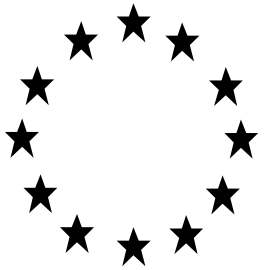
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Product identifier in R4BP	Wolsit T-33
Product type(s):	08 (wood preservative)
Active ingredient(s):	Permethrin
Case No. in R4BP	BC-BC023427-64
Asset No. in R4BP	DE-0015749-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/08.00013 710-05-08-00013-00-00-00-0000
Date	03.02.2020

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1 Conclusion

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use product, Wolsit T-33 with the active substance Permethrin (33.33 % w/w) is used as a wood preservative (product-type 08) for preventive protection of wood composites (e.g. plywood, oriented strand board or oriented structural board (OSB), medium density fibre boards, and particle board) for use in situation of use-class 1[1] against attack by wood destroying termites[2] (*Reticulitermes* spp.) by industrial users.

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[3] 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.

A classification according to Regulation (EC) No 1272/2008[4] is necessary. Detailed information on classification and labelling is provided in chapter 2.3.

The assessment of the intended use(s) as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

1. The conclusions and recommendations of the Biocidal Products Committee (BPC) Opinion on the application for approval of the active substance: Permethrin, Product type: 8 (ECHA/BPC/003/2014) including the “elements to be taken into account when authorising products” as requested by the Irish CA.
2. The specific provisions from the Commission Implementing Regulation (EU) No. 1090/2004 for the active substance Permethrin.

Approval of the active substance

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1 Use class according to EN 335

2 It should be noted that termites are recognised as relevant target organisms only in some member states. For details, please refer to chapter 3.6.2.

3 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.

4 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.

The active substance Permethrin is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:
The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. For biocidal products, authorisations are subject to the following conditions:

(1) For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.

(2) Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular: labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hardstanding, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

(3) Products shall not be authorised for wood that will be exposed to frequent weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 19 and Annex VI of Regulation (EU) No 528/2012, if necessary by the application of appropriate risk mitigation measures.

(4) Products shall not be authorized for treatment of outdoor constructions near or above water or for the treatment of wood that will be used for outdoor constructions near or above water, unless data are submitted to demonstrate that the product will not present unacceptable risks, if necessary by the application of appropriate mitigation measures.

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

Composition and formulation

Please refer to chapter 2.2.4 and the confidential annex for further information.
For the full composition of the product please refer to the confidential annexes.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.3).

Physical hazards and respective characteristics

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

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.5. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The product has been shown to be efficacious for the uses appropriate for authorisation listed in chapter 2. Please find more information on efficacy of the product in chapter 3.6.

Risk assessment for human health

A human health risk assessment has been carried out for industrial use of the product (see chapter 3.7) for the intended use (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use cause any unacceptable acute or chronic risk to professional users, bystanders and residents. 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 has been carried out for industrial use of the product (see chapter 3.9) indoors (see chapter 3.1).

No significant emissions of the biocidal product to the environment are expected considering the use conditions of the product and the wood-based products, treated with the product, as well as the instructions for use and risk mitigation measures (refer to chapter 3.9.4 and 3.9.5).

Based on the risk assessment it is unlikely that the intended use cause any unacceptable risk for the environment if the risk mitigation measures and directions for use are followed.

Information on endocrine disrupting properties

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore no corresponding regulatory measures are required.

Comparative Assessment

A comparative assessment has not been necessary (see chapter 3.11) since no candidate for substitution were identified.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Wolsit T-33

2.1.2 Manufacturer(s) of the product

Name of manufacturer	BASF Wolman GmbH
Address of manufacturer	Dr. Wolman Strasse 31-33 76547 Sinzheim Germany
Location of manufacturing sites	Dr. Wolman Strasse 31-33 76547 Sinzheim Germany

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

Active substance	Permethrin
Name of manufacturer	R2 Group A/S (Acting for Tagros Chemicals India Limited (India))
Address of manufacturer	Odinsvej 23 8722 Hedensted Denmark
Location of manufacturing sites	Tagros Chemicals India Limited A4/1&2, SIPCOT Industrial Complex, Kudikadu, Cuddalore, Tamil Nadu, India

Active substance	Permethrin
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz 1

	50569 Köln Germany
Location of manufacturing sites	Bilag Industries Limited 306/3, II Phase, GIDC, Vapi-396195 - India

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-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate The cis:trans ratio is 25:75.	Active substance	52645-53-1	258-067-9	technical: 33.33 (pure: 31)

- Information on the full composition is provided in the confidential[5] annex (see chapter 5).

- 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)

[5] Access level: "Restricted" to applicant and authority

2.2.3 Information on endocrine disrupting properties

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore no corresponding regulatory measures are required.

2.2.4 Information on the substance(s) of concern

No substance of concern was identified.

2.2.5 Candidate(s) for substitution

No candidate for substitution was identified.

2.2.6 Type of formulation

AL – any other liquid (ready-to-use emulsion)

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[6]

The environmental classification for the biocidal product "Wolsit T-33" is based on the classification of the active substance. Besides the active substance permethrin other components do not affect the environmental classification of the biocidal product.

- The currrent harmonised classification of the active substance **permethrin** is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):[7]

  Aquatic Acute 1 H400: Very toxic to aquatic life

  Aquatic Chronic 1 H410: Very toxic to aquatic life with long-lasting effects

6 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.

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

Taking the information for the environment into account, a classification of the biocidal product "**Wolsit T-33"** pursuant to the Regulation (EC) 1272/2008 is required, which results in:

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

The current harmonised classification for human health of the active substance is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):[8]

Acute Tox. 4, H302, Skin Sens. 1, H317

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 2.5 and if applicable to chapter 2.4.

Table 2

Classification Hazard classes, Hazard categories	**Hazard statements**	
Acute Tox. 4	H302	
Skin Sens. 1	H317	
Aquatic Acute 1	H400	
Aquatic Chronic 1	H410	
Labelling	**Code**	**Pictogram / Wording**
	GHS07	
	GHS09	
Signal word	-	Warning
Hazard statements	H302	Harmful if swallowed.
	H317	May cause an allergic skin reaction.
	H410	Very toxic to aquatic life with long lasting effects
Supplemental hazard information	-	-
Supplemental label elements	-	-
Precautionary statements	P261	Avoid breathing dust/fume/gas/mist/vapours/spray
	P264	Wash … thoroughly after handling

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

	P270	Do not eat, drink or smoke when using this product
	P272	Contaminated work clothing should not be allowed out of the workplace
	P273	Avoid release to the environment
	P280	Wear protective gloves
	P301 + P312	IF SWALLOWED: Call a POISON CENTRE or doctor/physician: if you feel unwell
	P302 + P352	IF ON SKIN: Wash with plenty of soap and water
	P321	Specific treatment (see… on this lable)
	P330	Rinse mouth
	P333 + P313	If skin irritation or rash occurs: Get medical advice/attention
	P362 + P364	Take off contaminated clothing and wash it before reuse
	P391	Collect spillage
	P501	Dispose of contents/container to…
Note	-	

For labelling according to Article 69 of Regulation 528/2012, in particular precautionary and risk mitigation measures (RMM), please refer to chapter 2.5 and 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

2.4.1 Use 1 appropriate for authorisation – Addition to the glue-line

Product Type(s)	08
Where relevant, an exact description of the use	Preventive protection of wood composites (e.g. plywood, oriented strand board or oriented structural board (OSB), medium density fibre boards, and particle board)) for use in use-class 1[9] against attack by wood destroying termites.
Target organism(s) (including development stage)	Subterranean termites (*Reticulitermes* sp.) Worker/Soldiers/ - Nymphs
Field(s) of use	Indoor; in situation of use-class 1

[9] Use class according to EN 335

Application method(s)	Glue-line treatment process The process involves adding the preservative to the resin binder. This resin-preservative mixture is then sprayed onto the particles (particle, OSB and fibre boards) or applied to the veneer by rollers (plywood, veneered laminated boards).
Application rate(s) and frequency	0.65 – 2 kg/m³, one-time non-recurring application At an average oven-dry wood composite density of 650 kg/m³, this would correspond to an application rate of 0.1 – 0.3 % m/m.
Category(ies) of users	Industrial
Pack sizes and packaging material	Jerry can, HDPE, 30 L, IBC, HDPE, 640 L, IBC, HDPE, 1000 L

2.4.1.1 Use-specific instructions for use

See chapter 2.5.1

2.4.1.2 Use-specific risk mitigation measures

See chapter 2.5.2

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 2.5.3

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

See chapter 2.5.4

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 2.5.5

2.5 General directions for use

2.5.1 Instructions for use

1) For industrial application only. 2) Always read the label or leaflet before use and respect all the instructions provided. 3) Treated wood-based products should only be used in compliance with the definition of Use Class 1 according to EN 335. *4)* 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. *5)* Prevent any release to the environment during storage and transport of treated wood-based products.

2.5.2 Risk mitigation measures

1) Do not use on wood which may come in direct contact with food,feeding stuffs and livestock animals.. 2) Keep pets, particularly cats, away from treated structures. **RMMs for industrial users:** The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures: • Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Use specific RMMs for manual loading / pouring of the product into the receiving vessel:

The use of a dosing pump for manual loading is required.

3) All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).
4) Freshly treated wood-based products shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal.

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

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

First Aid:
Keep the container or label available.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
Rinse mouth.

IMPAIRED CONSCIOUSNESS: do not give fluids or induce vomiting; place in recovery position and seek medical advice immediately.

INHALATION: Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.

SKIN CONTACT: Remove contaminated clothing and shoes. Wash contaminated skin with water. Get medical attention if symptoms occur.

EYE CONTACT: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs

2.5.4 Instructions for safe disposal of the product and its packaging

1) Disposal of product and of packaging shall comply with the waste disposal legislation and any

regional or local authority requirements.

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

1) Shelf-life: 24 months

2.5.6 Other information

-pure concentration of the active substance: 31,0% w/w

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
Jerry Can	30 L	HDPE	-	Professional (Industrial)	Yes
IBC	640 L	HDPE	-	Professional (Industrial)	Yes
IBC	1000 L	HDPE	-	Professional (Industrial)	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 glue-line

Product Type(s)	08
Where relevant, an exact description of the use	Preventive protection of wood composites (e.g. plywood, oriented strand board or oriented structural board (OSB), medium density fibre boards, and particle board) for use in use-class 1 against attack by wood destroying termites.
Target organism(s) (including development stage)	Subterranean termites (Reticulitermes sp.) Nymphs/Worker/Soldiers
Field(s) of use	Indoor use-class 1[10]
Application method(s)	Glue-line treatment process The process involves adding the preservative to the resin binder. This resin-preservative mixture is then sprayed onto the particles (particle, oriented strand board or oriented structural board (OSB) and fibre boards) or applied to the veneer by rollers (plywood, veneered laminated boards).
Application rate(s) and frequency	Ca. 0.65- 2kg/m^3 one-time non-recurring application
Category(ies) of users	Industrial
Pack sizes and packaging material	Jerry can, HDPE, 30 L, IBC, HDPE, 640 L, IBC, HDPE, 1000 L

[10] according to EN 335

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
001	08	A process used for protection against wood-destroying termites.The process involves adding the preservative to the resin binder. This resin-preservative mixture is then sprayed onto the particles (particle, OSB and fibre boards) or applied to the veneer by rollers (plywood, veneered laminated boards).	Reticulitermes sp. Subterranean termites Nymphs/Workers/Soldiers	indoor Use class 1	indoor Use class 1 Glue-line treatment process	0.65 - 2 kg/m³ one-time, non-recurring application 0.1 % m/m – 0.3 % m/m in the treated wood composites (percent mass/mass based on the oven-dried mass of the treated board). This corresponds to 0.650 kg/m³ - 2 kg/m³ Wolsit T-33 in the treated wood composite for an average density of the treated boards of of 650 kg/m³.	Industrial	IBC Plastic: HDPE 1000 Litre; IBC Plastic: HDPE 640 Litre Jerry can Plastic HDPE 30 Litre

Intended use name(s)

