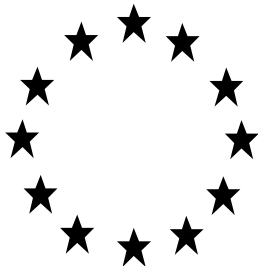
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Product identifier in R4BP	Wolsit F-15T
Product type(s):	08 (Wood preservatives)
Active ingredient(s):	Tebuconazole, ATMAC/TMAC, Propiconazole
Case No. in R4BP	BC-YH039264-29
Asset No. in R4BP	DE-0026665-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/08.00021 710-05-08-00021-00-00-00-0000
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Tables of content

1 Conclusion

In the course of evaluation of applications for active substance approval according to Regulation (EU) No 528/2012[1] (BPR), active substances are assessed against the exclusion criteria according to Article 5 (1) BPR. An active substance meeting the exclusion criteria shall not be approved unless at least one of the conditions for derogation set out under Article 5(2) BPR is met. During active substance approval, the applicant, the Member States and the stakeholders have the opportunity to submit to the Commission elements to demonstrate whether one or several of the conditions for derogation set out under Article 5(2) are met, or are not.[2]. On the basis of the information received, if any, the Commission will decide whether or not to propose to derogate to the principle that the substance shall not be approved[2]. Biocidal Products containing an active substance meeting the exclusion criteria according to Article 5 (1) BPR but approved in accordance with Article 5 (2) BPR are to be authorised only in Member States where the derogation conditions identified at active substance approval stage are met.

The product Wolsit F-15T contains among others the active substance propiconazole. Propiconazole was approved according to Directive 98/8/EC (BPD). Since entering into force of the 13th ATP[3], the active substance propiconazole is classified as toxic for reproduction category 1B, H360D and therefore meets the exclusion criteria according to Article 5 (1) c) BPR. The decision whether the conditions for derogation set out under Article 5 (2) BPR are met will be taken during the on-going renewal of approval of the active substance. Since it has not yet been decided whether the approval of propiconazol is renewed and if one or more of the conditions for derogation set out under Article 5(2) will be met, it is not possible to assess whether a biocidal product containing propiconazole fulfils the derogation conditions. This can only be done after the decision on the renewal of the approval of propiconazole and a derogation according to one or more conditions according Article 5 (2) BPR is finalized.
The product Wolsit F-15T is therefore authorised for a period of five years in accordance with Article 23 (6) BPR (see below) and the German CA will evaluate whether the biocidal product satisfies the conditions of Article 5 (2) BPR as identified during the active substance renewal once the decision on renewal of the

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

[2] CA-Nov14-Doc.4.5 – Final: Further Guidance on the Procedures related to the examination of the exclusion criteria and the conditions for derogation under Article 5(2)

[3] Commission regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776

active substance propiconazole has been taken. Depending of the outcome of this evaluation, the authorisation of Wolsit F-15T may be changed or withdrawn.

The assessment presented in this report has shown the efficacy but no unacceptable risks for the use "glue-line treatment in closed systems", if the ready-to-use product, Wolsit F-15T with the active substances tebuconazole (7.81 % w/w), propiconazole (7.89 % w/w) and ATMAC/TAMC (0.105 % w/w) is used as wood preservative (product-type 08) for the preventive protection of only derived timber products (Plywood -, particle -, OSB panels) in use-class 2 and 3.1[4] against wood destroying fungi by industrial users.
The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[5] (BPR) for the aforementioned use are fulfilled.

The intended use of Wolsit F-15T by glue-line treatment in semi-closed systems leads to unacceptable risks for industrial user and the conditions for granting an authorisation according to Article 19 (1) b) iii) BPR are therefore not 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[6] 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 Danish Assessment Report for the approval of the active substance tebuconazole including the "elements to be taken into account by Member States when authorising products" as requested by the Danish CA.
2. The conclusions and recommendations of the Italian Assessment Report for the approval of the active substance ATMAC/TMAC including the "elements to be taken into account by Member States when authorising products" as requested by the Italian CA.

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4 Use classes according to EN 335

5 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.

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.

3. The conclusions and recommendations of the Finish Assessment Report for the approval of the active substance propiconazole including the “elements to be taken into account by Member States when authorising products” as requested by the Finish CA.
4. The specific provisions from the Inclusion Directive for the active substance tebuconazole (Commission Directive 2008/86/EC).
5. The specific provisions from the Commission Implementing Regulation for the active substance ATMAC/TAMAC (Commission Implementing Regulation (EU) 2016/1934).
6. The specific provisions from the Inclusion Directive for the active substance propiconazole (Commission Directive 2008/78/EC).

Approval of the active substances

The active substances tebuconazole, ATMAC/TMAC and propiconazole are included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- Tebuconazole
    - In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
    - In addition, products cannot be authorised for the in situ treatment of wood outdoors or for wood that will be in continuous contact with water unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures
- ATMAC/TMAC
    - The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.
    - In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: (a) industrial and professional users; (b) soil and groundwater for wood in service that will be exposed to frequent weathering.
    - In view of the risks identified for soil, surface and ground water, labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, 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.
- Propiconazole

- In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means.
- In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
- In addition, products cannot be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

Composition and formulation

The liquid Wolsit F-15T contains the active substances tebuconazole, ATMAC/TMAC and propiconazole. The substances benzyl alcohol (CAS No 100-51-6) and ethoxylated isotridecanol (CAS No 69011-36-5) have been identified as substances of concern. Please refer to chapter 2.2.3 for further information.
Please refer to chapter 2.2 (Composition and formulation) and the confidential annex for detailed information.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics

Physical-chemical hazard(s) were not identified (please find more information in chapter 3.3).

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.3. 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 2.4. Please find more information on efficacy of the product in chapter 3.5.

Risk assessment for human health

The substances benzyl alcohol (CAS No 100-51-6) and ethoxylated isotridecanol (CAS No 69011-36-5) have been identified as substances of concern.

The human health risk assessment for this product is based on the active substance and substances of concern.

A human health risk assessment has been carried out for industrial/professional use of the product (see chapter 3.5) for all intended uses (see chapter 3.1). Based on the risk assessment it is unlikely that the intended use 1 (glue-line treatment in closed systems) causes any acute or chronic unacceptable risk to industrial users, bystanders or residents. However, the intended use 2 (glue-line treatment in semi-closed systems) leads to unacceptable risks for industrial/professional user and is therefore not appropriate for authorisation. Regarding industrial/professional users health protection, there are no objections against use 1 (glue-line treatment in closed systems) if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Risk assessment for the environment

Since no relevant substance of concern has been identified the risk assessment for the environment for this product is based on the active substances.

A risk assessment for the environment has been carried out for industrial application, storage of treated derived timber products and their use in use class 2 and 3 (see chapter 3.8) according to the intended use (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use causes any unacceptable risk for the environment if the risk mitigation measures and directions for use according to chapter 2.5 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

Since the active substances Tebuconazole and Propiconazole have been identified as candidates for substitution (see also chapter 2.2.4), a comparative assessment has been necessary (see chapter 3.10). The corresponding Comparative Assessment Report will be forwarded to ECHA.

The German CA concludes that there are no eligible alternative biocidal products and no non-chemical alternatives available on the German market. The product Wolsit F-15T is therefore authorised for a period not exceeding five years in accordance with Article 23 (6) BPR.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Wolsit F-15T

2.1.2 Manufacturer(s) of the product

Name of manufacturer	Wolman Wood and Fire Protection GmbH
Address of manufacturer	Dr. Wolman Str. 31-33 76547 Sinzheim Germany
Location of manufacturing sites	Dr. Wolman Str. 31-33 76547 Sinzheim Germany

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

Active substance	Coco alkyltrimethylammonium chloride (ATMAC/TMAC)
Name of manufacturer	Akzo Nobel Surface Chemistry AB
Address of manufacturer	Stenunge, Alle 3, SE 444 85 Stenungsund, Sweden
Location of manufacturing sites	Akzo Nobel Surface Chemistry A Stockviksverken 85013 Sundsvall Sweden

Active substance	Coco alkyltrimethylammonium chloride (ATMAC/TMAC)
Name of manufacturer	Lonza Cologne GmbH
Address of manufacturer	Nattermannallee 1 50829 Cologne Germany

