are not required.

Conclusion

No human health risk was identified.

Hence, the biocidal product is considered safe for the general public if used as intended and if all safety advices are followed during application.

The exposure assessment was based on the assumption that only contact do dried residues occur. Hence, children should be kept away from treated wood until dried. A corresponding risk mitigation measure is required.

A quantitative assessment for non-professional users and the general public from exposure to the solvent naphtha (petroleum), hydrotreated heavy (CAS number: 64742-48-9) was not performed since agreed reference values for these groups do not exist. However, it is known that high concentrations of

this compound are unpleasant and may lead to drowsiness. Thus, the biocidal product should only be used in well-ventilated areas. A corresponding labelling is required.
Due to the solvent, the biocidal product is classified with Asp. 1 and may be fatal if ingested orally.
Hence the biocidal product has to be stored locked up and out of reach of children and it has to be fitted with a child-resistant fastening if distributed to non-professional users.. These risk mitigation measures are already triggered by Regulation (EC) No. 1272/2008.

3.7.4.8 Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

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

Risk characterisation from combined exposure to the active substances and the substance of concern within the biocidal product Naphtha (petroleum), hydrotreated heavy (CAS-Nr. 64742-48-9 is not required. Relevant synergistic effects between the components are not expected.

3.7.4.10 Endocrine disrupting properties

During the REACH process one co-formulant (4-tert-butylphenol, CAS No 98-54-4, max . concentration: 0.03 %) of the biocidal product additional data are requested since potential endocrine disrupting properties regarding human health could not be ruled out.
For all other co-formulants, there are no data indicating that they may have

3.7.4.11 Summary of risk characterisation

3.7.4.11.1 Summary of risk characterisation for industrial user

No industrial applications are intended.

3.7.4.11.2 Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal product Anti-Insekt is unlikely for the intended uses spray treatment and brush treatment as well as from secondary exposure: mechanical processing of treated wood. Risk mitigation measures described in chapter 2.5 have to be taken into account in order to ensure safe use of the biocidal product Anti-Insekt

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.7.4.11.3 Summary of risk characterisation for non-professional user

Table 64

Scenario, Tier	**Relevant reference value**	**Estimated uptake** mg/kg bw/d	**Estimated uptake/reference value** (%)	**Acceptable** (yes/no)
Scenario [1]; Application by brushing, outdoor, dermal and inhalation exposure, Tier 1	0.5	0.1071	21	yes
Scenario [2] Application by brushing, indoor, dermal and inhalation exposure, Tier 1	0.5	0.1742	35	yes
Scenario [3]; Cleaning the brush, dermal exposure, Tier 1	0.5	0.0033	0.7	yes

3.7.4.11.4 Summary of risk characterisation for indirect exposure

Table 65

Scenario, Tier	**Relevant reference value**	**Estimated uptake** mg/kg bw/d	**Estimated uptake/reference value** (%)	**Acceptable** (yes/no)
Scenario [4], adult, sanding treated wood, Tier 1	0.5	0.00573	1.1	yes
Scenario [5] , toddler, chewing treated wood cut-off, Tier 1	0.5	0.0111	2.2	yes
Scenario [6], toddler, inhalation volatilised residues, Tier 1	0.05	0.000277	0.6	yes
Scenario [7], toddler, dermal contact to treated	0.05	0.0120	24	yes

surface, Tier 1				

3.8 Risk assessment for animal health

Due to the lack of an appropriate guidance a specific exposure and risk assessment for pets and domestic animals cannot be performed. For the private area it is expected that animals can be exposed to the active substance after treatment. It can be assumed that the health risk for these animals (except cats) is comparable to those of toddlers and children. Therefore, no specific measures are required for these animals if the biocidal product is used as intended.

However, cats are more sensitive against pyrethroids. Due to a slower metabolisation intoxications by pyrethroids are common. Thus, particularly the access of cats to treated surfaces has to be avoided.

3.9 Risk assessment for the environment

3.9.1 General information

The biocidal product Anti-Insekt with the active substance permethrin (0,2502 % w/w) is used as a wood preservative (product-type 08) against specific beetles and their larvae. The ready-to-use biocidal product is intended for the curative treatment of timber in Use Classes 1 and 2 and the preventive treatment of timber in Use Class 1. The following definitions apply to these classes (EN 335:2013[8]):

- Use Class 1 (UC1): Situation in which the wood-based product is inside a construction, not exposed to the weather and wetting.
- Use Class 2 (UC2): Situation in which the wood-based product is under cover and not exposed to the weather (particularly rain and driven rain) but not persistent wetting can occur.