1. Addition to the glue-line

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	Wolsit T-33 Batch: TH 3645	clear, homogenous liquid	anonymus (2015): Odour, physical state an pH value of Wolsit T-33 (Report No. 15-WD-031)
Colour at 20 °C and 101.3 kPa	Visual inspection	Wolsit T-33 Batch: TH 3645	slightly lutescent	anonymus (2015): Odour, physical state an pH value of Wolsit T-33 (Report No. 15-WD-031)
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304 (Odor)	Wolsit T-33 Batch: TH 3645	faint specific odour	anonymus (2015): Odour, physical state an pH value of Wolsit T-33 (Report No. 15-WD-031)
Acidity / alkalinity	CIPAC MT 75	Wolsit T-33 Batch: TH 3645	Mean values of three repeated measurements: pH (25°C) 1% w/w solution of Wolsit T-33: 5.33 pH (25°C) Wolsit T-33: 7.52	anonymus (2015): Odour, physical state an pH value of Wolsit T-33 (Report No. 15-WD-031)
Relative density	OECD Guideline 109 (oscillating densitometer)	Wolsit T-33 Batch: TH 3645	1.096 (20°C)	anonymus (2015): Density of Wolsit T-33 (Report No. 15-WD-039)
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Wolsit T-33 Batch: TH 3645	Accelerated storage: 14 days at 54±2°C **pH (Wolsit T-33; 25°C):** start: 7.52 end: 6.36	anonymus (2015): Accelerated storage test by heating of Wolsit T-33 (Report No. 15-WD-055)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pH (1% w/w; 25°C): start: 5.33 end: 5.24 **Density (20°C) [g/cm³]:** start: 1.0960 end: 1.0966 **Permethrin [%]:** start: 31.98 end: 31.04 (Degradation of a.s.: -2.94%) **cis/trans-ratio of Permethrin:** start: 25.6 : 74.4 end: 25.4 : 74.6 The product is stable under accelerated storage conditions.	
Storage stability test – **long term storage at ambient temperature**	OPPTS 830.6317	Wolsit T-33 Batch: TH 3645	Description of the storage stability test: ▫ 5L test sample in a HDPE container ▫ ambient conditions ▫ storage in a non-air conditioned storage room equipped with a glass window (natural daylight) ▫ temperature recorded (digital min-max-thermometer): storage temperature ranges between 4 °C and 32 °C **<u>Results:</u>** **pH (Wolsit T-33; 25°C):** start: 7.52	anonymus (2016): Stability of Wolsit T-33 (Report No. 16-WD-079)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			after 6 months: 6.68 after 13 months: 7.26 after 24 months: not determined **pH (1% w/w; 25°C):** start: 5.33 after 6 months: 4.96 after 13 months: 5.41 after 24 months: 4.9 **Density (20°C) [g/cm³]:** start: 1.0960 after 6 months: 1.0960 after 13 months: 1.0972 after 24 months: 1.097 **Permethrin [%]:** start: 32.0 after 6 months: 31.6 (Degrad. of a.s.: -1.25%) after 13 months: 31.4 (Degrad. of a.s.: -1.88%) after 24 months: 31.8 (Degrad of a.s.: -0.63%) **cis/trans-ratio of Permethrin:** start: 25.6 : 74.4 after 13 months: 25.0 : 75.0 after 24 months: 25.4 : 74.6 A shelf-life of 24 months can be granted.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT-39 - Stability of liquid formulations at 0°C	Wolsit T-33 Batch: TH 3645	The appearance of the product remains unchanged after storage at 0°C for 7 days; no precipitation occurred.	anonymus (2015): Low temperature stability of Wolsit T-33 (Report No. 15-WD-087-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				R0)
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	The effects of light on the content of the active substance and technical characteristics of the biocidal product were tested within the long term storage at ambient temperature. According to the label claim: Keep only in the original container in a cool, well-ventilated place away from ignition sources, heat or flame. Protect from direct sunlight. Protect from frost.)	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	The effects of temperature and humidity on the content of the active substance and technical characteristics of the biocidal product were tested within the long term storage at ambient temperature and the accelerated storage test. (According to the label claim: Keep only in the original container in a cool, well-ventilated place away from ignition sources, heat or flame. Protect from direct sunlight. Protect from frost.)	-
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**				Dangerous Goods Database http://www.dgg.bam.de/en/
Wettability	-	-	Data waiving was acceptable (data are only	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			required for solid preparations which are to be dispersed in water).	
Suspensibility, spontaneity and dispersion stability	-	-	Data waiving was acceptable (data are not required since the biocidal product is a ready-to-use emulsion).	-
Wet sieve analysis and dry sieve test	-	-	Data waiving was acceptable (data are only required for solid biocidal products, dispersible concentrates or suspensions).	-
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36 - Emulsion characteristics of emulsifiable concentrates	Wolsit T-33 Batch: TH 3645	Wolsit T-33 was emulsified in a 5.0 % w/w solution after 10 inversions as well as standing up to 24 hours. The solution is stable and homogenous, no separation or deposit formation observed.	anonymus (2015): Emulsifiability of Wolsit T-33 (Report No. 15-WD-79-R0)
Disintegration time	-	-	Data waiving was acceptable (data are only required for biocidal products supplied as tablets).	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Data waiving was acceptable (data are not required since the biocidal product is a ready-to-use emulsion).	-
Persistent foaming	CIPAC MT 47 - Persistent foaming	Wolsit T-33 Batch: TH 3645	The product Wolsit T-33 carried out a maximum of 1.5 ml corresponding to a maximum of 0.30 cm foam that built no continuous layer on the surface. There was a free zone on the surface for the whole test time. The foam is fading away in time, the product showing practically no foaming on the top of the liquid or inside the liquid after 30 minutes from the initial 30 times inverting procedure executed with the cylinder containing Wolsit T-33.-	anonymus (2015): Determination of the persistence of foaming of Wolsit T-33 (Report No. 15-WD-063-R0)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Flowability/Pourability/Dustability	-	-	Data waiving was acceptable (flowability/dustability is not applicable since the biocidal product is not a solid product like a granular preparation or a dustable powder; pourability is not applicable since the product is not a suspension concentrate, capsule suspension or suspoemulsion).	-
Burning rate — smoke generators	-	-	Data waiving was acceptable (not applicable since the biocidal product is not a smoke generator).	-
Burning completeness — smoke generators	-	-	Data waiving was acceptable (not applicable since the biocidal product is not a smoke generator).	-
Composition of smoke — smoke generators	-	-	Data waiving was acceptable (not applicable since the biocidal product is not a smoke generator).	-
Spraying pattern — aerosols	-	-	Data waiving was acceptable (not applicable since the biocidal product is not an aerosol).	-
Physical compatibility	-	-	Data waiving was acceptable (not applicable since the biocidal product is not intended to be used with other products).	-
Chemical compatibility	-	-	Data waiving was acceptable (not applicable since the biocidal product is not intended to be used with other products).	-
Degree of dissolution and dilution stability	-	-	Data waiving was acceptable (not applicable since the biocidal product is not a water soluble bag, tablet or a water-soluble preparation).	-
Surface tension	OECD Guideline 115 (plate method) EU Method A.5 (Surface Tension)	Wolsit T-33 Batch: 0013669334	35.49 ± 0.05 mN/m (20 °C)	2016): Wolsit T-33 - Determination of Surface Tension (Report No.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				161017BT/CPT17401)
Viscosity	OECD Test Guideline 114 (rotational viscometer)	Wolsit T-33 Batch: TH 3645	The dynamic viscosity of the product Wolsit T-33 is determined to 327 mPa*s at 20 °C and to 95.4 mPa*s at 40 °C.	anonymus (2015): Viscosity of Wolsit T-33 (Report No. 15-WD-047)

Table 5

Conclusion on the physical, chemical and technical properties
The data provided by the applicant was acceptable. The product is a slightly lutescent, clear homogenous liquid with a faint specific odour. The pH of a 1% w/w solution at 25°C is 5.33, measured as a mean value of three repeated measurements. The relative density is 1.096 at 20°C. The product is stable at higher temperatures and showed during an accelerated storage stability test at 54 °C for 14 d a slight degradation of a.s (-2.94%). The long term storage test at ambient temperature also showed a slight degradation of a.s that adds up to less than 2.0%. During both storage tests the physicochemical characteristics did not change (significantly).The shelf life of two years can be granted. The appearance of the product remains un-changed after storage at 0°C for 7 days and no pre-cipitation occurred. The emulsion characteristics showed that the solution is stable and homogenous, no separation or deposit formation observed. The surface tension is 35.49 ± 0.05 mN/m at 20 °C. The dynamic viscosity of the product is determined to 327 mPa*s at 20 °C and to 95.4 mPa*s at 40 °C.

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	Screening procedure: OECD 113 (DSC)	100 %	Exothermic decomposition energy: 190 J/g Decomposition temperature (T_{onset}): Temperature range of 50-190 °C and 250-370 °C	Not classified based on GHS/CLP criteria	anonymus (2016)
Flammable gases	study scientifically unjustified			Waiver	IUCLID[11]
Flammable aerosols	study scientifically unjustified			Waiver	IUCLID[11]
Oxidising gases	study scientifically unjustified			Waiver	IUCLID[11]
Gases under pressure	study scientifically			Waiver	IUCLID[11]

[11] 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
	unjustified				
Flammable liquids	DIN EN ISO 2719	100 %	Flash point: 111.5 °C	Not classified based on GHS/CLP criteria	anonymus (2016)
Flammable solids	study scientifically unjustified			Waiver	IUCLID[11]
Self-reactive substances and mixtures	study scientifically not necessary			Waiver: The product is a thermally stable liquid and not liable to undergo a strongly exothermic decomposition.	IUCLID[11]
Pyrophoric liquids	study scientifically not necessary			Waiver: The study does not need to be conducted because the product is known to be stable in contact with air at room temperature for prolonged periods of time (days).	IUCLID[11]
Pyrophoric solids	study scientifically unjustified			Waiver	IUCLID[11]
Self-heating substances and mixtures	study technically not feasible			Waiver: The study does not need to be conducted because the product is a liquid.	IUCLID[11]
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 product is known to be soluble in water to form a stable mixture.	IUCLID[11]
Oxidising liquids	UN Test O.2 (in Part III of the UN-MTC)	100 %	Mean pressure rise time:21.83 s	Not classified based on GHS/CLP criteria	anonymus (2016)
Oxidising solids	study scientifically unjustified			Waiver	IUCLID[11]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Organic peroxides	study scientifically not necessary			Waiver: The study does not need to be conducted because the proctuct does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	IUCLID[11]
Corrosive to metals	UN Test in Part III of the UN-MTC, 37.4	100 %	Corrosion rate: no corrosion Type of material: aluminium 7075 Corrosion rate: negative Type of material: steel DC 01	Not classified based on GHS/CLP criteria	anonymus (2015)
Auto-ignition temperature (liquids and gases)	DIN 51794	100 %	Auto-ignition temperature: 335 °C		anonymus (2016)
Relative self-ignition temperature for solids	study scientifically unjustified			Waiver	IUCLID[11]
Dust explosion hazard	study scientifically unjustified			Waiver	IUCLID[11]

Table 7

Conclusion on the physical hazards and respective characteristics

The data provided by the applicant was acceptable.
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 no labelling is required fpr physical-chemical hazards. Therefore there is no risk expected from the formulated product with regards to the physico-chemical properties.