Location of manufacturing sites	84508 Burgkirchen Germany

Active substance	Tebuconazole
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer 1	Bayer CropScience Corp. 2 T.W. Alexander Drive, Research Triangle Park, NC 27709, USA
Location of manufacturing site 1	P.O. Box 4913 Hawthorn Road, Kansas City MO 64120-001, USA
Address of manufacturer 2	JIANGSU SWORD AGROCHEMICALS CO.,LTD 1008, East Guanhua Road, Jianhu County, Jiangsu, 224700 China
Location of manufacturing site 2	Binhai Economic Development Zone, Coastal Industrial Park, Binhai County, Jiangsu, P.C. 224500, China

Active substance	Propiconazole
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz 1 50569 Cologne Germany
Location of manufacturing sites	Producer 1: Syngenta Crop Protection AG CH-4002 Basel, Switzerland Plant location CH-1870 Monthey, Switzerland Producer 2: Jiangsu Yangnong Chemical Group Co., Ltd Plant location

	Wenfeng Road, Yangzhou, Jiangsu 225009, P.R. China Producer 3: Jiangsu Seven Continent Green Chemical Co., Ltd Plant location North Area of Dongsha Chem-Zone, Zhanjiagang, Jiangsu, 215600, P.R. China

Active substance	Propiconazole
Name of manufacturer	Janssen PMP, a division of Janssen Pharmaceutica NV
Address of manufacturer	Turnhoutseweg 30 2340 Beerse Belgium
Location of manufacturing sites	North Area of Dongsha Chem-Zone, Zhanjiagang, Jiangsu, 215600, P.R. China

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 (%)
Tebuconazole	1-(4-chlorophenyl)-4,4-dimethyl-3-[(1H-1,2,4-triazol-1-yl)methyl]pentan-3-ol	Active substance	107534-96-3	403-640-2	7.81 (minimum purity: 95% w/w)
Propiconazole	1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1H-1,2,4-triazole	Active substance	60207-90-1	262-104-4	7.89 (minimum purity: 93% w/w)
ATMAC/TMAC	Coco alkyltrimethylammonium chloride	Active substance	61789-18-2	263-038-9	0.105

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
benzyl alcohol	benzyl alcohol	Non-active substance	100-51-6	202-859-9	36.6
Isotridecanol, ethoxylated	Isotridecanol, ethoxylated	Non-achtive substance	69011-36-5	500-241-6	30.717

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

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

2.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?
  Yes ☒
  No ☐

(The technical equivalence of the active substance from the new source was established by ECHA, see asset numbers):

- tebuconazole by
  - manufacturer 2 (Jiangsu Sword Agrochemicals Co., Ltd; Asset number: EU-0016012-0000)
- propiconazole by
  - Janssen PMP (Asset number: EU-0003416-0000)
  - Lanxess Producer 2 (Jiangsu Yangnong Chemical Group Co., Ltd; assessed by FI in November 2015)
  - Lanxess producer 3 (Jiangsu Seven Continent Green Chemical Co., Ltd, Asset number: EU-0013032-0000),

2.2.3 Information on the substance(s) of concern

The following substances of concern were identified:

- Benzyl alcohol (CAS-No. 100-51-6)
- Isotridecanol, ethoxylated (CAS-No. 69011-36-5)

Benzyl alcohol contributes to the classification of the biocidal product with Acute Tox. 4, H302. Isotridecanol, ethoxylated contributes to the classification of the biocidal product with Acute Tox. 4, H302 and Eye Dam. 1, H318.

- (Further) information on the substance(s) of concern is provided in the confidential annex

2.2.4 Candidate(s) for substitution

The following candidate(s) for substitution was/were identified:

- Tebuconazole
- Propiconazole

For tebuconazole, the following criteria for substitution are met:

- Very persistent
- Toxic

For propiconazole, the following criteria for substitution are met:

- Persistent
- Toxic
- Toxic to reproduction category 1B

Tebuconazole is not considered as a candidate for substitution meeting the exclusion criteria according to Article 5(1) BPR. However, propiconazole is considered as a candidate for substitution meeting the exclusion criteria according to Article 5(1) BPR.

2.2.5 Type of formulation

AL – any other liquid

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[7]

Besides the active substances propiconazole and tebuconazole, the other components do not affect the classification of the biocidal product except for the substances of concern benzyl alcohol and isotridecanol, ethoxylated.

7 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 current harmonised classification of the active substance propiconazole is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)[8] in connection with Comission Regulation (EU) 2018/1480 (13th ATP) [9]:

Acute Tox. 4 (H302)
Skin Sens. 1 (H317)
Repr. 1B (H360D)
Aquatic Acute 1 (H400), M=1
Aquatic chronic 1 (H410), M=1

The current harmonised classification of the active substance tebuconazole is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):[10]

Acute Tox. 4 (H302)
Repr. 2 (H361d)
Aquatic Acute 1 (H400), M=1
Aquatic chronic 1 (H410), M=10

Therefore, a classification of the biocidal product pursuant to the Regulation (EC) 1272/2008 is required.

The classification for the biocidal product Wolsit F-15T is based on the classification of the active substances, and on information on other components of the biocidal product (CLP classifications and Safety Data Sheets).

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.

8 See: https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/39494
9 Regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress,Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776
10 See: https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/995

Table 2

Classification Hazard classes, Hazard categories	Hazard statements
Acute Tox. 4	H302
Skin Sens. 1	H317
Eye Dam. 1	H318
Repr. 1B	H360D
Aquatic chronic 1	H410

Table 3

Labelling	Code	Pictogram / Wording
Pictograms	GHS05	
	GHS07	
	GHS08	
	GSH09	
Signal word	-	Danger
Hazard statements	H302	Harmful if swallowed.
	H317	May cause an allergic skin reaction.
	H318	Causes serious eye damage.
	H360D	May damage the unborn child.
	H410	Very toxic to aquatic life with longlasting effects.
Supplemental hazard information	-	-
Supplemental label elements	-	
Precautionary statements	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
	P264	Wash … thoroughly after handling.

	P270	Do no 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/protective clothing/eye protection/face protection.
	P301 + P312	IF SWALLOWED: Call a POISON CENTRE/doctor/… if you feel unwell.
	P302 + P352	IF ON SKIN: Wash with plenty of water/…
	P305 + P351 + P338 +	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P308 + P313	IF exposed or concerned: Get medical advice/attention.
	P310	Immediately call a POISON CENTER/doctor/…
	P321	Specific treatment (see … on this label).
	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.
	P405	Store locked up.
	P501	Dispose of contents/container according to regional or local authority requirements.
Note	-	

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[11]

2.4.1 Use 1 appropriate for authorisation – Glue-line treatment in closed systems

Product Type(s)	08

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

Where relevant, an exact description of the use	Fungicide used in derived timber products for Use Class 2 (OSB + particle board and coated plywood) and 3.1 (coated plywood) according to EN 335-1. Ready-to-use product.
Target organism(s) (including development stage)	Fungi: Wood destroying fungi (brown rot and white rot)
Field(s) of use	Plywood -, particle -, OSB panels (only derived timber products). It is mainly used for exterior cladding (panels) of facades and sub-roof. Also for scaffolding. Especially for plywood made of non-resistant hardwood. Treatment is done indoors. Treated wood will be used in areas protected or exposed to weathering sporadically but not in contact with soil. Use classes (UC) 2 and 3.1.
Application method(s)	Fully automated manufacturing spray process in a closed system. The biocidal product is directly added into the glue-line (mixing with glue and mortar).
Application rate(s) and frequency	OSB+particle board: minimum 0.64 % - maximum 0.69 % (w/w) relative to the finished product in the resin binder (minimum 0.75 % - maximum 0.8 % (w/w) relative to oven-dry wood chips) . Plywood: minimum 3.65 kg/m³ - maximum 4.5 kg /m³ in the finished plywood. One application
Category(ies) of users	Industrial
Pack sizes and packaging material	Jerry can (HDPE), 30 L; Closure: Screw cap of PP IBC (HDPE), 1000 L; Closure: Screw cap of PP

2.4.1.1 Use-specific instructions for use

See chapter 2.5

2.4.1.2 Use-specific risk mitigation measures

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

2.5 General directions for use

2.5.1 Instructions for use

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. If a topcoat is used it shall have no biocidal function. Treated plywood must always be coated with a non-biocidal phenolic resin. Only for plywood constituted of hardwood components and OSB or particle boards constituted of softwood components. The product may only be applied in a fully automated production system (closed system). During the treatment of the wood with the biocidal product as well as the drying phase, there is no dermal contact to the biocidal product or the treated wood. After drying the treated wood, mechanical manual processing of the treated wood may take place.