The following applications are intended for Anti-Insekt:

i) Spraying by professionals: The product is applied to wood structures outdoors (in protected areas, under roof, not exposed to weathering) and indoors.

ii) Brushing by professionals and non-professionals: The product is applied to wood structures indoors and outdoors (in protected areas, under roof, not exposed to weathering) as well as wooden furniture and smaller wooden items indoors.

The risk assessment for “Anti-Insekt” is based on data of the active substances permethrin, including relevant metabolites. No new information for the assessment of fate and behaviour and effects of permethrin compared to the CAR has been provided within product authorisation for “Anti-Insekt”, so that the assessment is based upon data given in the CAR (2014) for permethrin.

Anti-Insekt contains (2-Methoxymethylethoxy)propanol, which is identified as a substance of concern for the environment, as it is classified as H410 (worst-case classification for the environment in current notifications). A harmonized classification for this substance does not exist.
Furthermore, the product contains a considerable amount of the solvent “Solvent D60” (Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, <2% aromatics). Initially, the toxicity of the Solvent D60 was evaluated by the CAS No. 64742-48-9 provided in the safety data sheet (SDS). In the “CONCAWE” report (Classification Task Force “Hazard classification and labelling of petroleum substances in the European Economic Area – 2015/2012) the CAS No. 64742-48-9 is listed and the classification H411 is recommended.

8 Durability of wood and wood-based products - Use classes: definitions, application to solid wood and wood-based products; EN 335:2013.

However, in a second step, the classification of the Solvent D60 was based on the REACH Registration No. stated in the SDS (REACH Registration No.: 01-2119457273-39). With reference to the REACH Registration No. the Solvent D60 is not proposed for environmental classification in the SDS by the supplier nor is an environmental classification proposed in the databases of the European Chemicals Agency (ECHA), including data provided by third parties (https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14975/2/1).
This differentiation is applicable for the following reasons: Whilst the CAS No. 64742-48-9 comprises a mixture of hydrocarbons solvents consisting of various n-alkanes in the range of C6-C13 (https://echa.europa.eu/de/advanced-search-for-chemicals), the Solvent D60 contains hydrocarbons in the specific range of C10-C13. The special grade has a lower toxicity and does not trigger an environmental classification. Therefore, finally Solvent D60 is not identified as a substance of concern for the environment.

No further data were required and no additional environmental risk assessment of the SoC (2-Methoxymethylethoxy)propanol was performed in case of Anti-Insekt, since no significant emissions of the biocidal product to the environment are expected because of the use conditions of the product and the wood, treated with the product, as well as the instructions for use resulting from the single assessment of the active substance (refer to chapter 3.9.4 and 3.9.5).

3.9.2 Effects assessment

Effects assessment is performed based on the active substance in the product “Anti-Insekt”. For the active substance permethrin, as well as its metabolites, the evaluation is adapted from the respective assessment reports in PT8 and PT18 (CAR 2014; Rapporteur: Ireland).
For permethrin in PT 8 and PT 18 a new effect study on other terrestrial non-target organisms (*Folsomia candida*) has been provided (November 2016) for the compartment soil, which is currently evaluated by eCA IE with regard to active substance approval. The outcome of the MS e-consultation concerning the derivation of PNECsoil is still pending. Therefore, the effect assessment of the product “Anti-Insekt” is initially based on the data currently available in the CAR associated with the corresponding assessment factors.

3.9.2.1 Mixture toxicity

No ecotoxicological data for the biocidal product “Anti-Insekt” are available. The biocidal product “Anti-Insekt” consists of one active substance and the risk assessment can be based on data of this active substance. Moreover, the product contains (2-Methoxymethylethoxy)propanol, which is identified as

substance of concern for the environment. The co-formulate Solvent D60 is, as explained above, not considered as a substance of concern. For a mixture toxicity assessment, the active substance and the substance of concern should be taken into account.

Screening step

- **Screening Step 1: Identification of concerned environmental compartments**

This screening step identifies, if exposure of environmental compartments can be expected from the application of the product and if so, which environmental compartments are likely to be at risk (Transitional guidance on mixture toxicity assessment; ECHA 2014). The biocidal product Anti-Insekt is only applied in-situ and is used for protection of wood in UC 1 and 2. For in-situ application to wood of UC 1 and 2 and for service life of wood of UC 1 and 2, no emission scenarios are presented by the OECD (OECD ESD for PT 8, PART2), since for this wood classes the potential emissions from treated wood to the outer environment are considered negligible. Therefore, no environmental risk assessment and consequently no mixture toxicity assessment has to be performed.