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 in Wolsit T-33	GC-FID	no significant matrix peak is recognisable at the retention time of Permethrin; The cis/trans-ratio of Permethrin can be determined based on the areas of the single peaks, both peaks are well separated.	three point calibration (based on mean value of 3 runs for each conc.); range: 387-1935 mg/L; Correlation coefficient: 0.9984	Fortification range: 80-100%; number of measurements: five	Level 1 (1300 mg/L): 101.8-105.4; Level 2 (1650 mg/L): 96.8-103.9	Level 1 (1300 mg/L): 103.1; Level 2 (1650 mg/L): 100.2	Level 1 (1300 mg/L): 1.2 %; Level 2 (1650 mg/L): 2.3 %	n.a.	anonymus (2016): Validation of a Gas Chromatography Method for the Determination of Permethrin in Wolsit products (Report No. 15-WD-007)
Permethrin in Wolsit® EC-100			three point calibration (based on mean value of 3 runs for each conc.); range: 372-	Fortification range: 66-133%; number of measurements: five	Level 1 (500 mg/L): 103.3-107.2; Level 2 (750 mg/L): 97.1-99.7; Level 3 (1000	Level 1 (500 mg/L): 105.0; Level 2 (750 mg/L): 98.6; Level 3 (1000 mg/L): 95.6	Level 1 (500 mg/L): 1.3 % Level 2 (750 mg/L): 1.0 % Level 3 (1000 mg/L): 0.9 %		

			1861 mg/L; Correlation coefficient: 0.9985	(387 - 1861 mg/L)	mg/L): 94.8-97.1				

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 PT08 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 PT08 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.	anonymus, 2008 CAR PT08 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, R²)**	**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 R²=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	 89 – 105 % 100 – 103 % 82 – 98 % 92 – 95 % 91 – 108 % 99 – 102 %	 95 % 101 % 88 % 93 % 96 % 101 %	 6.4 % 1.3 % 7.3 % 1.6 % 7.1 % 1.3 %	0.005 mg/kg	LC MS/MS Synergi 2µ Polar RP column; ESI+ m/z 408→183 m/z 408→ 355

				sandy loam 0.005 mg/kg / 5 0.05 mg/kg / 5	83 – 98 % 91 – 94 %	89 % 93 %	7.0 % 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	Not given in DocIIIA	 87 % 90 % 92 % 91 %	 5 % 4 % 4 % 3 %	5 µg/m³	anonymus, 2008 CAR PT08 Bayer/Sumitomo DocIIIA, 4.2 (4); 12/2012

				5 µg/m³/ 5 48 µg/m³/ 5 warm humid air 4.8 µg/m³/ 5 49 µg/m³/ 5		88 % 90 % 91 % 90 %	6 % 4 % 2 % 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	anonymus, 2006CAR PT08 Tagros DocIIIA, 4.2.b; 12/2012

Table 13

Data waiving was acceptable for the following information requirements	
Information requirement	1. 5.1. Data waiving for the substances of concern is acceptable. 2. 5.2.1. Soil: No data waiving. 3. 5.2.2. Air: No data waiving. 4. 5.2.3. Water (including drinking water) and sediment: No data waiving. 5. 5.2.4 Body fluids and tissues: Data waving was accepted. 6. 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: Data waving was accepted.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 14

Conclusion on the methods for detection and identification
The method(s) provided regarding the active substance(s was/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 the CAR. Method regarding substances of concern was not necessary.

3.6 Efficacy against target organisms

3.6.1 Function and field of use

Wolsit T-33 is used for preventive protection of wood composites, e.g. plywood, oriented strand board (OSB), medium density fibre boards (MDF), and particle board, for use in situation of use-class 1 against attack by wood destroying termites.

The application process involves industrial adding of the preservative to the resin binder (glue). For OSB, particle and fibre boards, the resin-preservative mixture is sprayed onto the particles. All particles will be embedded in the resin-preservative mixture resulting in presumably full penetration from all sides into the wood particles (wood chips). For plywood and veneered laminated boards, the preservative is added to the glue line and applied to the veneers by rollers, resulting in penetration of the preservative through the respective treated surface. In all cases manufacturing includes pressure and high temperatures of 200 °C or more in order to successfully glue-bind all particles or veneer layers, respectively.

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

Wolsit T-33 is a ready for use formulation and is effective against termites[12] (workers, soldiers and nymphs). Wolsit T-33 is suitable for use of situation in use class 1. The product is for use as binder (glue) additive for wood composites (e.g. plywood, OSB, MDF, and other particle boards).

3.6.3 Effects on target organisms, including unacceptable suffering

Termite damage is prevented to the acceptable grade of attack.

3.6.4 Mode of action, including time delay

As an insecticide, when formulated as a wood preservative permethrin is an axonic poison, binding to voltage-gated sodium channels in nerves. By binding to these channels, the substance group of

[12] Note: In Germany, no termite species occur naturally and in relevant amounts. Thus, they are not recognised as relevant target species.

pyrethroids prevent the channels from closing which cause a prolonged sodium channel activation. The nervous system is irreversibly damaged, leading to death.

The biocidal product is used preventively. Time delay is not relevant in these uses.

3.6.5 Efficacy data

General:
Efficacy against termites, European termite *Reticulitermes* spec*.,* is supported by two key studies according to EN 117 and several additional studies following the AWPA E1 standard. EN 117 tests were carried out on mixed softwood OSB without and after artificial ageing according to EN 73 (evaporation) prior to termite exposure, which is relevant for use in situation of use class 1. EN 117 tests were carried out with Wolsit T-33 added to the resin binder (glue). The same applies for the AWPA E1 standards, were the product was added to the glue line to test various plywood boards. AWPA E1 is the accepted test method by the American Wood Protection Association (AWPA) for demonstrating efficacy against termites when the wood preservative product is intended to be placed on the US market. The basic principles of termite testing according to AWPA E 1 setup or EN 117 standard are the same: preservative-treated products or preservative/biocide-treated carrier material are exposed to a defined number of a specific termite species (mostly *Reticulitermes sp.*, but others are possible) for a defined time period. Differences between EN 117 and AWPA E1 are the sample size (in AWPA E1 to be 25 x 25 x 6 mm³), termite number (400 in AWPA E1) and test period (4 weeks in AWPA E1). So in comparison to EN 117 the test samples are smaller, the termite number is larger and therefore the test period is shorter. AWPA E1 tests mentioned below were only carried out in the “no choice” alternative (similar to the requirements in EN 117) and with a representative subterranean termite species for Europe: *Reticulitermes santonensis*. Both standards (AWPA E1 and EN 117) require a visual evaluation of the samples to determine the degree of termite attack at the end of the test period. In contrast to the European standardization system, that describes the pass criteria for an EN 117 test in EN 599-1, the pass criteria for test samples in AWPA E 1 are not described in a standard. They are discussed and set by expert judgement on a case by case basis. However, treated samples should have a visual rating equal to or better than “8” to match efficacy criteria of EN 599-1. The AWPA E 1 tests are regarded as valid additional information to support proof of efficacy derived from the key EN 117 tests.

Specific efficacy for OSB, particle and fibre boards with Wolsit T-33 added to the binder as described above (see 3.6.1):
In two key studies conducted according to test standard EN 117, the test product Wolsit T-33 was tested for efficacy against European termites (*Reticulitermes santonensis*) on OSB. From the study after evaporation according to EN 73 the minimum effective retention of Wolsit T-33 for an acceptable damage (no rating higher than 1 with only one rating of 2) was 0.54 kg/m³ of OSB. From the study

without any artificial ageing the minimum effective retention of Wolsit T-33 for an acceptable damage (no rating higher than 1 with only one rating of 2) was 0.53 kg/m³ of OSB. Evaporative ageing therefore did not result in any loss of efficacy. Wolsit T-33 contained 33 % permethrin, corresponding to effective retentions in the EN 117 tests of 0.18 kg permethrin/m³ OSB.
Test with a different kind of particle board (standard particle board - composite of beech, spruce and poplar) according to EN 117 without ageing showed similar results with acceptable attack by termites at Wolsit T-33 retentions of 0.9 kg and also of 1.035 kg per m³ particle board, corresponding to permethrin loads of 0.30 kg and of 0.38 kg per m³ particle board. This study, however, had too few specimens in the test. Results therefore are of supporting value only.
In addition, OSB was tested according to AWPA E1 standard without prior ageing. Loadings with Wolsit T-33 of 0.35 kg/m³ protected the interior of the board completely with only minor attack on the surfaces. With 0.82 kg of Wolsit T-33/m³ no damages (interior and surfaces) by termites were recorded. Permethrin content ranged from 0.12 kg to 0.27 kg per m³ OSB, respectively. This study, however, had too few specimens in the test. Results therefore are of supporting value only.
Efficacy of Wolsit T-33 on MDF (medium density fibre board) was demonstrated according to AWPA E1 without prior ageing. Sufficient protection was achieved at Wolsit T-33 retentions of 0.44 kg and of 0.55 kg per m³ MDF, corresponding to permethrin contents of 0.13 kg and of 0.18 kg per m³ MDF, respectively. This study, however, had too few specimens in the test. Results therefore are of supporting value only.

Efficacy for plywood and veneered laminated boards with Wolsit T-33 added to the glue line as described above (see 3.6.1):
For plywood and veneered laminated boards, a weight of evidence approach was chosen to assess efficacy of Wolsit T-33. The two studies according to EN 117, which were performed on OSB (see previous section), served as proof of principle for efficacy by addition of the biocidal product into the glue line. In addition, two studies performed according to AWPA E1 demonstrated efficacy specifically when mixed into the glue of plywood. These studies were not conducted with the number of replicates demanded by the AWPA E1 standard (3 replicates instead of 5), but were deemed acceptable in combination with the EN 117 studies on OSB to demonstrate efficacy of Wolsit T-33 in both hardwood and softwood plywood.
Efficacy of Wolsit T-33 on plywood was demonstrated according to AWPA E1 without prior ageing on two plywood varieties (Okoumé and Maritime Pine). On hardwood plywood (Okoumé), analysed average loadings of 0.54 – 0.74 kg Wolsit T-33/m³ in the glue line protected the interior of the boards completely. The specification of the loading rate implies that at least one of the tested boards contained the minimum rate of 0.54 kg Wolsit T-33/m³. As all three test specimen had the same damage ratings, it can be concluded that a loading of 0.54 kg Wolsit T-33/m³ is sufficient to protect Okoumé plywood. On softwood plywood (Maritime Pine), both tested loading rates of 0.26 kg Wolsit T-33/m³ and 0.30 kg Wolsit T-33/m³ protected the interior of the boards Permethrin retentions correspond to 0.18 to 0.24 kg

per m³ plywood (Okoumé) and 0.09 to 0.10 kg per m³ plywood (Maritime Pine). Only the surfaces of both plywood types were damaged by termite attack. Wolsit T-33 was not able to penetrate from the closest glue line all the way to the surface. Damage stopped, however, when the unprotected portion was destroyed by termites during the test, demonstrating sufficient efficacy of Wolsit T-33 in the achieved penetration zone. Unprotected portions on the surface cause no loss in structural integrity or loss in function of the wood composite material. On the other hand, user exposure to biocides is severely reduced by this effect. Only if termites are present, the outer layer of the material is attacked but only until its protected parts of the treated material are exposed.
Overall, minimum effective retention of Wolsit T-33 derived from the relevant studies is 0.54 kg/m³ for particle boards (0.18 kg permethrin/m³; particle boards include OSB, fibre and particle boards) and 0.54 kg/m³ in the glue line for hardwood plywood (0.18 kg permethrin/m³) as well as 0.26 kg for softwood plywood (0.09 kg permethrin/m³). Evaporative ageing prior to testing has no influence on efficacy.