2.5.2 Risk mitigation measures

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). Freshly treated derived timber products shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water. Any losses of the product shall be collected for reuse or disposal. Do not use the biocidal product on wood, which is intended to be used as part of playground structures and other indoor/ outdoor structures (e.g. flooring, furniture), to which persons of the general public and pets may have prolonged contact.

The product may only be loaded with an automatic dosing system.

The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).

- *Application of the product:*
  1. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
  2. The use of eye protection during handling of the product is mandatory.
- Mechanical processing of treated wood (secondary exposure)
  1. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
  2. A protective coverall (at least type 6, EN 13034) shall be worn.
  3. The use of eye protection during handling of the product is mandatory.

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

1. IF SWALLOWED: Call a POISON CENTRE/doctor/… if you feel unwell
2. IF ON SKIN: Wash with plenty of water/…
3. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
4. IF exposed or concerned: Get medical advice/attention.
5. Rinse mouth.
6. If skin irritation or rash occurs: Get medical advice/attention.
7. Take off contaminated clothing and wash it before reuse.

2.5.4 Instructions for safe disposal of the product and its packaging

Dispose of surplus chemical, contaminated material (including sawdust) and the empty container safely using a method approved by the waste disposal authority.

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

Shelf life: 13 months

Store protected from frost.

2.5.6 Other information

The product is compatible with urea-formaldehyde (UF), melamine-urea-formaldehyde (MUF) and melamine-urea-phenol-formaldehyde (MUPF) glues as well as with phenol-formaldehydes (PF). The product is incompatible with diphenylmethan-diisocyanate (pMDI) glues.

2.6 Packaging

Table 4

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	Screw cap of PP	industrial	Yes
IBC	1000 L	HDPE	Screw cap of PP	industrial	Yes

3 Assessment of the product

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

3.1.1 Intended use 1 – Use 1 – Glue-line treatment in closed systems

Product Type(s)	08
Where relevant, an exact description of the use	wood preservative Fungicide used in derived timber products for Use Class 2 (OSB + particle board and uncoated plywood) and 3.1 (coated plywood) according to EN 335-1 Ready-to-use product.
Target organism(s) (including development stage)	Fungi: Wood destroying fungi
Field(s) of use	Other Plywood -, particle -, OSB panels (only derived timber products). It is mainly used for exterior cladding (panels) of facades and sub-roof. Also for scaffolding. Especially for non-resistant hardwood. Treatment is done indoors. Treated wood will be used in areas protected or exposed to weathering sporadically but not in contact with soil. Use classes (UC) 2 and 3.1.
Application method(s)	Direct addition into the glue-line (mixing with glue and mortar), direct application in closed systems
Application rate(s) and frequency	OSB+particle board: minimum 0.5% - maximum 0.8% Wolsit F-15T/ in oven-dry (atro) wood chips. Plywood: minimum 3 kg/m³ - maximum 4.5 kg /m³. - One application
Category(ies) of users	Industrial
Pack sizes and packaging material	Jerry can, plastic: HDPE 30 L IBC, plastic: HDPE 1000 L

3.1.2 Intended use 2 – Use 2 – Glue-line treatment in semi-closed systems

Product Type(s)	08
Where relevant, an exact description of the use	wood preservative Fungicide used in derived timber products for Use Class 2 (OSB + particle board and uncoated plywood) and 3.1 (coated plywood) according to EN 335-1

	Ready-to-use product.
Target organism(s) (including development stage)	Fungi: Wood destroying fungi
Field(s) of use	Other Plywood -, particle -, OSB panels (only derived timber products). It is mainly used for exterior cladding (panels) of facades and sub-roof. Also for scaffolding. Especially for non-resistant hardwood. Treatment is done indoors. Treated wood will be used in areas protected or exposed to weathering sporadically but not in contact with soil. Use classes (UC) 2 and 3.1.
Application method(s)	Direct addition into the glue-line (mixing with glue and mortar), direct application in semi-closed systems
Application rate(s) and frequency	OSB+particle board: minimum 0.5% - maximum 0.8% Wolsit F-15T/ in oven-dry (atro) wood chips. Plywood: minimum 3 kg/m³ - maximum 4.5 kg /m³. - One application
Category(ies) of users	Industrial
Pack sizes and packaging material	Jerry can, plastic: HDPE 30 L IBC, plastic: HDPE 1000 L

3.2 Physical, chemical and technical properties

Table 5: 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	organoleptic observation	Lot/batch No.: LP 17724_V2 (Date of production: 04.12.2016); a.s. content: - Tebuconazole 7.56 % - Propiconazole 7.42 % - ATMAC/TMAC 0.104 %	liquid	Wittenzellner, J., *Odour, physical state and ph value of Wolsit® F-15T*, report no. 17-WD-030 (**2018**)
Colour at 20 °C and 101.3 kPa	organoleptic observation		yellow	
Odour at 20 °C and 101.3 kPa	organoleptic observation; EPA OPPTS 830.6304 (Odor)		characteristic	
Acidity / alkalinity	CIPAC MT 75.3 "Determination of pH values"		Mean values of three repeated measurements: pH (at 25°C), undiluted Wolsit F-15T: 8.1 pH (at 25°C), Solution of Wolsit F-15T (1 % w/w): 6.45	
Relative density / bulk density	OECD Guideline 109; EPA OPPTS 830.7300	Lot/batch No.: LP 17724_V2 (Date of production: 04.12.2016); a.s. content: - Tebuconazole 7.56 % - Propiconazole 7.42 % - ATMAC/TMAC 0.104 %	1.065 g/cm³ at 20.0 °C.	Wittenzellner, J., *Density of Wolsit® F-15T*, report no. 17-WD-031 (**2018**)
Storage stability test – **accelerated storage**	CIPAC-MT 46.3; CIPAC MT 75.3 "Determination of pH values";	Lot/batch No.: LP 17724_V2 (Date of production: 04.12.2016); a.s. content: - Tebuconazole 7.56 %	Storage for two weeks at 54°C ± 2°C in a glass bottle fitted with screw caps and polyethylene insert;	Wittenzellner, J., *Accelerated storage test by heating of Wolsit® F-15T*, report

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	DIN EN ISO 2811-3 “Paints and varnishes – Determination of density – Part 3: Oscillation method (DIN EN ISO2811-3:2001)”; UPLC method for the determination of Propiconazole and Tebuconazole (report No: 17-WD-013); GC method for the determination of TMAC (report No: 17-WD-038)	- Propiconazole 7.42 % - ATMAC/TMAC 0.104 %	**pH (Wolsit F-15T; 25°C):** start: 7.42 end: 7.26 **Density (20°C) [g/cm³]:** start: 1.0652 end: 1.0657 **Tebuconazole [%]:** start: 7.56 end: 7.54 **Propiconazole [%]:** start: 7.42 end: 7.47 **TMAC/ATMAC [%]:** start: 0.104 end: 0.098 No significant degradation of the active ingredients Tebuconazole, Propiconazole and ATMAC/TMAC within the testing period. The product is stable under accelerated storage conditions.	no. 17-WD-039 (**2017**)
Storage stability test – **long term storage at ambient temperature**	OPPTS 830.6317; Crop Life International, Technical Monograph n°17, 2nd Edition, Guidelines for Specifying the Shelf Life of Plant Protection Products;	Lot/batch No.: LP 17724_V2 (Date of production: 04.12.2016); a.s. content: - Tebuconazole 7.56 % - Propiconazole 7.42 % - ATMAC/TMAC 0.104 %	Description of the storage stability test: Storage in two 5 L HDPE canisters (original packaging) in a room equipped with a window and without heating device. Canister 2 was used for interim investigations.	Wittenzellner, J., *Long term stability of Wolsit® F-15T*, report no. 17-WD-040 (**2018**)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	UPLC method for the determination of Propiconazole and Tebuconazole (report No: 17-WD-013); GC method for the determination of TMAC (report No: 17-WD-038); HPLC-UV method for the determination of benzyl alcohol (SoC) (report ID P 04740 G).		Canister 1 stays unopened until storage finish. The temperature range in the storage room was between 3 °C – 30 °C for the first 12 months. Weightloss: Start: 5407.9 g After 13 months: 5407.1g Loss of 0.8 g The appearance did not change due to storage. **pH (Wolsit F-15T; 25°C):** start: 8.10 after 13 months: 7.62 **pH (1% w/w; 25°C):** start: 6.45 after 13 months: 6.01 **Density (20°C) [g/cm³]:** start: 1.0650 after 13 months: 1.0653 **Tebuconazole [%]:** start: 7.56 after 13 months: 7.58 **Propiconazole [%]:**	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			start: 7.43 after 13 months: 7.49 **TMAC/ATMAC [%]:** start: 0.104 after 13 months: 0.103 **SoC: Benzyl alcohol [%]:** start: 36.6 after 13 months: 36.1 No significant degradation of the active ingredients Propiconazole, Tebuconazole or ATMAC/TMAC after 13 months storage. The product is stable under ambient storage conditions for 13 months.	
Storage stability test – **low temperature stability test for liquids**	-	-	Not applicable because according to the label instructions the biocidal product has to be protected from frost. (Please also refer to the results of the accelerated and long term storage test.)	waiving[12]
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Not applicable as the packaging is light-proof. Therefore, the formulations are not exposed to light during storage.	waiving[12]