3.9.2.2 Aquatic compartment (including sediment and STP)

- **Acute aquatic toxicity**

Detailed data on the environmental effect assessment and PNEC derivation of the active substance permethrin and its metabolite DCVA and PBA can be found in the CAR for PT8 and PT18 (2014). For risk assessment a $PNEC_{surfacewater}$ = 0.00047 µg/L was concluded for permethrin. For the metabolites a $PNEC_{water}$ = 0.015 mg/L and $PNEC_{water}$ >0.010 mg/L was derived for DCVA and PBA, respectively.

- **Table 66**

Data waiving was acceptable for the following information requirements	
Information requirement	Tests on aquatic and terrestrial organisms with the product “Anti-Insekt” are not provided.
Justification	The risk assessment for the biocidal product “Anti-Insekt” can be based on data of the active substance permethrin, when considering the mixture toxicity assessment for biocidal products (Transitional guidance on mixture toxicity assessment; ECHA 2014)

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- **Table 67**

Conclusion used in Risk Assessment – Acute aquatic toxicity	
Value/conclusion	$PNEC_{water}$ permethrin = 0.00047 µg/L; DCVA= 0.015 mg/L;

	PBA >0.010 mg/L;
Justification for the value/conclusion	The lowest NOEC values of 0.0047 µg/L was derived from a study with *Daphnia magna* (CAR 2014). An AF of 10 was applied as long-term tests with species from three trophic levels are available.

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- **Sediment toxicity**

Detailed data on the environmental effect assessment and PNEC derivation of the active substance permethrin and its metabolite DCVA and PBA can be found in the CAR for PT8 and PT18 (2014). For risk assessment of permethrin a $PNEC_{sed}$ = 0.001 mg/kg dwt (2.17 x 10^{-4} wwt) was derived. For the metabolites DCVA and PBA a $PNEC_{sed}$ = 0.055 mg/kg dwt (0.012 mg/kg wwt) and $PNEC_{sed}$ = 0.042 mg/kg dwt (0.009 mg/kg wwt) was concluded, respectively.

Table 68

Conclusion used in Risk Assessment – Sediment toxicity	
Justification for the value/conclusion	permethrin: $PNEC_{sed}$ = 0.001 mg/kg dwt (2.17 x 10^{-4} wwt) DCVA: $PNEC_{sed}$ = 0.055 mg/kg dwt (0.012 mg/kg wwt) PBA: $PNEC_{sed}$ = 0.042 mg/kg dwt (0.009 mg/kg wwt)

- **Inhibition of microbial activity (aquatic)**

The effect of permethrin on aerobic biological sewage treatment processes was assessed according to OECD 209 by determining respiration inhibition of the micro-organisms present in activated sludge following 3 hours contact.

Since testing was conducted using concentrations above the water solubility and no inhibition was observed, the NOEC for permethrin is set equal to the water solubility of 4.95 µg/l. The $PNEC_{microorganisms\ (STP)}$ reported in the AR (2014) was 4.95 µg/l.

3.9.2.3 Terrestrial compartment (including groundwater)

Regarding terrestrial toxicity no data are available for the product “Anti-Insekt” itself. The toxicity of the active substance permethrin and the co-formulants is known and no synergistic effects are expected. Hence, the risk assessment for the product “Anti-Insekt” can be based on data of the active substance, when considering the mixture toxicity assessment for products (Transitional guidance on mixture toxicity assessment; ECHA 2014). The PNEC values for permethrin, and its metabolites were used according to the Assessment Reports and are summarized below:

Detailed data on the environmental effect assessment and PNEC derivation of the active substance permethrin and its metabolite DCVA and PBA are described in the CAR for PT8 and PT18 (2014). For risk assessment of permethrin a $PNEC_{soil}$ = >0.099 mg/kg dwt (>0.0876 mg/kg soil wwt) was concluded. For the metabolite DCVA a $PNEC_{soil}$= 4.6 mg/kg wwt and for the metabolite 3-Phenoxybenzoic Acid (PBA) a $PNEC_{soil.}$ = 1.44 mg/kg wwt was concluded (CAR 2014).

For the active substance approval of permethrin in PT8/PT18 a new study has been provided for the compartment soil (November 2016), which is currently evaluated by eCA IRE. As the outcome of the evaluation is still pending, the effect assessment of the product “Anti-Insekt” is initially based on the data currently available in the CAR associated with the corresponding AF.

3.9.2.4 Atmosphere

Exposure to the atmosphere is not considered relevant for the biocidal product “Anti-Insekt”, due to low vapour pressure (2.16E-06 Pa×m³/mol (20 °C)) of permethrin, a low Henry’s Law constant and a high adsorption potential. Calculations indicate that if permethrin were present in the atmosphere it would be expected to degrade rapidly, mainly via gas phase reaction with photo-chemically generated hydroxyl radicals (CAR 2014).