Wolsit T-33 in this assessment report contains 33 % permethrin. With an envisioned retention of 0.65 to 2 kg Wolsit T-33 per m³ of wood composite, the corresponding amount of permethrin ranges from 0.21 kg to 0.66 kg per m³ of wood composite

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; Preventive effectiveness against termites	Wood preservative in situation ofuse class 1 to protect wood composites	Wolsit T-33 containing ≥ 30 % to ≤ 33 % permethrin	*Reticulitermes santonensis*	EN 117 (2013) in combination with evaporation procedure (EN 73, 2014)	**Laboratory method**, Wood composite: OSB (mixed softwood strands) **Treatment:** Binder additive during manufacture, retentions 0.37 and 0.54 kg/m³; 8 weeks of exposure to	Effective protection at 0.54 kg/m³ with rating of damage of 1 (4x) and 2 (1x)	anonymus 2017

					insects, Replicates: 5 per retention		
Insecticide; Preventive effectiveness against termites	Wood preservative in situation of use class 1 to protect wood composites	Wolsit T-33	*Reticulitermes santonensis*	EN 117 (2013) in combination with conditioning procedure (ENV 12038, 2002)	**Laboratory method**, Wood composite: OSB (mixed softwood strands) **Treatment:** Binder additive during manufacture, retentions 0.18 and 0.53 kg/m³; 8 weeks of exposure to insects, Replicates: 5 per retention	Effective protection at 0.53 kg/m³ with rating of damage of 1 (4x) and 2 (1x)	anonymus 2016
Insecticide; Preventive effectiveness against termites	Wood preservative in situation of use class 1 to protect wood composites	Wolsit T-33	*Reticulitermes santonensis*	EN 117 (1990)	**Laboratory method**, Wood composite: standard particle board (beech, spruce, poplar) **Treatment:** Binder additive during manufacture, retentions 0.9 and 1.035 kg/m³; 8 weeks of exposure to insects, Replicates: 1 per retention	Effective protection at 0.9 kg/m³ with rating of damage of 1 (1x)	anonymus 2012
Insecticide;	Wood	Wolsit T-33	*Reticulitermes*	AWPA E1	**Laboratory**	Effective	anonymus

Preventive effectiveness against termites	preservative in situation of use class 1 to protect wood composites		*santonensis*	(1997)	**method**, Wood composite: bonded OSB (softwood) **Treatment:** Binder additive during manufacture, retentions 0.32 and 0.82 kg/m³; 4 weeks of exposure to insects, Replicates: 3 per retention	protection at 0.82 kg/m³ with rating of damage of 10 (2x) and 9 (1x)	2007a
Insecticide; Preventive effectiveness against termites	Wood preservative in situation of use class 1 to protect wood composites	Wolsit T-33	*Reticulitermes santonensis*	AWPA E1 (2006)	**Laboratory method**, Wood composite: bonded MDF **Treatment:** Binder additive during manufacture, retentions 0.44 and 0.55 kg/m³; 4 weeks of exposure to insects, Replicates: 3 per retention	Effective protection at 0.44 kg/m³ with rating of damage of 10 (3x)	anonymus 2016
Insecticide; Preventive effectiveness against termites	Wood preservative in situation of use class 1 to protect wood composites	Wolsit T-33	*Reticulitermes santonensis*	AWPA E1 (1997)	**Laboratory method**, Wood composite: bonded plywood (Okoumé) **Treatment:** glue line additive during	Effective protection at 0.54 to 0.74 kg/m³ with rating of damage of 9 (3x) interior layers as well as 4	anonymus 2007b

					manufacture, analysed average retentions 0.54 to 0.74 kg/m³; 4 weeks of exposure to insects, Replicates: 3	(3x) outer layers	
Insecticide; Preventive effectiveness against termites	Wood preservative in situation of use class 1 to protect wood composites	Wolsit T-33	*Reticulitermes santonensis*	AWPA E1 (1997)	**Laboratory method**, Wood composite: bonded plywood (Maritime Pine) **Treatment:** glue line additive during manufacture, retentions 0.26 and 0.30 kg/m³; 4 weeks of exposure to insects, Replicates: 3 each	Effective protection at 0.26 and 0.30 kg/m³ with rating of damage of 10 (6x) in interior layers as well as 4 (3x) and 0 (3x) outer layers	anonymus 2007c

3.6.6 Occurrence of resistance and resistance management

There are no reported cases of development of resistance involving the use of permethrin in wood preservation. However, cases of resistance have been documented in a wide variety of insects when permethrin has been used as a general insecticide (PT18 product). The level of resistance is less than ten-fold in some of the species but high levels of resistance have been observed in others such as cockroaches. In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms.

3.6.7 Known limitations

There are no limitations when Wolsit T-33 is added to the binder for particle boards. When Wolsit T-33 is added to the glue line for plywood or laminated boards in general middle layers should not exceed 3 mm and outer layers should not exceed 2 mm in thickness to allow sufficient penetration of Wolsit T-33 from the glue line into the respective layers. If full surface protection of treated plywood or laminated boards against termites is desired, a superficial treatment with another biocidal product may be necessary.

3.6.8 Evaluation of the label claims

The draft label describes Wolsit T-33 as a preventive wood preservative for protection of wood composites against attack by wood-destroying insects, including termites, in use class 1. 0.65 – 2 kg Wolsit T-33/m³ composite, which are applied via glue treatment, correspond to 0.1 – 0.3% (m/m) when the density of the treated wood composite is 650 kg/m³. The German CA agrees with the label claims, except for target organisms. Here, only termites should be named, as no efficacy data against other wood-destroying insects (beetles) has been submitted.

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

Not applicable here.

3.6.10 Data waiving and conclusion

No data waiving

Table 16

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

Table 17

Conclusion on the efficacy
The biocidal product is efficacious at preventing wood destruction in wood composites by termites (*Reticulitermes* spp.) when it is applied as binder or glue additive. From the key studies the critical value is 0.54 kg Wolsit T-33/m³ for particle boards (including OSB, fibre and particle boards) as well as plywood (0.18 kg permethrin/m³). This is well achieved with the intended rate of application for Wolsit T-33 of 0.65-2 kg Wolsit T-33/m³, which includes a safety margin. However, in case of laminated boards the thickness of laminates should not exceed the abovementioned maxima (section 3.6.7).

3.7 Risk assessment for human health

3.7.1 Assessment of effects of the active substance on human health

Table 18

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

Table 19

Permethrin	Value	Reference
Inhalative absorption	100 %	Default value
Oral absorption	100 %	Assessment-Report (RMS IE (2014))
Dermal absorption	3 %	Assessment-Report (RMS IE (2014)) Human dermal penetration study

3.7.2 Assessment of effects of the product on human health

3.7.2.1 Skin corrosion and irritation

Table 20

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 21

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to the skin. May cause paresthesia.
Justification for the value/conclusion	Evaluation and classification is based on the toxicological properties of the single components. The biocidal product does not contains any component classified for skin irritation or corrosion. 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 for paresthesia.

3.7.2.2 Eye irritation

Table 22

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.

Table 23

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 biocidal product does not contain components classified for eye irritation or damage.
Classification of the product according to CLP	Classification for eye irritation/damage is not required.

3.7.2.3 Respiratory tract irritation

Table 24

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 25

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 26

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 27

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Sensitising to the skin.
Justification for the value/conclusion	The active substance is classified for skin sensitisation according to Regulation (EC) No 1272/2008: Permethrin (33.3 %): Skin Sens. 1 [1)] (H317: C ≥ 1%) [2) 3)]
Classification of the product according to CLP	Skin Sens. 1 (H317)

[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. Hence, the current classification is legally binding.

3.7.2.5 Respiratory sensitization (ADS)

Table 28

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal product or their components are not available.

Table 29

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Based on the available data respiratory sensitisation is not expected.
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 30

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 31

Value used in the Risk Assessment – Acute oral toxicity	
Value	Acutely toxic via the oral route.
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 1550 mg/kg bw. The minimum LD_{50} of the active substance is 480 mg/kg bw. The LD_{50} of all other components is above 5000 mg/kg bw.
Classification of the product according to CLP	Acute Tox. Cat. 4 (H302)

3.7.2.6.2 Acute toxicity by inhalation

Table 32

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 33

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 34

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 35

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route.
Justification for the	Based on the dermal LD_{50} available for the single components the dermal LD_{50}

selected value	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 36

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 permethrin solved mainly in propan-2-ol. It is not known if the test formulation contains other components. Due to the high content of emulsifier in the biocidal product for authorisation (33.3%), which is considered to have a significant impact on dermal absorption, the tested solution of the active substance is not comparable with the biocidal product. In addition, although the active substance concentration is higher in the product than in the tested formulation, no data are submitted to confirm that dermal absorption of permethrin is inversely proportional to the concentration. Thus, the submitted data are not applicable for the product,. In the absence of product-specific data and in accordance to the EFSA Guidance on Dermal Absorption (2012), the default value of 25% for formulations containing > 5% active substance should be used for primary application scenarios. The amount in treated materials is in maximum 0.3%. Hence, for secondary exposure by contact to treated materials the default value of 75% for formulations containing ≤ 5% active substance has to be applied.

Table 37

Value(s) used in the Risk Assessment – Dermal absorption		
Substance exposure scenario(s) (e.g. undiluted formulation or 1:100 in-use dilution, etc.)	Application of the biocidal product	Secondary exposure by contact to treated materials
Value(s)	25%	75%
Justification for the selected value(s)	EFSA Guidance on Dermal Absorption (2012)	EFSA Guidance on Dermal Absorption (2012)

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

Not relevant.

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 38

Endpoint	Brief description
Skin corrosion and irritation	Not classified for skin irritation or corrosion. 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	Classification with Skin Sens. 1, (H317 due to classification of the active substance.
Respiratory sensitization (ADS)	Not classified for respiratory sensitisation.
Acute toxicity by oral route	Classified with Acute Tox. 4, H302 Oral LD_{50} calculated from information on the components: 1550 mg/kg bw.
Acute toxicity by inhalation	Not classified for acute inhalation toxicity. Inhalation LC_{50} calculated from information on the components: > 5.0 mg/L
Acute toxicity by dermal route	Not classified for acute dermal toxicity. Dermal LD_{50} calculated from information on the components: > 2000 mg/kg bw
Information on dermal absorption	In the absence of a dermal absorption study with a comparable formulation and in accordance to the EFSA Guidance on Dermal Absorption (2012) a default of 25 % is used for exposure assessment of primary application scenarios and of 75 % for secondary exposure scenarios with dermal contact to treated materials.
Available toxicological data relating to non-active substance(s)	Not relevant.
Available toxicological data relating to a mixture	Not relevant.
Other relevant information	Not relevant.

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 39

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

List of scenarios

Table 40

Summary table: scenarios (professionals)			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Addition to the glue-line	Primary exposure of workers resulting from loading of the b.p. into the storage tank of the manufacturing plant using an automated dosing device. The b.p. is then added to wood chips prior to pressing them into panels, all steps being part of an automatic manufacturing process in a closed system (glue-line treatment process spraying or glue-line treatment process by rollers).	Professional , Industrial
2.	Manual loading (pouring the b.p. from a jerry can into the receiving vessel)	Primary exposure of workers resulting from manual loading of the b.p. from a jerry can into the storage tank of the manufacturing plant. The b.p. is then added to wood chips prior to pressing them into panels, all steps except from loading being part of an automatic manufacturing process in a closed system (glue-line treatment process spraying or glue-line treatment process by rollers).	Professional , Industrial
3.	Secondary exposure: Mechanical processing of preventively treated wood	Secondary exposure of workers resulting from mechanical processing (e.g., sawing or sanding) of preventively treated wood.	Professional , Industrial

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

3.7.3.1.1 Professional exposure

Wolsit T-33 is a liquid ready-to-use emulsion wood preservative. It is applied for preventive treatment during manufacturing of wood composites such as plywood or OSB by addition to the glue-line.

Wolsit T-33 is a concentrate wood preservative containing “Permethrin” (CAS-No.: 52645-53-1, 33.33 %).

The biocidal product is marketed in different package sizes:

IBC Plastic: HDPE 1000 Litre
IBC Plastic: HDPE 640 Litre
Jerry can Plastic HDPE 30 Litre

The applicant requested the authorisation for the application methods “glue-line treatment process spraying” and “glue-line treatment process by rollers”. The process (application phase) involves adding the preservative to the resin binder. This resin-preservative mixture is then sprayed onto the particles (particle, OSB and fibre boards) or is then applied to the veneer by rollers (plywood, veneered laminated boards).
This actual manufacturing process of the wood composites, in which the product is applied, is performed in fully automated production lines. Therefore, exposure during the actual application phase is not expected.
However, exposure is expected for the loading process which can either be performed by using an automated dosing device or, according to the applicant, in some plants also by manually pouring of the b.p. into the storage tank. The exposure to the a.s. is therefore assessed separately for the different ways of loading the b.p. into the production line 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 Annex Annex 4.3.1, the details of the exposure calculations to the a.s. for the professional user are laid out.

The classification of the b.p. and the application liquid require additional assessment of local risks (see 3.7.4.4 Risk characterisation for human health***Fehler! Verweisquelle konnte nicht gefunden werden.***.