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

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			(Please also refer to the results of the accelerated and long term storage test.)	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Not applicable because according to the label instructions the biocidal product has to be protected from frost in closed, original container. (Please also refer to the results of the accelerated and long term storage test.)	waiving[12]
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The data about the packaging material is sufficient.	waiving[12]
Wettability	-	-	Data waiving acceptable (data are only required for solid preparations which are to be dispersed in water).	waiving[12]
Suspensibility, spontaneity and dispersion stability	-	-	Data waiving acceptable (data are not required since the biocidal product is a ready-to-use liquid).	waiving[12]
Wet sieve analysis and dry sieve test	-	-	Data waiving acceptable (data are only required for solid biocidal products, dispersible concentrates or suspensions).	waiving[12]
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Data waiving acceptable (data are not required since the biocidal product is a ready-to-use product),	waiving[12]

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Disintegration time	-	-	Data waiving acceptable (data are only required for biocidal products supplied as tablets).	waiving[12]
Particle size distribution, content of dust/fines, attrition, friability	-	-	Data waiving acceptable (data are not required since the biocidal product is a liquid),	waiving[12]
Persistent foaming	-	-	Data waiving acceptable (data are not required since the biocidal product is not intended for dilution with water).	waiving[12]
Flowability/Pourability/Dust ability	-	-	Data waiving 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).	waiving[12]
Burning rate — smoke generators	-	-	Data waiving acceptable (not applicable since the biocidal product is not a smoke generator).	waiving[12]
Burning completeness — smoke generators	-	-	Data waiving acceptable (not applicable since the biocidal product is not a smoke generator).	waiving[12]
Composition of smoke — smoke generators	-	-	Data waiving acceptable (not applicable since the biocidal product is not a smoke generator).	waiving[12]
Spraying pattern — aerosols	-	-	Data waiving acceptable (not applicable since the biocidal product is not an aerosol).	waiving

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical compatibility	-	-	Data waiving acceptable (not applicable since the biocidal product is not intended to be used with other products).	waiving
Chemical compatibility	-	-	Due to the long term experience (in)compatibilities are known and as follows. The product is compatible with many urea-formaldehyde (UF), melamine-urea-formaldehyde (MUF) and melamine-urea-phenol-formaldehyde (MUPF) glues as well as with several phenol-formaldehyde (PF). The product is incompatible with conventional diphenylmethan-diisocyanate (pMDI) glues. In cases where the product is incompatible with the glue it should be used successively.	
Degree of dissolution and dilution stability	-	-	Data waiving acceptable (not applicable since the biocidal product is not a water soluble bag, tablet or a water-soluble preparation).	waiving
Surface tension	OECD Guideline 115 (Surface Tension of Aqueous Solutions); EU Method A.5 (Surface Tension)	Lot/batch No.: LP 17724_V2 (Date of production: 04.12.2016); a.s. content: - Tebuconazole 7.56 % - Propiconazole 7.42 % - ATMAC/TMAC 0.104 %	surface tension (1 g/L aqueous solution of Wolsit F-15T; 20 °C): 29.28 mN/m (standard deviation ± 0.05 mN/m). Considering that distilled water has a surface tension of 72.75 mN/m at 20 °C and Wolsit F-15T showed a surface tension below 60 mN/m	Vinh An Thieu-Simchen, *Wolsit F-15T - Determination of Surface Tension,* report no. 170510BW / CPT17711 (**2017**)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Wolsit F-15T should be regarded as being surface-active material.	
	OECD Guideline 115 (Surface Tension of Aqueous Solutions); EU Method A.5 (Surface Tension)	Wolsit F-15T Lot/batch No.: LP 18226 a.s. content: - Tebuconazole 7.09 % - Propiconazole 6.98 % - ATMAC/TMAC 0.096 %	Undiluted product: 35.53 mN/m at 20°C	Riedl, S., *Determination of Surface Tension,* report no.: 190130BT / CPT18561 (**2019**)
Viscosity	OECD Test Guideline 114 (Viscosity of Liquids); DIN 53019 Part 1; EPA OPPTS 830.7100 (Viscosity)	Lot/batch No.: LP 17724_V2 (Date of production: 04.12.2016); a.s. content: - Tebuconazole 7.56 % - Propiconazole 7.42 % - ATMAC/TMAC 0.104 %	rotational viscometer (dynamic): The dynamic viscosity of Wolsit F-15T is 72.2 mPa s at 20°C and 25.9 mPa s at 40°C.	Wittenzellner, J., *Viscosity of Wolsit® F-15T*, report no. 17-WD-032 (**2018**)

Table 6

Conclusion on the physical, chemical and technical properties
The data provided by the applicant were acceptable. Wolsit F-15T is a yellow liquid with a characteristic odour. The density of Wolsit F-15T is 1.065 g/cm³ at 20.0°C. The pH value of the undiluted product is 8.1 and the corresponding value of a 1% w/w solution is 6.45 (both at 25°C). The surface tension of a 1 g/L aqueous solution of Wolsit F-15T is 29.28 mN/m at 20 °C, of the undiluted product the surface tension is 35.53 mN/m at 20°C and the dynamic viscosity of the product is 72.2 mPa.s at 20 °C and 25.9 mPa.s at 40 °C. The product respectively its active substance concentrations, pH value and density are stable under accelerated storage conditions (14 days at 54°C ± 2°C). Wolsit F-15T has a shelf-life of 13 months.

3.3 Physical hazards and respective characteristics

Table 7: 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: Appendix 6 of the UN-MTC, DSC	Wolsit F-15T Lot/batch No.: LP 17724_V2 a.s. content: Tebuconazole 7.18 % Propiconazole 7.43 % ATMAC/ TMAC 0.109 %	Exothermic decomposition energy: -440 J/g Decomposition temperature (T_{onset}): 290 °C	The study does not need to be conducted because the product is a mixture containing chemical groups associated with explosive properties, but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500°C. Not classified based on GHS/CLP criteria.	IUCLID[13] and Möller, M., 2017, report no. CSL-17-0618.01
Flammable gases	-	-	-	Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[13]
Flammable aerosols	-	-	-	Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[13]
Oxidising gases	-	-	-	Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[13]

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

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Gases under pressure	-	-	-	Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[13]
Flammable liquids	DIN EN ISO 3679	Wolsit F-15T Lot/batch No.: LP 17724_V2 a.s. content: Tebuconazole 7.18 % Propiconazole 7.43 % ATMAC/ TMAC 0.109 %	Flash point: 117 °C	Not classified based on GHS/CLP criteria	Möller, M., 2017, report no. CSL-17-0618.01
Flammable solids	-	-	-	Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[13]
Self-reactive substances and mixtures	Screening procedure: Appendix 6 of the UN-MTC, DSC	Wolsit F-15T Lot/batch No.: LP 17724_V2 a.s. content: Tebuconazole 7.18 % Propiconazole 7.43 % ATMAC/ TMAC 0.109 %	Exothermic decomposition energy: -440 J/g Decomposition temperature (Tonset): 290 °C	Due to the fact that the exothermic effect started above 200 °C it can be stated that the SADT is > 75 °C. Therefore, the full classification procedure does not need to be applied. Not classified based on GHS/CLP criteria.	Möller, M., 2017, report no. CSL-17-0618.01