3.9.2.5 Non-compartment specific effects

According to the BPR guidance Vol IV part B (2015) an assessment of secondary poisoning is performed if a substance shows bioaccumulation potential and is classified as very toxic (T+), toxic (T) or harmful (Xn) with at least one of the risk phrases R48 "Danger of serious damage to health by prolonged exposure", R60 "May impair fertility", R61 "May cause harm to the unborn child", R62 " Possible risk of impaired fertility", R63 "Possible risk of harm to the unborn child", R64 "May cause harm to breastfed babies" or if there are other indications (e.g.) endocrine disruption.

The log Kow = 4.7 reveals a potential for bioaccumulation for the active substance permethrin. Moreover, according to the CAR 2014, some of the estimated BCF values indicate a potential of permethrin to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) and subsequently bioaccumulate through the food chain. Therefore, the potential of secondary poisoning was assessed for the aquatic and terrestrial compartment in chapter 3.9.4.3.

For a summary of relevant BCF values taken into account for secondary poisoning reference is made to the permethrin CAR PT8 and PT 18 (2014). For risk assessment a $PNEC_{oral\ bird}$ = 16.7 mg a.s./kg food and a $PNEC_{oral\ mammal}$ = 120 mg a.s./kg food was concluded.

Table 69

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	$PNEC_{oral\ bird}$ = 16.7 mg a.s./kg food $PNEC_{oral\ mammal}$ = 120 mg a.s./kg food
Justification for the value/conclusion	For the ecotoxicological studies taken into account for secondary poisoning reference is made to the respective assessment reports in PT8 and PT18 (CAR 2014; Rapporteur: Ireland)

3.9.2.6 Summary of effects assessment

For the active substance permethrin, as well as its metabolites, the evaluation is adapted from the assessment reports in PT8 and PT18 (CAR 2014; Rapporteur: Ireland). The PNEC values for permethrin and the relevant metabolites are summarized in the following table.

Table 70

Summary table on calculated PNEC values		
Compartment	**Active substance**	**PNEC (µg/L)**
STP	permethrin	4.95 µg/L;
	DCVA & PBA	-
Surface water	permethrin	0.00047 µg/L;
	DCVA	15 µg/L;
	PBA	> 10 µg/L;
Sediment	permethrin	0.001mg/kg dwt;
	DCVA	0.055 mg/kg dwt (0.012 mg/kg wwt);
	PBA	0.042 mg/kg dwt;
Soil	permethrin	>0.099 mg/kg dwt (>0.0876 mg/kg soil wwt);
	DCVA	4.6 mg/kg wwt;
	PBA	1.44 mg/kg wwt;
Bird	permethrin	≥16.7 mg a.s/kg food;
	DCVA & PBA	
Mammals	permethrin	120 mg a.s/kg food;
	DCVA & PBA	-

3.9.3 Fate and behaviour

For the general assessment of the environmental fate and behaviour of permethrin, please refer to relating Assessment Reports in PT8 and PT18 (CAR 2014; Rapporteur: Ireland).
The active substance permethrin, as notified for active substance authorization, relates to permethrin as a reaction mass of four stereoisomers (1Rcis, 1Scis, 1Rtrans, and 1Strans), with two pairs of diastereoisomers in a isomeric ratio of 25:75 (*cis*:*trans*). Studies were conducted with permethrin 25:75 or with a mixture of isomers where the permethrin samples contain 50-78% of the *trans*- isomer. Two relevant metabolites of permethrin were assessed: 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA).

Permethrin was observed to be hydrolytically stable between pH 3.0/4.0 to 7.6/7 at 25/50˚C respectively. Only at pH 9.0/9.6 permethrin was observed to hydrolyse, with DT_{50} values for *cis*- and *trans*-permethrin estimated at 35 days and 42 days, respectively (at pH 9.6 and 25°C). No significant photolysis of the a.s. in water was identified under environmentally relevant pH and temperature conditions (12°C).

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

Considering the fate behaviour of permethrin in air, a volatilization is considered to be negligible based on the vapour pressure (2.155 x 10^{-6} Pa at 20°C, 25:75 *cis:trans*) and Henry's law constant (4.6 x 10^{-3} -> 4.5 x 10^{-2} Pa m^3 mol^{-1}). A half-life of 0.701 days for the gas phase reaction of permethrin with photo-chemically produced hydroxyl radicals was derived using AOPWIN v1.91 (24-hour day, hydroxyl radical concentration: 5 x 10^5 radicals/cm^3). Based on this short half-life for this transformation pathway, it is concluded that permethrin is rapidly degraded in air and is not likely for long-range transport in the atmosphere in the gaseous phase.