- **Scenario 1 – Addition to the glue-line**

Table 41

Description of Scenario 1 – Addition to the glue-line

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

Glue-line addition of wood preservatives is the most common application method in Europe during manufacturing of wood based composites. Although Wolsit T-33 is a concentrate usually requiring a dilution process, it can be used as a ready-to-use product in this case. It is transferred via transfer lines to a storage tank which is connected to the processing unit by additional transfer lines. Mixing of the biocidal product and the resin (and additional chemicals, e.g. hardener, adhesives, water etc.) is a fully automatic process in a closed system. Alternatively, preservative and resin may be applied to the timber chips separately. In this case, the preservative is sprayed or rolled on the chips. In either case, during this process workers are only present for supervision. A direct contact to the wood preservative is only expected during the loading phase.

The application of the wood preservative is integrated in an automatic manufacturing process. There, treated wood chips are collected and pressed to panels. Due to the various chemicals used in addition to the b.p. (e.g., formaldehyde in adhesives), the plants are equipped with suitable installations to avoid unacceptable exposures. Especially in the area of the press, sufficient workplace ventilation is required to reduce the inhalation exposure to volatile substances.

Dermal exposure

This application method is described as a fully automatic process. Therefore, only for the loading phase, during connecting to transfer lines, exposure to hands is expected to occur. An appropriate model for assessment of this scenario is recommended by the Human Exposure Expert Group (HEEG) and is used to calculate the hand exposure.

Dermal exposure during the post-application phase is not expected since a fully automatic process is assumed for the cleaning process.

Exposure by inhalation

The technical requirements and installations minimize the amount of the respirable fraction of the b.p. Therefore, inhalation exposure to aerosols is considered to be negligible.

Local risk assessment

The classification of the b.p. requires additional assessment of local risks (see 3.7.4.4 Risk for professional users). Local risk assessment has indicated a risk for skin due to incidental contact to hands. Notwithstanding the assessment of systemic risks, the expected exposure therefore requires the use of protective gloves to manage the identified local risks.

Conclusion

The risk characterisation in chapter **Fehler! Verweisquelle konnte nicht gefunden werden.** shows no unacceptable risks in Tier 1 resulting from systemic exposure. However, chemical protective gloves are required to manage risks resulting from local effects (classification with Skins Sens. 1, H317) due to the expected exposure of the hands (see chapter 3.7.4.4). For information, a quantitative Tier 2 assessment taking chemical protective gloves into account has been performed and can be found in the detailed calculations laid out in Annex 4.3.1 of this PAR.

	Parameters	Value

Tier 1	Concentration of the a.s. permethrin in the b.p.	33.33%
	Concentration of the b.p. in the application liquid	100%
	Density of the b.p.	1.096 g/cm^3 (20°C)
	Duration	10 min

Calculations for Scenario 1

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 und Tier 2) are summarised in Table 44.

For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR.

For risk charakterisation, see chapter 3.7.4.4

Further information and considerations on scenario 1

Scenario 2: Manual loading (pouring the b.p. from a jerry can into the receiving vessel)

Table 42

Description of Scenario 2: Manual loading (pouring the b.p. from a jerry can into the receiving vessel)

The applicant describes the loading / pouring process as follows:

"*The product can be manually poured from the 30 litre jerry can into the glue mix tank. Manually filling is not a daily task but occurs generally at maximum 1 time per month as a singular event.*

The product is dosed from the 30 litre jerry can into the glue mix tank by taking the plastic jerry can in one hand and help lifting from the bottom with the other. The feed opening of the jerry can has a diameter of 48.5 mm; the jerry can represents therefore a wide-necked container. The respective indicative value for hands is therefore according to the mixing and loading model 4, 0.1 ml.

There is an opening device on the mix tank for manually filling some of the glue components (e.g. filler or other additives like wood preservatives). The glue mix tank installation is integrated in a platform which enables a comfortable and safe working height (normally ca. 0.5 – 0.7 m). It might be completed by a special fixing/dropping platform for plastic canisters to be used with a tap (fully closed canister). In the latter case, the manual dosing is completely without any risk of product contact."

Dermal exposure

This application method is described as a fully automatic process. Therefore, only for the loading phase, during manual loading (pouring the b.p. from a jerry can into the receiving vessel), exposure to the hands is expected to occur. The "*Mixing and Loading Model 4*" from the "*Biocides Human Health Exposure methodology*" document is considered to be an appropriate model for assessment of the resulting exposure and is therefore used to calculate the hand exposure resulting from manual pouring of the b.p. from the 30 litre jerry can. Since the applicant provided the information that the jerry can has a neck diameter of 48.5 mm, the specific dermal exposure value for pouring of a container with 45 mm neck diameter from "*Mixing and Loading Model 4*" is chosen.

According to information provided by the applicant (*vide supra*), manual loading of one 30 litre jerry can takes place on a single working day, up to once per month. The competent authority considered that for manual loading a dosing pump is required. This technical measure will ensure a safe use even if more manual loadings are performed by the worker.

Dermal exposure during the post-application phase is not expected since a fully automatic process is assumed for the cleaning process.

Exposure by inhalation

The technical requirements and installations minimize the amount of the respirable fraction of the b.p. Therefore, inhalation exposure to aerosols is not expected during any phase of the application.

Local risk assessment

The classification of the b.p. requires additional assessment of local risks (see 3.7.4.4). Local risk assessment has indicated a risk for skin due to the expected contact to hands, thus protective gloves are required. Notwithstanding the assessment of systemic risks, the expected exposure requires of the use of protective gloves to address the risks identified during local risk assessment.

Conclusions
The risk characterisation in chapter 3.7.4.4 shows unacceptable risks in Tier 1 resulting from systemic exposure, even if loading of no more than one jerry can is considered on a single working day, performed as a daily task. Since hand exposure is predominant, chemical protective gloves have been considered in Tier 2, in addition to the provision that the use of a dosing pump is required. Chemical protective gloves are also required to manage risks resulting from local effects (classification with Skins Sens. 1, H317) due to the expected exposure of the hands (see chapter 3.7.4.4).

	Parameters	**Value**

Tier 1	Concentration of the a.s permethrin in the b.p.	33.33%
	Concentration of the b.p. in the application liquid	100 %
	Number of pourings (loadings)	1
	Density of the b.p.	1.096 g/cm³ (20°C)
Tier 2	Protective gloves (EN 374)	10% penetration

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 44.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR.
For risk characterisation, see chapter 3.7.4.4.

Scenario 3: Secondary exposure: Mechanical processing of preventively treated wood

Table 43

Description of Scenario 3: Secondary exposure: Mechanical processing of preventively treated wood

Secondary exposure due to mechanical processing of preventively treated wood 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
Inhalation exposure from mechanical processing of preventively treated wood is assessed taking the German limit value for the wood dust concentration in air of 2 mg/m^3 into account (German *Hazardous Substances Ordinance* ("*Gefahrstoffverordnung*") and *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 active substance applied during the manufacturing process of the wood composites is distributed evenly in this material. Mechanical processing, such as sanding or sawing, releases wood dust created from this material which includes the a.s. in the calculated concentration. As a worst case, it is considered that the a.s. concentration is not depleted during the baking step.

Dermal exposure
Due to the closed nature of the production process of the wood composites, which involves a final baking step, skin contact to the liquid b.p. on the wood is not expected. For assessment of dermal exposure, it is assumed that during handling of the treated wood some wood dust is transferred to the hand resulting from direct contact and settled dust. It is considered that both hands are exposed to the wood dust in this way. The thickness of this layer was derived from Vermeire et al.[1], who reported a typical thickness of a liquid film layer on the skin to be 0.01 cm. However, taking the low abrasion characteristics of the wood and the – by regulatory requirements (*vide supra*) - limited amount of wood dust in the air into account as well, a factor of 100 lower than for the liquid film was assumed reasonable, resulting in a film layer with a thickness of 0.0001 cm.

Local risk assessment

The classification of the b.p. and the application liquid require additional assessment of local risks (see 3.7.4.4 Risk for professional users. As discussed above, skin contact to wood surfaces and to wood dust is expected to occur. The amount of b.p. in the wood dust can be up to 0.31 % (w/w), based on the maximum application rate of 2 kg b.p./m³ wood and a minimum wood density of 650 kg/m³ (plywood)[2], which equals an a.s. "concentration" of 0.1 %. As shown by the quantitative exposure assessment, the exposure level to the b.p. contained in the wood is very low.

Conclusions
The risk characterisation in chapter 3.7.4.4 shows no unacceptable risks in Tier 1 with regard to systemic exposure. However, for information an exposure assessment taking chemical protective gloves into account has been performed and was included in the detailed calculations laid out in Annex 4.3.1of this PAR.

	Parameters	Value
Tier 1	Concentration of the a.s permethrin in the b.p.	33.33%
	Concentration of the b.p. in the application liquid	100 %
	Density of the b.p.	1.096 g/cm³ (20°C)
	German limit value for wood dust concentration	2 mg/m³
	Density of wood (plywood)[2]	650 kg/m³
	Exposed hand area (both hands)	820 cm²
	Layer thickness on skin	0.0001 cm²

[1)] Vermeire, T. G.; van der Poel, P.; van de Laar, R. T. H.; Roelfzema, H. "Estimation of consumer exposure to chemicals: application of simple models", Sci. Tot. Environ., 1993, 136, 155-176.
[2)] The average density of softwoods (400 kg/m³) indicated in the *Technical Agreements for Biocides*, which is generally used for assessment of exposure to wood protectants, is considered to be unsuitable in the present case, because this b.p. is exclusively applied to wood composites. Instead, the value of 650 kg/m³ specified by the applicant for plywood, is considered here as a representative density of wood composites.

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 44.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR.
For risk characterisation, see chapter 3.7.4.4.

Summary of professional exposure

The scenarios described here only include the values of the mixing and loading phase. Exposure for the application and post-application phase is not expected due to industrial processing.

Table 44

Exposure scenario	Tier/PPE	a.s.: Permethrin	
		Estimated external inhalation exposure [mg/m³]	Estimated external dermal exposure [mg/day]
Scenario 1: Addition to the glue-line	Tier 1 No PPE	Not expected	3.36
Scenario 2: Manual loading (pouring the b.p. from a jerry can into the receiving vessel)	Tier 1 No PPE	Not expected	36.53
	Tier 2: Protective gloves[1]	Not expected	3.65
Scenario 3: Secondary exposure: Mechanical processing of preventively treated wood	Tier 1 No PPE	2.05E-03	5.47E-05

[1] Chemical protective gloves (EN 374)

- **Combined scenarios**

Not applicable

3.7.3.1.2 Non-professional exposure

Not assessed. The biocidal product is for professional use only.