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Pyrophoric liquids	-	-	-	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) and hence, the classification procedure does not need to be applied.	IUCLID[13]
Pyrophoric solids	-	-	-	Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[13]
Self-heating substances and mixtures	-	-	-	Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[13]
Substances and mixtures which in contact with water emit flammable gases	-	-	-	The study does not need to be conducted because the experience in production or handling shows that the product does not react with water, e.g. the substance is manufactured with water or washed with water (Two components of the biocidal product are water based solutions. The mixture does not react and emit flammable gases. Furthermore based on structure no flammability on contact with water is expected.)	IUCLID[13]
Oxidising liquids	-	-	-	The components Tebuconazole. Propiconazole. TMAC, Benzylalcohol and the two polymeric structures contain O-atoms and Cl-atoms chemically only bonded to C-atoms. Based on the fulfilment of the above cited requirements of Appendix 6 of the UN-MTC for each component it can be stated that the test item has no oxidizing properties according to UN Test 0.2.	Möller, M., 2017, report no. CSL-17-0618.01
Oxidising solids	-	-	-	Not applicable	IUCLID[13]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
				The study does not need to be conducted because the product is a liquid.	
Organic peroxides	-	-	-	The study does not need to be conducted because the product does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	IUCLID[13]
Corrosive to metals	The study procedures based on DIN 52168-1 and UN Test in Part III of the UN-MTC, 37.4	Wolsit F-15T Lot/batch No.: LP 17724_V2 a.s. content: Tebuconazole 7.5 % Propiconazole 7.5 % ATMAC/ TMAC 0.10 %	Mass loss: < 1%Localized corrosion: no Type of material: Al-7075-T6 S234JR+CR (St37.2)	Due to the composition of the product the test results are plausible. Not classified based on GHS/CLP criteria	Önem-Siakou, E., 2017, report no.: 17-WD-017
Auto-ignition temperature (liquids and gases)	DIN 51794	Wolsit F-15T Lot/batch No.: LP 17724_V2 a.s. content: Tebuconazole 7.18 % Propiconazole 7.43 % ATMAC/ TMAC 0.109 %	Auto-ignition temperature: 400°C		Möller, M., 2017, report no. CSL-17-0618.01

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Relative self-ignition temperature for solids	-	-	-	Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[13]
Dust explosion hazard	-	-	-	Not applicable The study does not need to be conducted because the product is a liquid.	IUCLID[13]

Table 8

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. Experimental data on flash point (117 °C) and auto-ignition temperature (400 °C) were provided. A test has indicated that the product is not corrosive to metals.Wolsit F-15T is not expected to have any explosive or oxidising properties. Based on experience in production and handling it can be concluded that the product is not pyrophoric, does not evolve flammable gases in contact with water. Conclusions on classification and labelling: The physical and chemical properties of the biocidal product do not fulfil the criteria for a classification according to Regulation (EC) No 1272/2008 and therefore, no labelling is required for physical-chemical hazards.

3.4 Methods for detection and identification

Table 9

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**		
Propiconazole	UPLC with UV detection	specific, very small (below the LOD) or no peaks of the matrix at the retention time of Propiconazole	range: 2.87 to 11.5 mg/L (three-point calibration); Correlation coefficient: 0,999966 Slope: 0.00007098 intercept: -0.025	Level A: 4.5 mg/L	102.0 – 103.3	102.6	0.48	LOQ is not required for determination of a.s. in the biocidal product. For completeness the determined values are displayed. LOQ: 0.05 mg/L LOD: 0.02 mg/L	Wittenzellner, J., *UPLC method for the determination of Propiconazole and Tebuconazole in Wolsit® F-15T*, report no. 17-WD-013 (**2017**)
				Level B: 6.0 mg/L	101.3 – 102.3	101.9	0.33		
				Level C: 7.5 mg/L (five measurements per level) (range: 75% - 125%)	102.8 – 104.1	103.3	0.44		
Tebuconazole	UPLC with UV detection	specific, very small (below the LOD) or no peaks of the matrix at the	range: 2.65 to 10.6 mg/L (three-point calibration);	Level A: 4.5 mg/L	102.7 – 103.5	103.1	0.41	LOQ is not required for determination of a.s. in the biocidal	
				Level B: 6.0 mg/L	101.3 – 102.5	101.9	0.44		
				Level C: 7.5 mg/L		103.1	0.41		

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**		
		retention time of Tebuconazole	Correlation coefficient: 0,999965 Slope: 0.00006597 Intercept: -0.0084	(five measurements per level) (range: 75% - 125%)	102.6 – 103.9			product. For completeness the determined values are displayed. LOQ: 0.05 mg/L LOD: 0.02 mg/L	
ATMAC/TMAC	GC-FID	specific, no/small influence of the matrix of Wolsit® F-15T concerning the peaks of the C12- and C14-chain of TMAC (prefered peaks)	range: 89.5 - 358 mg/L (three-point calibration); Correlation coefficient: C12-chain: 0.99969 Slope: 0.001156 Intercept: 18.0 C14-chain: 0.99986 Slope: 0.002787 Intercept: 13.9	Level A: 158 mg/L Level B: 198 mg/L Level C: 237 mg/L (five measurements per level) (range: 80% - 120%) results based on C12 and C14	94.6 – 98.7 105.1 – 114.5 101.3 – 104.0	95.5 108.9 102.8	1.59 2.78 1.04	LOQ is not required for determination of a.s. in the biocidal product. For completeness the determined values are displayed. LOQ : C12-chain: 26 mg/L C14-chain: 29 mg/L	Wittenzellner, J., *Validation of a Gas Chromatography Method for the determination of TMAC in Wolsit® F-15T*, report no. 17-WD-038 (**2018**)

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**		
Benzyl alcohol (SoC)	HPLC/UV	specific	range: 1.0 to 50 mg/L (eight-point calibration); Correlation coefficient: 0.999 Slope: 94,51435 Intercept: 28,28196	100 g/kg = 250 mg/L n=10	83 - 96	89	5.1	LOQ is not required for determination of SoC in the biocidal product. For completeness the determined values are displayed. 100 g/kg	Bacher, R., *Analysis of Benzyl Alcohol and Lutensol TO 89 in Wolsit F-15 T*, report no. P 05234 G (**2019**)
				200g/kg = 500 mg/L n=9	91 – 103	96	3.9		
Isotridecanol, ethoxylated (SoC)	LC/MS	specific	20 µg/L – 500 µg/L n=6 Correlation coefficient: >0.998 Slope: $2.05*10^6$ Intercept: $5,41*10^7$	50 g/kg = 50 mg/L n=3	96 - 104	100	3.61	LOQ is not required for determination of SoC in the biocidal product. For completeness the determined values are displayed. 50 g/kg	Bacher, R., *Analysis of Benzyl Alcohol and Lutensol TO 89 in Wolsit F-15 T*, report no. P 05234 G (**2019**)
				100 g/kg = 100 mg/L n=4	87 – 94	90	2.75		
				200 g/kg = 200 mg/L n=3	82 - 83	82	0.73		
Justification for non-submission of a combined method: For the biocidal product containing more than one active substance, a method capable of determining each, in the presence of the other, should be provided. A combined method for tebuconazole/propiconazole and coco alkyltrimethylammonium chloride (ATMAC/TMAC) could not be developed based on the different chemical structure and properties. Tebuconazole/propiconazole are UV active and were analysed with a UV detector.									

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**		
ATMAC/TMAC, on the other hand, does not contain any UV active groups and can therefore not be analysed with a UV detector. Therefore, no combined analytical method was provided for all three active substances.									

Table 10

Relevant residue definitions for monitoring of Propiconazole and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	propiconazole, 1,2,4-triazole (CGA71019), CGA 118245	0.05 mg/kg 0.02 mg a.i./ kg wet soil	common limit PNECsoil CAR Doc I, 12/2007, chapter 2.8.1
Drinking water	propiconazole	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	propiconazole	1.6 µg/L	PNECwater based on NOEC Scenedesmus subspicatus: 16 µg/L, AF: 10 CAR Doc I, 12/2007, chapter 2.8.1
Air	propiconazole	24 µg/m^3	AOEL: 0.08 mg/kg bw/d, AR for PT8; 2007, list of endpoints
Animal and human body fluids and tissues	no relevant residues expected		not classified as toxic or very toxic, AR for PT8; 2007, list of endpoints
Food of plant origin	no relevant residues expected		no exposure expected from intended use as wood preservative (PT8)

Relevant residue definitions for monitoring of Propiconazole and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Food of animal origin	no relevant residues expected		no exposure expected from intended use as wood preservative (PT8)