Biodegradation / Metabolites

Apart from the post approval submission of an aerobic water/sediment degradation study (OECD 308) for the permethrin metabolite DCVA in PT 8/ PT18 currently under evaluation by eCA IE, no new data regarding biodegradation behaviour are available for authorisation of the biocidal product "Anti-Insekt". Therefore, the data presented in the respective Competent Authority Report (2014) are used for the exposure and risk assessment. No further data are required.

Permethrin is not readily biodegradable. For environmental exposure and risk assessment results from both aerobic laboratory degradation studies in soil as well as from aerobic water/ sediment studies were considered.

The range of reliable SFO DT_{50} values in several soils ranged from 77 to ~141 days at 12 °C. The corresponding geomean DT_{50} was 106 days. The *cis* isomer degraded more slowly than the *trans* isomer. The geomean DT_{50} is derived from permethrin samples containing 50-78% of the *trans*- isomer. It is stated in the CAR that it can be expected that a DT_{50} value of 106 days is conservative enough to represent the degradation in soil at 12 °C of permethrin samples containing a *cis:trans* ratio of 25:75.

In the soil compartment permethrin breaks down to form DCVA (max 11.3 % AR, SFO DT_{50} 33.1- ~175 days at 12 °C) and PBA (max 15.0 % AR, DT_{50} 1.7-2.5 days at 12 °C), and ultimately converts to CO_2. For risk refinement purposes worst case DT_{50} (12 °C) values of 175 days resp. 2.5 days are used for the two metabolites DCVA resp. PBA.

In the aquatic environment, the whole water/ sediment system first order degradation DT_{50} values of permethrin at 12 °C ranged from 21.1 to 46.1 days for vinyl-label treatment and 46.7 to 46.7 days for

phenoxyphenyl-treatment. For risk refinement purposes the worst case DT_{50} value of 46.7 days was used.

In line with the request for further information after active substance approval, a confirmatory water/ sediment degradation study for the permethrin metabolite DCVA investigating the route and rate of degradation of [cyclopropane-1-14C] DCVA in two water/ sediment systems under aerobic laboratory conditions according to OECD 308 has been submitted 2016 post-approval for PT 8 and PT 18. For refinement of exposure assessment the use of these new data is still awaiting the final outcome of the EU evaluation of the eCA IE and approval of BPC.

3.9.3.1 Bioconcentration

- **Aquatic bioconcentration**

The reported Log Kow values for permethrin range from 4.6 to 6.1 (CAR April 2014 for PT8 and PT18), indicating it is a fat-soluble molecule with a potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms). The CAR 2014 for PT8 and PT18 provides a BCF value for fish (BCF 570). However the half-life for depuration of tissue residues in fish was approximately 4/5 days with approximately 80% of the accumulated residues depurated within 14 days. Therefore, it was concluded that bioconcentration in fish tissues would not significantly occur and any residues accumulated are readily eliminated. Moreover, exposure of organisms to permethrin in use class 1 and 2 is not expected.

Table 71

Summary table – Estimated aquatic bioconcentration					
Basis for estimation	**Log K_{ow} (measured)**	**Estimated BCF for fish (freshwater)**	**Estimated BCF for fish eating bird/predator**	**Remarks**	**Reference**
Permethrin	4.7	500 – 570[m] L/kg (fish) 166[m] L/kg (chironomid in water) (published study) 415[m] L/kg (chironomid in sediment) (published study) 166[m] L/kg (chironomid in porewater) (published study)	-	DT_{50} for depuration of tissue residues in fish = 4.7 ± 0.34 days	Permethrin LOEP Update 2016

Table 72

Conclusion used in Risk Assessment –Aquatic bioconcentration	
Value/conclusion	BCF_{fish} = 570
Justification for the value/conclusion	The active substance Permethrin in the product “Anti-Insekt” possesses a potential to bioconcentrate. In CAR 2014 for PT8 and PT18, it was concluded that bioconcentration in fish tissues would not significantly occur. Moreover, in Use Class 1 and 2 exposure of aquatic and terrestrial organisms is not expected when used according to the label.

3.9.4 Exposure assessment

3.9.4.1 General information

The environmental exposure assessment is based on the OECD series on emission scenario documents (Number 2; OECD ESD) “Revised Emission Scenario Document for Wood Preservatives” (OECD, 2013) (see Table 73). Where necessary the “Guidance on the Biocidal Products Regulation” (Volume IV Environment – Part B Risk Assessment (active substances); Version 1.0; April 2015) is also taken into consideration.
The ready-to-use biocidal product (0,2502 % w/w permethrin) is intended for the curative treatment of timber via spraying or brushing in UC 1 and 2 and the preventive treatment of timber in UC1.