3.7.3.1.3 Secondary exposure of the general public

- **Scenario [1]**

Table 45

Description of Scenario [1]		
Secondary exposure, acute, adult - sanding treated wood, The assessment is based on the assumption that an adult process (sanding/cutting) treated wood or wood-based composite without any PPE. Inhalation and dermal exposure is assessed using the highest application rate (2000 g/m³). The biocidal product is evenly distributed in the wood. The density of the wood-based composites is between 0.6 to 0.9 g/cm³. The applicant proposed 0.565 g/cm³ as a worst case. For dermal exposure, it is assumed that the 0.2-cm-outerlayer is available for dermal uptake. Data, which support this assumption, are not available. However, this value has already been used in many other PAR for wood preservatives.		
	Parameters	Value
Tier 1	Application rate (applicant)	2000 g/m³
	Concentration active substance (technical) in the b.p.	33.33 %
	Concentration a.s. in the treated wood: application rate x concentration a.s	0.6666 mg a.s./cm³
	Amount available for dermal contact 1)	0.13332 mg a.s./cm²
	Hand inner surface (both hands), adult (HEAdhoc Recommendation No. 14, 2017), half of both hands	410 cm²
	Percentage of hand surface getting in contact to the biocidal product (TNsG on Human Exposure, 2002)	20 %
	Transfer coefficient, rough sawn wood, dried fluid (Biocides Human Health Exposure Methodology, 2015)	2 %
	Dermal Absorption (default acc. to EFSA Guidance on Dermal Absorption (2012), refer also to 3.7.2.7)	75%
	Body weight, adult (HEAdhoc Recommendation No. 14, 2017)	60 kg
	Density of the treated wood-based composite (applicant, worst case)	0.565 g/cm³
	Wood dust concentration in the air during sanding (EU, OEL, 2004)	5 mg/m³
	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 m³/h
	Inhalation absorption (CAR/AR, 2014)	100%

2) It is assumed that the amount in the 0.2-cm-outerlayer is potentially available for dermal exposure

Calculations for Scenario [1]

$Exposure_{dermal}$ = concentration a.s. on the treated wood x hand inner surface of both hands x percentage contaminated skin x transfer coefficient x dermal absorption / body weight adult
= 0.13332 mg a.s./cm^2 x 410 cm^2 x 20 % x 2% x 75 % / 60 kg
= 2.73 x 10^{-3} mg a.s./kg bw

$Exposure_{inhalation}$ = concentration a.s. in the treated wood x aerial wood dust concentration / density wood dust x exposure duration x inhalation rate x inhalation absorption/ body weight adult
= 0.6666 mg a.s./cm^3 x 5 mg/m^3 x 1 h x 1.25 m^3/h x 100% / (565 mg/cm^3 x 60 kg)
= 1.23 x 10^{-4} mg a.s./kg bw

Total systemic exposure = 2.86 x 10^{-3} mg a.s./kg bw

- **Scenario [2]**

Table 46

Description of Scenario [2]		
Secondary exposure, acute, toddler - chewing treated wood off-cut. The scenario is based on the assumption that a toddler ingests the active substance from a piece of treated wood.-based composite with a dimension of 4 cm x 4 cm x 1 cm (16 m^3).		
	Parameters	Value
Tier 1	Application rate (applicant)	2000 g/m^3
	Concentration active substance (technical) in the b.p.	33.33 %
	Concentration a.s. in the treated wood: application rate x concentration a.s	0.66666 mg a.s./cm^3
	Total amount a.s. in wood (= volume of wood treated with the biocidal product x concentration a.s. in the treated wood)	16 cm^3 x 0.6666 mg a.s./ cm^3 = 10.6656 mg a.s.
	Extraction coefficient (TNsG Human Exposure to Biocidal Products (2002) Part 3)	10 %
	Oral absorption (CAR/AR, 2014)	100 %
	Body weight, toddler (HEAdhoc Recommendation No. 14, 2017)	10 kg

Calculations for Scenario [2]

$Exposure_{oral}$ = Total amount a.s. in wood x extraction coefficient x oral absorption / body weight toddler
= 10.6656 mg a.s.x 10 % x 100 % / 10 kg
= 1.07 x 10^{-2} mg a.s./kg bw

Total systemic exposure = 1.07x 10^{-2} mg a.s./kg bw

- **Scenario [3]**

Table 47

Description of Scenario [3]		
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 (25 °C, CAR/AR, 2014)	2.155 x 10^{-6} Pa
	Gas constant R (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 (SVC calculated acc. to HEEG opinion No. 13, 2011)	3.46 x 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, 2013, default)	100 %
	Body weight, toddler (HEAdhoc Recommendation No. 14, 2017)	10 kg

Calculations for Scenario [3]

SVC = moleculare weight x vapour pressure / (R x temperature)
= 391.3 g/mol x 2.155 x 10^{-6} Pa / (8.31451 J mol^{-1} K^{-1} x 293 K)
= 3.46 x 10^{-4} mg/m^3

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

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

= 2.77 x 10^{-4} mg a.s./kg bw/d

Total systemic exposure = 2.77 x 10^{-4} mg a.s./kg bw/d

Further information and considerations on scenario [3]

The exposure estimate is based on the HEEG opinion No. 13 “Assessment of Inhalation Exposure of Volatilised Biocide Active Substance”.

- **Scenario [4]**

Table 48

Description of Scenario [4]		
Secondary exposure, long-term, toddler - playing on treated structure and mouthing (dermal, oral). For dermal exposure, it is assumed that the 0.2-cm-outerlayer is available for dermal uptake. Data, which support this assumption, are not available. However, this value was used in many other PAR for wood preservatives.		
	Parameters	Value
Tier 1	Application rate (applicant)	2000 g/m^3
	Concentration active substance (technical) in the b.p.	33.33 %
	Concentration a.s. in the treated wood: application rate x concentration a.s	0.6666 mg a.s./cm^3
	Amount a.s. available on wood surface for transfer to skin 1)	0.13332 mg a.s./cm^2
	Hand surface (toddler, palms of both hands, HEAdhoc Recommendation No. 14, 2013)	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 acc. to EFSA Guidance on Dermal Absorption (2012), refer also to 3.7.2.7)	75 %
	Oral absorption (CAR/AR, 2013)	100 %

	Body weight, toddler (HEAdhoc Recommendation No. 14)	10 kg

[2)] It is assumed that the amount in the 0.2-cm-outerlayer is potentially available for dermal exposure

Calculations for Scenario [4]

$Exposure_{dermal}$ = concentration a.s. on the treated wood 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

= 0.13332 mg a.s./cm^2 x 115.2 cm^2 x 3 % x 40 % x 75 % / 10 kg

= 1.38 x 10^{-2} mg a.s./kg bw/d

$Exposure_{oral}$ = concentration a.s. on the treated wood 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

= 0.13332 mg a.s./cm^2 x 115.2 cm^2 x 3 % x 40 % x 50 % x 100 % / 10 kg

= 9.22 x 10^{-3} mg a.s./kg bw/d

Total systemic exposure = 2.30 x 10^{-2} mg a.s./kg bw/d

Further information and considerations on scenario [4]

The exposure estimate is based on 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.

Table 49

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	1	1.23 x 10^{-4} mg a.s./kg bw	2.73 x 10^{-3} mg a.s./kg bw	-	2.86 x 10^{-3} mg a.s./kg bw
Scenario [2]	1	-	-	1.07 x 10^{1} mg a.s./kg bw	1.07 x 10^{-1} mg a.s./kg bw
Scenario [3]	1	2.77 x 10^{-4} mg a.s./kg bw/d	-	-	2.77 x 10^{-4} mg a.s./kg bw/d
Scenario [4]	1		1.38 x 10^{-2} mg a.s./kg bw/d	9.22 x 10^{-3} mg a.s./kg bw/d	2.30 x 10^{-2} mg a.s./kg bw/d

- **Combined scenarios**

Not relevant.

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

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 50

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.	General public, secondary exposure, acute, adult - processing (sanding/cutting) treated wood, (inhalation, dermal)	1	2.86 x 10^{-3} mg a.s./kg bw
2.	General public, secondary exposure, acute, toddler - chewing treated wood off-cut, (oral)	1	1.07 x 10^{-1} mg a.s./kg bw

3.	General public, secondary exposure, long-term, toddler (represents also worst case for older children and adults) - inhalation of volatilised residues indoors (inhalation)	1	2.77 x 10^{-4} mg a.s./kg bw/d
4.	General public, secondary exposure, long-term, toddler - playing on treated structure and mouthing, (dermal, oral)	1	2.30 x 10^{-2} mg a.s./kg bw/d

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 42.

Table 421

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	50 mg/kg bw	100	No	0.5 mg/kg bw
$AEL_{medium\text{-}term}$	12-month dog study	5 mg/kg bw	100	No	0.05 mg/kg bw
$AEL_{long\text{-}term}$	12-month dog study	5 mg/kg bw	100	No	0.05 mg/kg bw

3.7.4.2 Maximum residue limits or equivalent

Residue definitions

Table 52

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL (permethrin)	Reg. (EC) No 839/20082017/623	Allall (except bovine edible tissues) Bovine fat Bovine muscle, liver, kidney, milk	0.05* or 0.1*mg/kg 0.5 mg/kg 0.05 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 Risk for industrial users

The risk assessment for industrial users for Wolsit T-33 is covered by the risk assessment as presented in section **Fehler! Verweisquelle konnte nicht gefunden werden.**. For details refer to this section.

3.7.4.4 Risk for professional users

The occupational risk assessment for the biocidal product Wolsit T-33 takes into account systemic and local effects of the active substance permethrin.
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.

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 AEL 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 Wolsit T-33, inhalation and dermal exposure to permethrin is assessed. For this, the systemic reference value $AEL_{long\text{-}term}$ (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 $AEL_{long\text{-}term}$ is converted to an external inhalation reference value (RV_{inhal}) and an external dermal reference value (RV_{derm}) according to the following equations:

RV_{inhal} (in mg/m³) = $AEL_{long\text{-}term}$ of permethrin (in mg/kg bw/d) x 60 kg / 10 m³ x100 % / 100%-inhalation absorption

RV_{derm} (in mg/kg bw/d) = $AEL_{long\text{-}term}$ of permethrin (in mg/kg bw/d) / 25 and 75%-dermal absorption x 100%.

By this means RV_{inhal} equivalent to 0.3 mg/m³ and RV_{derm} equivalent to 0.2 mg/kg bw/d and 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 Wolsit T-33. Therefore, the default value of 25 % for active substance concentration above 5 % (according to the EFSA Guidance on Dermal Absorption, 2012) has to be taken into consideration for risk assessment of the scenarios 'addition to the glue-line' and 'manual loading (pouring the b.p. from a jerry can into the receiving vessel)'.
Valid data are also not available for 'secondary exposure: mechanical processing of preventively treated wood'. 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 of secondary exposure.

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

The risk quotient for the inhalation route (RQ_{inhal}) and dermal route (RQ_{derm}) referring to the active substance permethrin resulting from use of the biocidal product Wolsit T-33 is determined according to the following equations:

RQ_{inhal} = inhalation exposure to permethrin (in mg/m³) / RV_{inhal} of permethrin (in mg/m³).

RQ_{derm} = dermal exposure to permethrin (in mg/kg bw/d) / RV_{derm} 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 RQ_{inhal} and RQ_{derm} for a substance within a scenario gives the corresponding substance specific risk index (RI). Table 47 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 53. 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 Wolsit T-33 is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 53, the scenarios ‘addition to the glue-line’ and ‘secondary exposure: mechanical processing of preventively treated wood’ yield RIs of less than 1 already in TIER 1. By contrast, the RI of the scenario ‘manual loading (pouring the b.p. from a jerry can into the receiving vessel)’ exceeds 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 scenario. However when risk reduction measures are implemented the risk characterisation results consistently yield RI of less than 1 in TIER 2.

Table 53: Overview of detailed risk assessment results referring to the active substance permethrin for the biocidal product Wolsit T-33

Scenario		inhalation external			dermal external					
		potential / actual exposure	RV_{inhal}	RQ_{inhal}	potential / actual exposure		RV_{derm}	RQ_{derm}	RI	Acceptable
		mg/m³	mg/m³		mg/person	mg/kg bw/d	mg/kg bw/d			
Addition to the glue-line	Tier 1	not expected, no aerosol			3.36	0.06	0.20	0.28	0.28	yes
Manual loading (pouring the b.p. from a jerry can into the receiving vessel)	Tier 1				36.53	0.61	0.20	3.04	3.04	no
	Tier 2				3.65	0.06	0.20	0.30	0.30	yes
Secondary exposure: Mechanical processing of preventively treated wood	Tier 1	2.05×10^{-3}	0.30	6.84×10^{-3}	5.47×10^{-5}	9.11×10^{-7}	0.07	1.37×10^{-5}	6.85×10^{-3}	yes

Tier 1: no PPE ('addition to the glue-line', 'manual loading (pouring the b.p. from a jerry can into the receiving vessel)', 'secondary exposure: mechanical processing of preventively treated wood'); Tier 2: protective gloves ('manual loading (pouring the b.p. from a jerry can into the receiving vessel')

RV_{inhal}: reference value for the inhalation route

RQ_{inhal}: risk quotient for the inhalation route

RV_{derm}: reference value for the dermal route

RQ_{derm}: 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 intended uses ('addition to the glue-line', 'manual loading (pouring the b.p. from a jerry can into the receiving vessel)') with the biocidal product Wolsit T-33 as well as from secondary exposure ('mechanical processing of preventively treated wood') is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 at least after TIER 2 consideration. Regarding occupational safety, there are no objections against the intended uses as well as secondary exposure taking into account the provisions described in chapter 2.5.2 of this PAR.