Table 11

Analytical methods for Propiconazole and 1,2,4-triazole in 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**		
Propiconazole	GC-MS, NCI, RTX-50, m/z 256+305+341	no confirmation, since validation data for sum of 3 fragment ions	6.25 – 125 ng/mL R^2=0.9966	0.05 µg/L / 5 0.5 µg/L / 5	75.9 – 92.6 76.6 – 96.8	85.3 85.9	8.3 10.5	0.05 µg/L	Pointurier, 2000 CAR, docIIIA, 4.2/10B
Propiconazole	LC-MS/MS, ESI+, Inertsil C8, m/z 342→159	no confirmation, since validation data for a single transition	2.5 – 50 ng/mL R^2=0.9999	0.1 µg/L / 5 1 µg/L / 5 100 µg/L / 2	81 - 89 83 – 104 92, 93	85 93 93	4.8 12.2 -	0.1 µg/L	Vargo, 1997 CAR, doc IIIA, 4.2/17A, 4.2/17B
CGA 118245 determined as sum of CGA118244, CGA118245 and CGA 136735	LC-MS/MS, ESI+, Inertsil C8, m/z 358→256	no confirmation, since validation data for a single transition	2.5 – 50 ng/mL R^2=0.9999	0.1 µg/L / 5 1 µg/L / 5 100 µg/L / 2	83 - 97 87 – 100 95, 97	90 96 96	5.9 5.5 -	0.1 µg/L	Vargo, 1997 CAR, doc IIIA, 4.2/17A, 4.2/17B
1,2,4-triazole	LC-MS/MS, ESI+, Zorbax 300 SCX, m/z 70→70 (no fragmentation)	no confirmation, since validation data for a single fragment ion	2.5 – 50 ng/mL R^2=0.9999	0.1 µg/L / 5 1 µg/L / 5 100 µg/L / 2	90 - 103 87 – 94 99, 102	99 90 101	5.4 3.0 -	0.1 µg/L	Vargo, 1997 CAR, doc IIIA, 4.2/17A, 4.2/17B

Analytical methods for Propiconazole and 1,2,4-triazole in 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**		
Propiconazole	LC-MS, Zorbax SB-CN, ESI+, m/z 342	no confirmation	0.05 – 1 ng/mL R^2=0.9999	0.1 µg/L / 4 0.5 µg/L / 2 1.6 µg/L / 2 5 µg/L / 1 25 µg/L / 1 100 µg/L / 1 500 µg/L / 2	85 - 90 91, 89 54, 51 95 87 92 99, 98	87.0 90.0 52.5 95 87 92 98.5	2.8 - - - - - -	0.1 µg/L	Vargo, 1995, CAR, doc IIIA, 4.2/18

Table 12

Analytical methods for Propiconazole and 1,2,4-triazole in soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Propiconazole	GC-NPD, DB-1	no confirmation	0.06 – 1.8 µg/mL	0.04 mg/kg / 15 0.4 mg/kg / 15	71 – 85 75 – 115	78.5 91.1	6.3 13.7	0.04 mg/kg; acceptable for common limit, but LOQ > MRL based on PNEC soil	Forrer, 1991 CAR, docIIIA, 4.2/01 (2004)
1,2,4-triazole	LC/LC-UV, 2x Lichrospher 100 Si, 270 nm	no confirmation	0.005 – 0.1 µg/mL	0.02 mg/kg / 9 0.1 mg/kg / 9	66 – 95 69 – 90	83.0 81.6	10.8 9.7	0.02 mg/kg	Formica & Giannone, 1991 CAR, doc IIIA, 4.2/05

Analytical methods for Propiconazole and 1,2,4-triazole in soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
1,2,4-triazole	LC/LC-UV, Nucleosil Amin + Lichrospher 100 Si, 270 nm	no confirmation	0.005 – 0.1 µg/mL	0.02 mg/kg / 4 0.1 mg/kg / 4	63 – 86 68 – 79	74.3 73.8	16.1 6.1	0.02 mg/kg	Formica & Giannone, 1991 CAR, docIIIA, 4.2/06
CGA 118245 for separation from isomers CGA 118244, CGA 136735 with column switching	LC/LC-MS/MS, Dicovery C18 & Thermo Hypersil Keystone, ESI+, m/z 358→256, 358→159	confirmation included by second transition	0.2 – 4 ng/mL R^2=0.9996	Sandy loam 0.005 mg/kg / 5 0.05 mg/kg / 5 silty clay 0.005 mg/kg / 5 0.05 mg/kg / 5	98 - 100 99 – 118 99 - 118 98 – 103 %	99 102 110 101 %	1.1 1.9 8.0 2.1 %	0.005 mg/kg	Tribolet, 2001 CAR, doc IIIA, 4.2/08
Propiconazole	LC-MS/MS, ESI+, Inertsil C8, m/z 342→159	no confirmation, since validation data for a single transition	2.5 – 50 ng/mL R^2=0.9999	0.005 mg/kg / 5 0.05 mg/kg / 5 0.5 mg/kg / 2	91 - 110 86 – 92 94, 93	100 88 94	7.3 2.9 -	0.005 mg/kg	Vargo, 1997 CAR, doc IIIA, 4.2/17A, 4.2/17B
CGA 118245 determined as sum of CGA118244, CGA118245 and CGA 136735	LC-MS/MS, ESI+, Inertsil C8, m/z 358→256	no confirmation, since validation data for a single transition	2.5 – 50 ng/mL R^2=0.9999	0.005 mg/kg / 5 0.05 mg/kg / 5 0.5 mg/kg / 2	95 - 120 95 – 97 98, 95	10 % 96 97	11.0 0.87 % -	0.005 mg/kg	Vargo, 1997 CAR, doc IIIA, 4.2/17A, 4.2/17B

Analytical methods for Propiconazole and 1,2,4-triazole in soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
1,2,4-triazole	LC-MS/MS, ESI+, Zorbax SAX, m/z 70→70 (no fragmentation)	no confirmation, since validation data for a single fragment ion	2.5 – 50 ng/mL R^2=0.9993	0.005 mg/kg / 5 0.05 mg/kg / 5 0.5 mg/kg / 2	73 - 104 75 – 98 72, 77	90 89 75	15.3 11.2 -	0.005 mg/kg	Vargo, 1997 CAR, doc IIIA, 4.2/17A, 4.2/17B
Propiconazole	LC-MS, Zorbax SB-CN, ESI+, m/z 342	no confirmation	0.05 – 1 ng/mL R^2=0.9999	0.01 mg/kg / 4 0.025 mg/kg / 2 0.1 mg/kg / 1 0.25 mg/kg / 2	90 - 107 100, 100 84 96, 100	96.5 100 84 98	7.9 - -- -	0.01 mg/kg	Vargo, 1995, CAR, doc IIIA, 4.2/18

Table 13:

Analytical methods for Propiconazole in 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**		
Propiconazole	GC-NPD, DB-5	no confirmation	0.08 – 1.0 µg/mL	10 µg/m³ / 2 20 µg/m³ / 2 100 µg/m³ / 2	103; 111 90; 95 90; 85	107 92.5 87.5	- - -	10 µg/m³	Tribolet, 1992 CAR, doc IIIA, 4.2/11

Table 14

Analytical methods for Propiconazole in surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specifi Propiconazole in city**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Propiconazole	GC-MS, NCI, RTX-50, m/z 256+305+341	no confirmation, since validation data for sum of 3 fragment ions	6.25 – 125 ng/mL R^2=0.9991	0.05 µg/L / 5 0.5 µg/L / 5	100.5 – 107.8 88.4 – 100.1	102.9 93.8	2.9 5.3	0.05 µg/L	Pointurier, 2000 CAR, docIIIA, 4.2/10B

Table 15

Relevant residue definitions for monitoring of Tebuconazole and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	Tebuconazole	0.1 mg/kg wet soil	PNECsoil AR for PT08, chapter 2.2.2.2., 11/2007
Drinking water	Tebuconazole	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	Tebuconazole	1 µg/L	PNECwater based on NOEC rainbow trout, AF: 10 AR for PT08, chapter 2.2.2.2., 11/2007
Air	Tebuconazole	9 µg/m³	AOEL: 0.03 mg/kg bw/d, AR for PT08, list of endpoints, 11/2007
Animal and human body fluids and tissues	no relevant residues expected		not classified as toxic or very toxic
Food of plant origin	no relevant residues expected		AR for PT08, 11/2007
Food of animal origin	no relevant residues expected		AR for PT08, 11/2007