Table 73

General information on exposure assessment	
Assessed PT	PT 8
Assessed scenarios	none
ESD(s) used	OECD series on emission scenario documents, Number 2, “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 the Biocidal Products Regulation, Volume IV Environment, Part B Risk Assessment (active substances, version 1, ECHA, 2015)
Groundwater simulation	not required
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use (application): Yes (qualitative) Storage: Yes (qualitative) Service life: Yes (qualitative)

3.9.4.2 Emission estimation

Uses of Anti-Insekt include professional and non-professional applications. Emissions to the environment can generally occur during professional and non-professional in-situ applications and the service life of the treated wood.

Anti-Insekt is a ready-to-use-product which is used for treatment of wood indoors and outdoors under roof fully protected from weather and not exposed to permanent wetting (UC 1 and UC 2). The product is intended for preventive or remedial treatment of wood against insects by brushing or spraying. The product contains 0.2502% of the a.s. permethrin and is applied by rates of 300-350 mL/m^2 for remedial treatments or 200-250 mL/m^2 for preventive treatments.

Formulation

Environmental emission estimation for formulation has not been performed as the product is manufactured in a closed system and unacceptable emissions to the environment are not expected. Furthermore, other EU legislation already covers this step.

In-situ-application (professional, non-professional)

The product is only used for the treatment of wood that is installed under the conditions of UC 1 and UC 2. According to revised OECD ESD PT 8 (2013), potential emissions to the environment regarding in-situ-treatment of wood in UC 1 and UC 2 by brushing or spraying are considered negligible for professional and non-professional applications, respectively. A prerequisite is that application solutions are collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer.

Conclusion: Emissions to the environment are considered negligible for professional and non-professional in-situ-treatment of wood in UC 1 and UC 2, respectively. The following instruction for use is part of the authorisation: Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer. Discharge to wastewater by cleaning of equipment is not allowed.

Storage of treated wood

Emissions to the environment can potentially occur during storage of wood after application of Anti-Insekt if the treated wood is not installed, e.g. treatment of wooden furniture and smaller wooden items. However, according to the intended uses, these cases refer to UC 1 (indoor use). Thus, no significant emissions to the environment are expected. Therefore, no emission and exposure calculation is performed.

Conclusion: Potential emissions to the environment during storage of treated timber are considered negligible for the claimed uses of the biocidal product Anti-Insekt (professional and non-professional in-situ-treatment of wood in UC 1 and UC 2, respectively).

Service life of treated wood (UC 1 and UC 2)

No emission scenarios for wood in service are available for UC 1 and UC 2 (OECD ESD, 2013), since the potential emissions from treated wood to the outer environment are considered negligible.

Table 74: Use Classes and the receiving compartments (CEN, 1992)

Class	Description	Scenarios proposed	Primary receiving environmental compartment
1	Situation in which wood or wood-based product is under cover, fully protected from the weather and not exposed to wetting	No scenario	Indoor air (emissions to outdoor air, soil and water compartment are considered negligible)
2	Situation in which wood or wood-based product is under cover, fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting	No scenario	

Conclusion: Emissions to the environment are considered negligible for treated timber that is used according to UC 1 and UC 2.

3.9.4.3 Non-compartment specific effects

- **Primary poisoning**

Not relevant for PT8.

- **Secondary poisoning**

According to the BPR guidance Vol IV part B (2015) for substances with a log K_{ow} ≥ 4.5 (permethrin: Kow = 4.7), the uptake through the food chains potentially leading to secondary poisoning should be considered. The assessment is usually based on a comparison of the (predicted) concentration in the food of the top predator (PEC oral) and the (predicted) no-effect concentration based on toxicity studies (PNEC oral) in laboratory animals.

However, for wood of UC 1 and 2 no emission scenarios are presented by the OECD (OECD ESD for PT 8, PART2), since for this wood classes the potential emissions from treated wood to the outer environment are considered negligible.

3.9.4.4 Calculated PEC values

Significant emissions to the environmental compartments, regarding the formulation and in-situ application of the product, as well as the use of treated timber are not expected if the respective instructions for use are applied. Therefore, no PEC values have to be derived.

3.9.4.5 Aggregated exposure (combined for relevant emission sources)

It is assumed that the intended uses of Anti-Insekt will not result in significant emissions to any environmental compartment. Thus, an aggregated exposure assessment is not necessary.

3.9.5 Risk characterisation

Application (in-situ non-professional and professional treatment)
The product is applied in-situ to wood by non-professional or professional users by brushing or spraying. The application takes place under the conditions of UC 1 and UC 2. Therefore, emission to the environment are considered to be negligible.