- **Local effects**

The local toxicity profile of the active substance permethrin is considered. This substance contributes to the classification of the biocidal product Wolsit T-33 with H317 (May cause an allergic skin reaction).

Table 54: Relevant classification and resulting hazard categories

b.p. concentration in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2015)
100	Skin Sens.1, H317	Medium

For the biocidal product local risk assessment is triggered by the sensitizing properties (Skin Sens.1, H317) as this classification is allocated to the hazard category medium (Table 48). Local risk assessment for professional users takes into account handling of the concentrated product ('addition to the glue-line' and 'manual loading (pouring the b.p. from a jerry can into the receiving vessel)') as well as secondary exposure to the biocidal product while processing the preventively treated wood.

Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (2015) the following tables are prepared to carry out the qualitative risk assessment for local effects regarding skin contact of the biocidal product Wolsit T-33 for the intended uses 'addition to the glue-line' (Table 49), 'manual loading (pouring the b.p. from a jerry can into the receiving vessel)' (Table 50), as well as from secondary exposure ('mechanical processing of preventively treated wood') (Table 51). With the proposed protection measures the reduction of dermal contact minimizes the anticipated health risk to an acceptable level for the intended uses and for secondary exposure.

Table 55: Summary of qualitative conclusions for local risk assessment for scenario 'addition to the glue-line'

Tasks, uses, processes	concentration b.p. (max.) in application solution	Local Effects in terms of C&L	Hazard Category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing and loading Connecting lines (Automated/Semi-Automated)	100 %	Skin Sens.1, H317	Medium	10 minutes per day	Skin: Contact to hands expected	- **Technical Measure:** - Automated Dosing System **Organisation[1]:** - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - Protective gloves	**Acceptable** + Low frequency/used for short duration + Engineering controls: full automation + Minimization of manual phases + Professionals using appropriate PPE

1) Organisational measures include implementation of occupational hygiene standards. In Germany, the provisions of the Hazardous Substances Ordinance are obeyed.

Table 56: Summary of qualitative conclusions for local risk assessment for scenario 'manual loading (pouring the b.p. from a jerry can into the receiving vessel)'

Tasks, uses, processes	concentration b.p. (max.) in application solution	Local Effects in terms of C&L	Hazard Category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing and loading Manual loading/pouring	100 %	Skin Sens.1, H317	Medium	1 pouring few minutes per day	Skin: Contact to hands expected	**Technical Measure:** - **Organisation[1]:** - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - Protective gloves	**Acceptable** + Used for short duration + Professionals using appropriate PPE

1) Organisational measures include implementation of occupational hygiene standards. In Germany, the provisions of the Hazardous Substances Ordinance are obeyed.

Table 57: Summary of qualitative conclusions for local risk assessment for scenario Secondary exposure: Mechanical processing of preventively treated wood

Tasks, uses, processes	concentration b.p. (max.) in the treated wood	Local Effects in terms of C&L	Hazard Category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Application (sawing or sanding of treated wood)	0.31%	Skin Sens.1, H317	Medium	Several times a day	Hand exposure from contact to wood surfaces and to wood dust created during mechanical processing of the wood	**Technical Measure: -** **Organisation[2]:** - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene - Treated wood is dried until it is at least surface dry before further treatment may be carried out	**Acceptable** + Low hazard category + Most of the b.p. is expected to be absorbed by the wood, limiting the potential for dermal exposure to the b.p. + Low concentration of the b.p. in the treated wood

1) Organisational measures include implementation of occupational hygiene standards. In Germany, the provisions of the Hazardous Substances Ordinance are obeyed

Conclusion

Concerning the sensitizing properties of biocidal product Wolsit T-33, exposure should be minimized with protection measures. If the proposed protection measures are implemented, the intended uses ('addition to the glue-line' and 'manual loading (pouring the b.p. from a jerry can into the receiving vessel)') as well as secondary exposure resulting from 'mechanical processing of preventively 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 Wolsit T-33 is unlikely for the intended uses 'addition to the glue-line' and 'manual loading (pouring the b.p. from a jerry can into the receiving vessel)' as well as from secondary exposure ('mechanical processing of preventively treated wood'). Risk reduction measures described in chapter 2.5.2**Fehler! Verweisquelle konnte nicht gefunden werden.** have to be taken into account in order to ensure safe use of the biocidal product Wolsit T-33.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

For the components Preventol HS 75 and Dipropyleneglycol, BASF SE (Oxydipropanol) (CAS-Nr.: 25265-71-8) contained in the biocidal product Wolsit T-33 the composition is not fully known.
The component Wettol® EM, BASF, SE (Castor oil, ethoxylated) (CAS-Nr.: 61791-12-6) contained in the biocidal product Wolsit T-33 is of unknown purity.
The risk assessment is based on the assumption that the biocidal product contains no further substances relevant for evaluation.

3.7.4.5 Risk for non-professional users

Not assessed. The biocidal product is for professional use only.

3.7.4.6 Risk for the general public

Table 58: 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)
General public, secondary exposure, acute, adult – processing (sanding/	1	50	0.5	2.66 863 x 10^{-3}	0.56	yes

cutting) treated wood, (inhalation, dermal)						
General public, secondary exposure, acute, toddler - chewing treated wood off-cut, (oral)	1	50	0.5	9.921.07 x 10^{-2} [1]	2021	yes
General public, secondary exposure, long-term, toddler (represents also worst case for older children and adults) – inhalation of volatilised residues indoors (inhalation)	1	5	0.05	2.77 x 10^{-4}	0.6	yes
General public, secondary exposure, long-term, toddler – playing on treated structure and mouthing, (dermal, oral)	1	5	0.05	2.14 30 x 10^{-2}	4346	yes

- **Local effects**

Local effects are not expected for the general public after secondary exposure. However, it is known that pyrethroids may cause dermal paresthesia. This effect normally disappears when exposure is terminated. An appropriate labelling is required to warn susceptible persons.

Conclusion

Exposure of the general public to the biocidal product containing permethrin as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed. Non-professional use was not assessed since the biocidal product is for professional use only.

The active substance permethrin is a pyrethroid, which may cause paresthesia (burning and prickling of the skin without irritation) in susceptible persons. This local effect is normally not severe and disappears when direct exposure is terminated. However, an advice is required to warn susceptible persons (e.g. “Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.”).

3.7.4.7 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.

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

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product is not required as the product contains only the active substance Permethrin and no SoC for human health.

3.7.4.9 Summary of risk characterisation

3.7.4.9.1 Summary of risk characterisation for industrial user

The risk assessment for industrial users for Wolsit T-33 is covered by the risk assessment as presented in section 3.7.4.5. For details refer to this section.

3.7.4.9.2 Summary of risk characterisation for professional user

For the summary of the risk assessment please refer to Table 43 in section 3.7.4.5.

3.7.4.9.3 Summary of risk characterisation for indirect exposure

Table 59

Scenario, Tier	**Relevant reference value** mg/kg bw[/d]	**Estimated uptake** mg/kg bw[/d]	**Estimated uptake/reference value** (%)	**Acceptable** (yes/no)
General public, secondary exposure, acute, adult – processing (sanding/cutting) treated wood, (inhalation, dermal), Tier 1	0.5	2.66 86 x 10^{-3}	0.56	yes
General public, secondary exposure, acute, toddler –	0.5	9.921.07 x 10^{-21}	201	yes

chewing treated wood off-cut, (oral) Tier 1				
General public, secondary exposure, long-term, toddler (represents also worst case for older children and adults) – inhalation of volatilised residues indoors (inhalation), Tier 1	0.05	2.77 x 10^{-4}	0.6	yes
General public, secondary exposure, long-term, toddler – playing on treated structure and mouthing, (dermal, oral), Tier 1	0.05	2.14 30 x 10^{-2}	4346	yes

3.8 Risk assessment for animal health[13]

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, the access of cats to treated objects has to be avoided.

[13] Pets and domestic animals. Regarding wild animals, please refer to chapter 3.9.

3.9 Risk assessment for the environment

3.9.1 General information

The biocidal product “Wolsit T-33” with the active substance permethrin (33.33 % w/w) is used as a wood preservative (product-type 08) against subterranean termites. The biocidal product is industrially applied for the preventive treatment of wood-based products (particle, OSB and fibre boards, plywood, veneered laminated boards) used in Use Class 1 (UC1). The following definition applies to UC1 (EN 335:2013[14]):

- Situation in which the wood-based product is inside a construction, not exposed to the weather and wetting.

The product is applied as a glue-line treatment via spraying or by rollers to particleboards and veneer. Before treatment, the preservative and the raisin binder need to be mixed.

The risk assessment for “Wolsit T-33” is based on data of the active substance permethrin, including relevant metabolites. No new information for the assessment of fate and behaviour and effects of permethrin compared to the CAR (CAR 2014 for PT8 and PT18; Rapporteur: Ireland) has been provided within product authorisation for “Wolsit T-33”, so that the assessment is based upon data given in the CAR (2014) for permethrin.

No further data were required in case of “Wolsit T-33”, since no significant emissions of the biocidal product to the environment are expected considering the use conditions of the product and the wood-based products, treated with the product, as well as the instructions for use and risk mitigation measures (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 “Wolsit T-33”. 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

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

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 “Wolsit T-33” 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 “Wolsit T-33” are available. The biocidal product “Wolsit T-33” consists of one active substance. The risk assessment can be based on data of this active substance. No substances of concern were identified. Therefore, a mixture toxicity assessment is not considered necessary.

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 metabolites 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 60

Data waiving was acceptable for the following information requirements	
Information requirement	Tests on aquatic and terrestrial organisms with the product “Wolsit T-33” are not provided.
Justification	The risk assessment for the biocidal product “Wolsit T-33” can be based on data of the active substance permethrin.

Table 61

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 value 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.

- **Sediment toxicity**

Detailed data on the environmental effect assessment and PNEC derivation of the active substance permethrin and its metabolites 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 62

Data waiving was acceptable for the following information requirements	
Justification	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 “Wolsit T-33” itself. The toxicity of the active substance permethrin is known and the risk assessment for the product “Wolsit T-33” can be based on data of the active substance. 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 derived (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 “Wolsit T-33 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 “Wolsit T-33”, 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 with 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 PT18 (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 63

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 64

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 and 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 and 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 "Wolsit T-33". 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 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 is not expected.

Table 65

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 66

Conclusion used in Risk Assessment –Aquatic bioconcentration	
Value/conclusion	BCF_{fish} = 570
Justification for the value/conclusion	The active substance permethrin in the product “weolsit T-33” possessed 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 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 3-109). 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 biocidal product “Wolsit T-33” (0,2502 % w/w permethrin) is intended for the industrial treatment of wood-based products via glue-line treatment processes in UC 1.

Table 67

Assessed PT	PT8
Assessed scenarios	none
ESD(s) used	OECD series on emission scenario documents, Number 2, “Revised Emission Scenario Document for Wood Preservatives (OECD 2013)
Approach	Assessed based on 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

Emissions to the environment can generally occur during application of the product and storage and service life of the treated wood-based products. The Use of “Wolsit T-33” is limited to industrial application.

“Wolsit T-33” is a wood preservative product, which is used for treatment of wood-based products of UC1. The product is intended for preventive treatment of wood composites against termites by glue-line application via rollers or spraying. The product contains 33.33 % (w/w) of the a.s. permethrin and is applied non-recurring by rates of 0.65 to 2 kg/m³.

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.

Application (industrial)

The product is used for the industrial treatment of wood-based products that are installed under the conditions of UC 1. Before treatment, biocidal product and resin binder are mixed. According to the applicant, mixing of the biocidal product and the resin (and additional chemicals e.g. hardener, adhesives, water etc.) is a fully automatic process in a closed system. Alternatively, preservative and resin may be applied to the timber chips separately. The biocidal product – resin binder mixture is applied to the veneer (plywood, veneered laminated boards) by rollers and to particles (particle, OSB and fibre boards) by spraying.