Table 16

Analytical methods for Tebuconazole in 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**		
Tebuconazole	GC-MS; DB-5MS, m/z 250	no confirmation, since validation data for a single fragment ion	0.00503 – 0.67 µg/mL R^2=0.9994	0.05 µg/L / 5 0.5 µg/L / 5	85 – 105 75 – 93	97 86	8.0 7.8	0.05 µg/L validated in surface water, also accepted for drinking water	Weeren (2000) CAR Doc IIIA, 4.2/08
Tebuconazole	LC-MS/MS; Phenomenex Aqua C18, ESI+, m/z: 308→70, 308→125	confirmation included	0.03 – 5 ng/mL	drinking water m/z: 308→70 0.1 µg/L / 5 1 µg/L / 5 m/z: 308→125 0.1 µg/L / 5 1 µg/L / 5 mineral water m/z: 308→70 0.1 µg/L / 5 1 µg/L / 5 m/z: 308→125 0.1 µg/L / 5 1 µg/L / 5		 94 137 106 137 111 118 100 121	 14 8 21 8 10 7 14 6	0.1 µg/L	Greulich & Alder (2006)

Table 17

Analytical methods for Tebuconazole in soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Tebuconazole	GC-NPD, DB-5 column	confirmation included by GC-MS; DB-5MS, m/z 250 but not sufficiently validated	0.01 – 2.01 µg/mL R^2=1.0	GC-NPD 0.01 mg/kg / 5 0.1 mg/kg / 5 GC-MS 0.01 mg/kg / 1 0.1 mg/kg / 1	 94 – 105 92 – 95	 100 94 98 101	 4.3 1.2 - -	0.01 mg/kg	Weeren (2000) CAR, Doc IIIA, 4.2/06
Tebuconazole	LC-MS/MS; LiChroCART Superspher 60 RP-select B, ESI+, m/z: 308→70	no confirmation	0.001 – 0.1 µg/mL R=0.9999	sandy clay loam 5.08 µg/kg / 5 50.8 µg/kg / 5 209 µg/kg / 5 silt loam 5.08 µg/kg / 5 50.8 µg/kg / 5 209 µg/kg / 5 sediment 5.08 µg/kg / 5 50.8 µg/kg / 5	 98.4 – 104 102 – 104 98.3 – 104 96.4 – 114 99.5 – 107 98.0 – 104 79.9 – 85.4 75.3 – 77.6	 101 103 101 103 102 101 82.0 76.5	 2.1 0.9 2.3 7.4 3.8 2.6 3.1 1.4	0.005 mg/kg	Schramel (2001)

Analytical methods for Tebuconazole in soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
				209 µg/kg / 5	72.6 – 78.7	76.5	3.5		

Table 18:

Analytical methods for Tebuconazole in 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**		
Tebuconazole	GC-NPD, CP Wax 52 CB	no confirmation included, but confirmation by GC-MS, HP-1701, EI, m/z 250 (Hellpointner (2000); CAR, Doc IIIA, 3.2/07)	0.017 – 1.701 µg/mL R^2=0.9986	Tenax 1.1 µg/m³ / 4 142 µg/m³ / 4 XAD-2 1.1 µg/m³ / 4 142 µg/m³ / 4	 99.4 – 106 89.9 – 104 95.3 – 100 91.8 – 95.2	 104 97.1 97.9 93.6	 2.8 6.3 2.1 2.0	1.1 µg/m³	Riegner (1992) CAR, Doc IIIA, 4.2/02

Table 19

Analytical methods for Tebuconazole in surface 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**		
Tebuconazole	GC-MS; DB-5MS, m/z 250	no confirmation, since validation data for a single fragment ion	0.00503 – 0.67 µg/mL R^2=0.9994	0.05 µg/L / 5 0.5 µg/L / 5	85 – 105 75 – 93	97 86	8.0 7.8	0.05 µg/L	Weeren (2000) CAR Doc IIIA, 4.2/08

Table 20

Relevant residue definitions for monitoring of ATMAC/TMAC and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	ATMAC/TMAC	0.05 mg/kg	common limit (since PNECsoil> 0.05 mg/kg) combined AR for ATMAC and TMAC, PT8 chapter 2.2.2.2
Drinking water	ATMAC/TMAC	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	ATMAC TMAC	0.57 µg/L 0.11 µg/L	PNECwater =0.00057 mg/L based on read across to DDAC and correction for MW PNECwater =0.00011 mg/L based on read across to C12-16-BKC and correction for MW combined AR for ATMAC and TMAC, PT8 chapter 2.2.2.2
Air	no relevant residues expected		combined AR for ATMAC and TMAC, PT8 chapter 2.1.1 and LoEP, 11/2014

Relevant residue definitions for monitoring of ATMAC/TMAC and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Animal and human body fluids and tissues	no relevant residues expected		combined AR for ATMAC and TMAC, PT8 chapter 2.1.1 and LoEP, 11/2014
Food of plant origin	no relevant residues expected		combined AR for ATMAC and TMAC, PT8 chapter 2.1.1 and LoEP, 11/2014
Food of animal origin	no relevant residues expected		combined AR for ATMAC and TMAC, PT8 chapter 2.1.1 and LoEP, 11/2014

Table 21

Analytical methods for ATMAC/TMAC in 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**		
TMAC (active substance) determined as C8, C10, C12, C14, C16, C18, unsaturated C18	LC-MS/MS, C18, ESI+ C8 m/z 172→60; m/z 172→57 C10 m/z 200→60; m/z 200→57 C12	included by second MS/MS transition	0.01 – 1.04 µg/L (total C8-C18un) R^2: 0.999068 – 0.999961	Primary method groundwater C8 0.014/5 0.14/5 C10 0.014/5 0.14/5 C12 0.014/5 0.14/5	 C8 <LOQC8 84-94 C10 <LOQC10 90-95 C12 79-87 89-96	 C8 <LOQC8 90 C10 <LOQC10 93 C12 83 93	 C8 - 4.1 C10 - 2.2 C12 4.1 3.0	0.1 µg/L (lowest fortification level as total TMAC) For individual constituents LOQC8, LOQC10, LOQC12, LOQC14, LOQC16, LOQC18 and LOQC18un = 0.014 µg/L	Combined CAR ATMAC-TMAC Doc IIA, Water, 04/2016

Analytical methods for ATMAC/TMAC in 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**		
	m/z 228→60; m/z 228→57 C14 m/z 256→60; m/z 256→57 C16 m/z 284→60; m/z 284→57 C18 m/z 312→60; m/z 312→57 C18un m/z 310→60; m/z 310→69			C14 0.014/5 0.14/5 C16 0.014/5 0.14/5 C18 0.014/5 0.14/5 C18un 0.014/5 0.14/5 tap water C8 0.014/5 0.14/5 C10 0.014/5 0.14/5 C12 0.014/5 0.14/5 C14	C14 75-83 89-97 C16 <LOQC16 72-81 C18 <LOQC18 63-77 C18un <LOQC18un 65-76 C8 <LOQC8 84-92 C10 <LOQC10 91-94 C12 74-84 89-97 C14	C14 81 94 C16 <LOQC16 79 C18 <LOQC18 72 C18un <LOQC18un 71 C8 <LOQC8 88 C10 <LOQC10 93 C12 81 94 C14	C14 4.1 3.5 C16 - 5.5 C18 - 9.6 C18un - 5.8 C8 - 4.5 C10 - 1.6 C12 3.6 3.2 C14		

Analytical methods for ATMAC/TMAC in 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**		
				0.014/5 0.14/5 C16 0.014/5 0.14/5 C18 0.014/5 0.14/5 C18un 0.014/5 0.14/5 Confirmatory method groundwater C8 0.014/5 0.14/5 C10 0.014/5 0.14/5 C12 0.014/5 0.14/5	79-84 91-98 C16 <LOQC16 81-88 C18 <LOQC18 82-89 C18un <LOQC18un 73-79 C8 <LOQC8 86-100 C10 <LOQC10 88-94 C12 81-90 90-96	82 95 C16 <LOQC16 85 C18 <LOQC18 85 C18un <LOQC18un 76 C8 <LOQC8 93 C10 <LOQC10 91 C12 86 95	2.3 2.7 C16 - 3.5 C18 - 3.4 C18un - 3.3 C8 - 6.5 C10 - 2.5 C12 3.9 2.9		

Analytical methods for ATMAC/TMAC in 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**		
				C14 0.014/5 0.14/5 C16 0.014/5 0.14/5 C18 0.014/5 0.14/5 C18un 0.014/5 0.14/5 tap water C8 0.014/5 0.14/5 C10 0.014/5 0.14/5 C12 0.014/5 0.14/5	C14 79-88 87-96 C16 <LOQC16 73-84 C18 <LOQC18 71-85 C18un <LOQC18un 66-75 C8 <LOQC8 89-95 C10 <LOQC10 85-103 C12 77-90 90-97	C14 84 92 C16 <LOQC16 81 C18 <LOQC18 80 C18un <LOQC18un 71 C8 <LOQC8 94 C10 <LOQC10 93 C12 84 94	C14 4.0 3.9 C16 - 6.1 C18 - 5.1 C18un - 4.7 C8 - 3.1 C10 - 6.9 C12 5.9 2.9		