Conclusion: No unacceptable risk for the environment is expected during non-professional and professional in-situ applications, respectively, under the conditions of UC 1 and UC 2. The following instruction for use is part of the authorisation: Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer. Discharge to wastewater by cleaning of equipment is not allowed.

Storage of treated wood
No significant emissions to the environment are expected under the conditions of the intended uses in UC 1 and UC 2. Therefore, no emission and exposure calculation is performed.

Conclusion: Potential emissions to the environment during storage of treated timber are considered negligible for the claimed uses of the biocidal product Anti-Insekt (professional and non-professional in-situ-treatment of wood in UC 1 and UC 2, respectively).

Service life

Regarding the service life of timber treated with the product no risk quotients for the environment were derived. Emissions to the environment are considered negligible because the use of timber, treated with the product, is restricted to UC 1 and 2.

Conclusion: No unacceptable risk for the environment is expected during the service life in UC 1 and UC 2.

Overall conclusion

Because of the use conditions of the product and the wood, treated with the product, as well as the resulting instructions for use no significant emissions to the STP, the terrestrial and the aquatic compartment are expected. Therefore, a separate risk characterisation is not required.

3.9.5.1 PBT assessment

P

Permethrin as the isomeric mixture 25:75 cis:trans is not persistent in aquatic systems, on the basis that its whole system DT50 (12 ºC) values do not fulfil the P criterion for sediment. However, a constituent of permethrin (the cis isomer) may have the potential to be persistent. For further detailed information please refer to Permethrin CAR 2014, PT 8/ PT18; Rapporteur: Ireland; April 2014.
Permethrin (25:75) is not considered to fulfil the P or vP criteria.

B&T

Permethrin does not fulfil the B criterion. BCF_{fish} and $BCF_{chironomid}$ values are < 2000. For further detailed information please refer to permethrin CAR 2014 for PT 8/ PT18; Rapporteur: Ireland. Permethrin meets the criteria for Toxicity. The measured NOEC values aquatic organisms are all lower than the specified T criterion trigger value of 0.01 mg/L.

3.9.5.2 Endocrine disrupting properties

Permethrin is not classified as an identified ED substance in wildlife. For further details, please refer to CAR 2014.

There are indications that 4-tert-butylphenol contained in the anti-skinning agent of the product may have endocrine disrupting properties based on the data provided by the applicant as it is labelled as REPRO 2 in the MSDS . The eCA considered in its evaluation also further information available on the non-active substances. 4-ter-butylphenol contained in anti-skinning agent is also included in the ECHA’s

endocrine disruptor assessment list, the PACT list as well as in the CoRAP-list according to Regulation (EU) 1907/26006 for potential ED-hazards (for environment). It is currently under evaluation by DE and will be included in the SVHC candidate list soon. However, based on the information available to the RefMS at the moment, it is not possible to conclude whether this co-formulant should be considered to have ED properties or not. This is further assessed in the frame of the REACH Regulation. In case the co-formulant is finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.
The other co-formulants are neither contained in the candidate list for substances of very high concern for authorisation, the community rolling action plan (CoRAP) or the public activities coordination tool (PACT) according to Regulation (EU) 1907/26006 for potential ED-hazards. No indications on potential ED effects on environmental non-target organisms were found in scientific literature.

3.9.5.3 Summary of risk characterisation

The biocidal product Anti-Insekt with the active substance permethrin contains (2-Methoxymethylethoxy)propanol as substance of concern for the environment. Therefore, the environmental risk assessment for the product should be based on the active substance permethrin as well as the SoC. Because of the use conditions of the product and the wood, treated with the product, as well as the instructions for use resulting from the single assessment of the active substance, no significant emissions of the biocidal product to the environment are expected at all. Therefore, no unacceptable risks for the environment are expected for the intended uses of Anti-Insekt. No further data were required and no additional environmental risk assessment of the SoC was performed in case of Anti-Insekt.

3.10 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.11 Comparative assessment

No candidate for substitution was identified (see chapter 2.2.4), hence a comparative assessment is not necessary.