In principal, emissions to the environment can occur during industrial application of the wood preservative and subsequent storage of the treated structures. However, it is assumed that treatment facilities producing wood-based products are subject to similar requirements as timber treatment installations.

A state of the art report for wood preservatives and the environment published by the Deutsche Bauchemie (Dt. Bauchemie, 2002[15]) refers to the safe operation of timber treatment installations. Save use can be achieved through a number of measures, both technical and organisational. To avoid or minimise harm to health and damage to the environment, additional preventive measures must be taken

[15] Wood Preservative and the Environment, State-of-the-Art Report 2002, 2nd Edition, March 2002, Deutsche Bauchemie

into account in the event of an accident. For instance to achieve a high degree of safety, regular control measures are scheduled for the operation of closed impregnation facilities like pressure impregnation. These include checks for leaks in the facility as well as proper functioning of the leak monitoring devices. Exactly defined measures for procedures ensure that the impregnation process runs safely. Just as with pressure procedures, the tightness of facilities for pressureless procedures is of utmost importance. While control instruments are also checked in closed facilities to ensure safety, the functioning of overflow safety devices is continuously monitored in open tank facilities (Dt. Bauchemie, 2012[16]).

A risk of contaminating the direct surrounding area of an impregnation facility exists, for example, if the preservative escapes through run off. When a facility is built, local conditions and prerequisites are taken into consideration first. Such facilities are not constructed in the vicinity of lakes, dams or in areas that are used as a water supply. The construction of collecting basins, not only for the impregnation facility itself but also for storing preservatives, practically eliminates the risk of ground, groundwater and surface water contamination.

The design and safe operation of timber treatment installations are regulated by national laws which implement EU directives and correspond to the current state of technique and scientific knowledge. A detailed description for the safety measures of timber treatment installations is given in a European Code of Practice for their Safe Design and Operation (EWPM, 2011[17]). The document provides generic guidance on environmental, safety and health aspects relevant to all companies in the European Union engaged in the activity of industrial wood preservation.

The principle of total containment should be followed during site design and applied to processing plant, wood preservative storage area and the holding area for treated timber. A covered and/or contained and impermeable dripping area for freshly treated timber should be provided and be situated adjacent to the plant and the storage tank bund. Treated timber will be further processed, i.e., they are basically not stored in an open outdoor area. Especially treated timber foreseen for use class 1 applications should not be exposed to rain to avoid any leaching of the product. It is recommended that bulk quantities of dry treated timber be stored under cover and/or on an impermeable surface to prevent possible contamination of surface and / or groundwater.

16 Fachgerechte Tränkung von Bauholz – Planung und Ausführung zum Schutz von Holz im Nichtdruckverfahren, 1. Ausgabe, März 2012, Deutsche Bauchemie.

17 Timber Treatment Installations, European Code of Practice for their Safe Design and Operation, Issue 1, 2011, European Wood Preservative Manufacturers Group (EWPM)

In general, emissions to sewage water system during applications in treatment plants are not likely to occur, because treatment containers are stand-alone devices without direct connection to the sewage. It has to be stated that at impregnation plants the redundant preservative solution will be collected and recycled into the process whenever possible. Furthermore, residues like sludge, debris from tanks and other materials from application will be classified as hazardous waste, and require to be disposed of accordingly.

In addition to the previous considerations, potential emissions to the environment during industrial treatment can be controlled by implementation of an appropriate risk mitigation measure like: “All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump)”.

Conclusion: During industrial treatment with the biocidal product “Wolsit T-33”, no significant emissions to the environment (air, soil and water) will occur, since the treatment processes take place in an industrial system with safety measures being on the state of the art of the chemical industry.
In addition, potential emissions to the environment during industrial treatment can be controlled by implementation of an appropriate risk mitigation measures. The following instructions for use are part of the authorisation as well: (a) For industrial application only. (b) 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.

Storage of treated wood

Emissions to the environment can potentially occur during storage of wood-based products after industrial application of “Wolsit T-33”. As it can be concluded from the respective CAR on permethrin (CAR April 2014 for PT8 and PT18) storage of treated timber exposed to wetting will pose a risk to soil and groundwater unless risk mitigation measures (storage under shelter or on impermeable hard standing), as required in the Inclusion Directive, are undertaken. Taking into account the risk mitigation measure, only negligible emissions to the environment are expected. Therefore, no emission and exposure calculation is performed for storage.

Conclusion: Potential emissions to the environment during storage of treated wood-based products can be controlled by implementation of a risk mitigation measure. Thus, no exposure assessment is conducted.

Service life of treated wood (UC 1)

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

Table 3-68: 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)

Conclusion: Emissions to the environment are considered negligible for treated wood-based products that are used according to UC 1. The following instructions for use are part of the authorisation: "Treated wood-based products should only be used in compliance with the definition of Use Class 1 according to EN 335." and "Prevent any release to the environment during storage and transport of treated wood-based products.". The latter is imposed to prevent a potential release of Wolsit T-33 to the environment due to storage and transport of wood-based products during their service-life.

3.9.4.3 Non-compartment specific effects

- **Primary poisoning**

Not relevant for PT 8.

- **Secondary poisoning**

According to the BPR guidance Vol IV part B (2015) for substances with a log $K_{ow} \geq 4.5$, 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.

The relevant PNEC oral values are documented in chapter 3.9.2.5.

However, potential emissions to the environment during application of the biocidal product and storage of treated wood-based products can be controlled by implementation of appropriate risk mitigation

measures. For wood-based products of UC 1 no emission scenarios are presented by the OECD (OECD ESD for PT 8, PART2), since for indoor use the potential emissions from treated wood-based products to the outer environment are considered negligible. Therefore, no unacceptable risk to the aquatic and terrestrial compartment from secondary poisoning is given.

3.9.4.4 Calculated PEC values

Significant emissions to the environmental compartments, regarding the formulation and application of the product, as well as the storage and use of treated wood-based products are not expected if the respective risk mitigation measures and the instructions for use are applied. Therefore, no PEC values are derived.

3.9.4.5 Aggregated exposure (combined for relevant emission sources)

It is assumed that the intended uses of “Wolsit T-33” will not result in significant emissions to any environmental compartment. Thus, an aggregated exposure assessment is not necessary.

3.9.5 Risk characterisation

Application (industrial)

The product is only used for the industrial treatment of wood-based products that are installed under the conditions of UC 1. Industrial treatment usually takes place in closed manufacturing systems with several kinds of control measures (e.g. to avoid leakage) and safety measures being on the state of the art of the chemical industry. Therefore, emissions to the environment are considered as negligible.

Conclusion: No unacceptable risk for the environment is expected during industrial application of “Wolsit T-33”.

The following risk mitigation measure is part of the authorisation:

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

The following instructions for use are part of the authorisation:

- For industrial application only.
- 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.

Storage of treated wood

As it can be concluded from the respective CAR for permethrin (CAR April 2014 for PT8 and PT18) storage of treated timber may pose a risk to soil and groundwater unless risk mitigation measures are undertaken. Consequently, the inclusion directive demands appropriate risk mitigation measures to protect those compartments. Therefore, freshly treated wood-based products must be stored under shelter and/or on impermeable hard standing after treatment to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.

Conclusion: The following risk mitigation measure is part of the authorisation and reduces potential risks to soil and (ground)water to an acceptable level.

- Freshly treated wood-based products shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal..

Service life

Regarding the service life of wood-based products treated with the product no risk quotients for the environment were derived. Emissions to the environment are considered negligible because the use of treated wood-based products is restricted to UC 1 and exposure of the environment due to transport and storage of treated wood-based products shall be prevented.

Conclusion: Emissions to the environment are considered negligible for treated wood-based products that are used according to UC 1.

The following instruction for use is part of the authorisation:

- Treated wood-based products should only be used in compliance with the definition of Use Class 1 according to EN 335.
- Prevent any release to the environment during storage and transport of treated wood-based products.

Overall conclusion

Considering the use conditions of the product and the wood-based products, treated with the product, as well as the resulting risk mitigation measures and instructions for use, no significant emissions to the STP, the terrestrial and the aquatic compartment are expected. Therefore, acceptable risks for the environment are assessed.

3.9.5.1 Non-compartment specific

Acceptable risks regarding secondary poisoning are assessed.

3.9.5.2 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). 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.

3.9.5.3 Endocrine disrupting properties

Permethrin is not a classified as an identified ED substance in wildlife. For further details please refer to CAR (2014).
The full composition of the product is listed in the confidential Annex 5. There are no indications that a non-active substance of the product may have endocrine disrupting properties based on the data provided by the applicant. Nonetheless, the eCA considered in its evaluation further information available on the non-active substances: None of the co-formulants is 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) 1907/2006 for potential environmental ED-hazards. For none of the co-formulants indications on potential ED effects on environmental non-target organisms were found in scientific literature.

3.9.5.4 Summary of risk characterisation

Considering the use conditions of the product and the wood-based products, treated with the product, as well as the risk mitigation measures and 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 and regarding secondary poisoning are expected for the intended uses of “Wolsit T-33”.

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 2.2.5), hence a comparative assessment is not necessary.

4 Annexes

4.1 List of studies for the biocidal product

Table 69

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	No 3	Odour, physical state an pH value of Wolsit T-33	Anonynus	2015	BASF Wolman GmbH
	No. 3	Density of Wolsit T-33	Anonynus	2015	BASF Wolman GmbH
	No. 3	Accelerated storage test by heating of Wolsit T-33	Anonynus	2015	BASF Wolman GmbH
	No. 3	Stability of Wolsit T-33	Anonynus	2015	BASF Wolman GmbH
	No. 3	Stability of Wolsit T-33	Anonynus	2016	BASF Wolman GmbH
	No. 3	Stability of Wolsit T-33	Anonynus	2018	BASF Wolman GmbH

	No. 3	Low temperature stability of Wolsit T-33	Anonynus	2015	BASF Wolman GmbH
	No. 3	Wolsit T-33 - Determination of Surface Tension	Anonynus	2016	
	No. 3	Viscosity of Wolsit T-33	Anonynus	2015	BASF Wolman GmbH
	No. 4	Determination of physicochemical properties according to UN Transport Regulation and Regulation (EC) No. 440/2008	Anonynus	2016	BASF Wolman GmbH
	No. 4	Corrosive to metal of Wolsit T-33	Anonynus	2015	BASF Wolman GmbH
	No. 5	Validation of a Gas Chromatography Method for the Determination of Permethrin in Wolsit products	Anonynus	2016	BASF Wolman GmbH
	No. 6	Determination of toxic values against Reticulitermes species (European termites) according to DIN EN 117:2013	Anonynus	2014	BASF Wolman GmbH
	No. 6	Determination of the resistance of „Wolsit T-33" treated OSB against subterranean termites following AWPA E1-97	Anonynus	2007	BASF Wolman GmbH
	No. 6	Determination of the resistance to Reticulitermes santonensis according to AWPA E1-06	Anonynus	2016	BASF Wolman GmbH

	No. 6	Determination of toxic values against European Reticuliterrnes species (Laboratory method) according to DIN EN 117:8/1990	Anonynus	2012	BASF Wolman GmbH
	No. 6	Determination of the resistance of a „Wolsit T-33" treated Maritime Pine-plywood against subterranean termites following AWPA E1-97	Anonynus	2007	BASF Wolman GmbH
	No. 6	Determination of the resistance of Wolsit T-33 treated Okoumé-plywood against subterranean termites following AWPA E1-97	Anonynus	2007	BASF Wolman GmbH
	No. 6	Determination of toxic values against Reticulitermes species (European termites) according to DIN EN 117:2013-01	Anonynus	2017	BASF Wolman GmbH

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[18]) of the active substance Permethrin for use in wood preservative (product-type 08). Please, refer to the corresponding Assessment Report for a reference list.

4.2.1.2 New information on the active substance

No new data of the active substance was submitted.

4.2.1.3 List of studies 3rd party dossier

No 3rd party dossier was submitted.

18 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

Exposure Assessment for Profe

Output tables from environmental exposure assessment tools

5 Confidential annex (Access level: “Restricted” to applicant and authority)