4 Annexes

4.1 List of studies for the biocidal product

Table 75

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.1.1. Physical state (at 20 °C and 101,3 kPa)	Determination of the accelerated storage of Anti Insekt according to CIPAC, MT 46	Affolter, O.	2016	LAUS GmbH, Kirrweiler, Germany
2	3.1.2. Colour (at 20 °C and 101,3 kPa)	Determination of the accelerated storage of Anti Insekt according to CIPAC, MT 46	Affolter, O.	2016	LAUS GmbH, Kirrweiler, Germany
3	3.1.3. Odour (at 20 °C and 101,3 kPa)	Determination of the accelerated storage of Anti Insekt according to CIPAC, MT 46	Affolter, O.	2016	LAUS GmbH, Kirrweiler, Germany
4	3.4.1.1. Accelerated storage test	Determination of the accelerated storage of Anti Insekt according to CIPAC, MT 46	Affolter, O.	2016	LAUS GmbH, Kirrweiler, Germany
5	3.9. Viscosity	Determination of the viscosity of Anti Insekt according to OECD 114 / DIN 53015	Henke, W.	2016	LAUS GmbH, Kirrweiler, Germany
6	4.6. Flammable liquids	Untersuchungsbericht Auftrags-Nr.: 17-1238 Version: 02	Pieper, M.	2017	Remmers Baustofftechnik GmbH

7	4.17.1. Auto-ignition temperatures of products (liquids and gases)	Determination of the auto ignition temperature of Anti Insekt, study no. 16011104N962	Henke, W.	2016	Remmers Baustofftechnik GmbH
8	5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product	Validation of an analytical method using GC/FID for the determination of the stability of the active ingredient permethrin in Anti Insekt	Affolter, O.	2016	LAUS GmbH, Kirrweiler, Germany
9	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46 - 1(2009) after evaporative ageing procedure according to EN 73 (2014)	Fennert, E.-M. & Kolling, T.	2016	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany

10	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Determination of the eradicant action against larvae of Hylotrupes bajulus (L.) according to EN 1390 (2006)	Fennert, E.-M. & Kolling, T.	2015	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany
11	6.7. Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Determination of the eradicant action against larvae of Anobium punctatum De Geer according to EN 48 (2005)	Fennert, E.-M. & Kolling, T.	2016	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany

4.2 List of studies for the active substance(s)

4.2.1 Permethrin

- The applicant has access to the data from the active substance approval (see chapter 4.2.1.1 for details).

4.2.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[9]) of the active substance Permethrin for use in Wood preservatives (product-type 08). Please, refer to the corresponding Assessment Report for a reference list.

9 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

4.3 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

4.3.1 Safety for professional users


Adobe Acrobat Document

4.3.2 Safety for non-professional professional users

Calculations for scenario 3

General Exposure Calculator For Washing Out Of Brushes **The systemic dermal exposure is calculated as follows:**		
Activity and Parameters	**Permethrin No gloves**	**Units**
Volume of brush	**200**	**ml**
Volume of paint remaining on brush after painting ($^1/_8$ of 200 ml = 25 ml)	25	ml
Density of paint	**0.79**	**g/ml**
Weight of paint on brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	19.87	g
Concentration of a.s. in paint	**0.25**	**% w/w**
A. Weight of a.s. on brush after painting	49.6625	mg
B. Residues of a.s. on brush after 1st washing (10% of A)	4.9663	mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	44.6963	mg
C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	2.4831	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore. weight of a.s. available to contaminate the hand (10% of C)	0.2483	mg
Penetration of a.s. through gloves	**100**	**%**
Weight of a.s. on hand	0.24831	mg
Dermal absorption of a.s.	**75.00**	**%**
Weight of a.s. entering the body	0.18623	mg
D. Weight of a.s. left on the brush after 1st wash and squeezing (B – C)	2.4831	mg
E. Residues of a.s. on brush after 2nd washing (10% of D)	0.2483	mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	2.2348	mg
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	0.1242	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of F)	0.0124	mg
Penetration of a.s. through gloves	100	%
Weight of a.s. on hand	0.01242	mg
Dermal absorption of a.s.	75.00	%

Weight of a.s. entering the body	0.00931	mg
G. Weight of a.s. left on the brush after 2nd wash and squeezing (**E** – **F**)	0.1242	mg
H. Residues of a.s. on brush after 3rd washing (10% of G)	0.0124	mg
Amount of a.s. removed from the brush into the cleaning fluid (G – H)	0.1117	mg
I. Weight of a.s. squeezed out from a brush onto a cloth (50% of H)	0.0062	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of I)	0.0006	mg
Penetration of **a.s.** through gloves	100	%
Weight of a.s. on hand	0.00062	mg
Dermal absorption of a.s.	75.00	%
Weight of a.s. entering the body	0.00047	mg
Total weight of a.s. entering the body *(to 4 decimal places)*	**0.1960**	**mg**
Body weight	**60**	**kg**
TOTAL SYSTEMIC DERMAL DOSE OF ACTIVE SUBSTANCE *(to 4 decimal places)*	**0.00327**	**mg a.s./kg bw**