Analytical methods for ATMAC/TMAC in 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**		
				C14 0.014/5 0.14/5 C16 0.014/5 0.14/5 C18 0.014/5 0.14/5 C18un 0.014/5 0.14/5	C14 77-92 88-98 C16 <LOQC16 79-88 C18 <LOQC18 96-103 C18un <LOQC18un 73-80	C14 85 94 C16 <LOQC16 84 C18 <LOQC18 99 C18un <LOQC18un 78	C14 6.9 4.5 C16 - 4.8 C18 - 3.3 C18un - 4.5		
ATMAC (active substance) determined as C12	LC-MS, ESI+, m/z 228.3	no confirmation included, since validation data for a single fragment ion	0.01 – 0.5 µg/L R2 = 0.9986	drinking water C12 0.01/5 0.1/5 groundwater C12 0.01/5 0.1/5	 94-109 77-86 71-103 79-95	 103 80 87 82	 5.5 4.5 14.5 9.0	0.1 µg/L	CAR DocIIIA ATMAC, 4.2c(1); 01/2014 Brewin, 2004

Table 22

Analytical methods for ATMAC/TMAC in soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
TMAC (active substance) determined as C8, C10, C12, C14, C16, C18, unsaturated C18	LC-MS/MS, C18, ESI+ C8 m/z 172→60; m/z 172→57 C10 m/z 200→60; m/z 200→57 C12 m/z 228→60; m/z 228→57 C14 m/z 256→60; m/z 256→57 C16 m/z 284→60; m/z	included by second MS/MS transition	0.01 – 1.04 µg/L (total C8-C18un) R^2: 0.999068 – 0.999961	Primary method C8 0.00714/5 0.0714/5 C10 0.00714/5 0.0714/5 C12 0.00714/5 0.0714/5 C14 0.00714/5 0.0714/5 C16 0.00714/5 0.0714/5 C18 0.00714/5 0.0714/5 C18un 0.00714/5 0.0714/5	C8 <LOQC8 93-98 C10 <LOQC10 93-101 C12 97-99 97-101 C14 89-99 94-103 C16 <LOQC16 78-87 C18 <LOQC18 75-88 C18un <LOQC18un 87-93	C8 <LOQC8 95 C10 <LOQC10 96 C12 98 99 C14 93 96 C16 <LOQC16 82 C18 <LOQC18 82 C18un <LOQC18un 90	C8 - 2.0 C10 - 3.1 C12 1.0 1.4 C14 4.1 4.0 C16 - 3.9 C18 - 5.9 C18un - 2.0	0.05 mg/kg (lowest fortification level as total TMAC) For individual constituents LOQC8, LOQC10, LOQC12, LOQC14, LOQC16, LOQC18 and LOQC18un = 0.00714 mg/kg	Combined CAR ATMAC-TMAC Doc IIA, Soil, 04/2016

Analytical methods for ATMAC/TMAC in soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
	284→57 C18 m/z 312→60; m/z 312→57 C18un m/z 310→60; m/z 310→69			Confirmatory method C8 0.00714/5 0.0714/5 C10 0.00714/5 0.0714/5 C12 0.00714/5 0.0714/5 C14 0.00714/5 0.0714/5 C16 0.00714/5 0.0714/5 C18 0.00714/5 0.0714/5 C18un 0.00714/5 0.0714/5	C8 <LOQC8 90-103 C10 <LOQC10 94-102 C12 92-100 98-100 C14 92-98 93-101 C16 <LOQC16 81-88 C18 <LOQC18 76-92 C18un <LOQC18un 88-95	C8 <LOQC8 95 C10 <LOQC10 98 C12 95 99 C14 95 95 C16 <LOQC16 85 C18 <LOQC18 81 C18un <LOQC18un 90	C8 - 5.3 C10 - 3.2 C12 3.5 1.0 C14 2.5 3.8 C16 - 3.8 C18 - 8.0 C18un - 3.0		

Analytical methods for ATMAC/TMAC in soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
ATMAC (active substance) determined as C12	LC-MS, ESI+, m/z 228.3	no confirmation included, since validation data for a single fragment ion	0.002 – 0.2 mg/kg R2 = 0.9997	clay loam 0.01/5 0.1/5 sandy loam 0.01/5 0.1/5	 81-93 77-99 82-98 80-101	 85 86 90 88	 5.9 9.5 8.1 10.7	0.1 mg/kg	CAR DocIIIA ATMAC, 4.2a(1); 01/2014 Brewin, 2004

Table 23:

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**		

Table 24

Analytical methods for ATMAC/TMAC in surface water									
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**		
TMAC (active substance) determined as C8, C10, C12, C14, C16, C18, unsaturated C18	LC-MS/MS, C18, ESI+ C8 m/z 172→60; m/z 172→57 C10 m/z 200→60; m/z 200→57 C12 m/z 228→60; m/z 228→57 C14 m/z 256→60; m/z 256→57 C16 m/z 284→60; m/z	included by second MS/MS transition	0.01 – 1.04 µg/L (total C8-C18un) R²: 0.999068 – 0.999961	Primary method C8 0.014/5 0.14/5 C10 0.014/5 0.14/5 C12 0.014/5 0.14/5 C14 0.014/5 0.14/5 C16 0.014/5 0.14/5 C18 0.014/5 0.14/5 C18un 0.014/5 0.14/5	 C8 <LOQC8 76-84 C10 <LOQC10 80-89 C12 81-82 84-94 C14 80-82 83-94 C16 <LOQC16 73-80 C18 <LOQC18 68-79 C18un <LOQC18un 67-78	 C8 <LOQC8 81 C10 <LOQC10 85 C12 82 89 C14 81 88 C16 <LOQC16 77 C18 <LOQC18 72 C18un <LOQC18un 71	 C8 - 5.0 C10 - 4.8 C12 0.8 4.8 C14 1.0 5.1 C16 - 3.6 C18 - 7.2 C18un - 6.4	0.1 µg/L (lowest fortification level as total TMAC) For individual constituents LOQC8, LOQC10, LOQC12, LOQC14, LOQC16, LOQC18 and LOQC18un = 0.014 µg/L	Combined CAR ATMAC-TMAC Doc IIA, Water, 04/2016

Analytical methods for ATMAC/TMAC in surface 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**		
	284→57 C18 m/z 312→60; m/z 312→57 C18un m/z 310→60; m/z 310→69			Confirmatory method C8 0.014/5 0.14/5 C10 0.014/5 0.14/5 C12 0.014/5 0.14/5 C14 0.014/5 0.14/5 C16 0.014/5 0.14/5 C18 0.014/5 0.14/5 C18un 0.014/5 0.14/5	C8 <LOQC8 76-85 C10 <LOQC10 78-90 C12 79-83 84-95 C14 79-83 83-93 C16 <LOQC16 75-82 C18 <LOQC18 68-79 C18un <LOQC18un 69-77	C8 <LOQC8 82 C10 <LOQC10 84 C12 82 89 C14 94 88 C16 <LOQC16 79 C18 <LOQC18 74 C18un <LOQC18un 73	C8 - 4.2 C10 - 5.3 C12 2.1 5.2 C14 2.4 4.7 C16 - 3.8 C18 - 7.2 C18un - 4.6		

Analytical methods for ATMAC/TMAC in surface 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**		
ATMAC (active substance) determined as C12	LC-MS, ESI+, m/z 228.3	no confirmation included, since validation data for a single fragment ion	0.01 – 0.5 µg/L R2 = 0.9986	surface water C12 0.01/5 0.1/5	 75-106 81-107	 97 92	 13.0 13.9	0.1 µg/L	CAR DocIIIA ATMAC, 4.2c(1); 01/2014 Brewin, 2004

Table 25

Data waiving was acceptable for the following information requirements	
Information requirement	1. 5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product 2. 5.2.2. Air: Data waving was accepted for residues of of ATMAC/TMAC. No relevant quantities of inhalable particles (far below the reference value) are to be expected during processing of the b.p., so that appropriate analysis methods for the a.s. are dispensed with. 3. 5.2.4 Body fluids and tissues: Data waving was accepted for propiconazole, tebuconazole and ATMAC/TMAC. 4. 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 for propiconazole, tebuconazole and ATMAC/TMAC.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 26

Conclusion on the methods for detection and identification
The methods provided regarding the active substances, residues and substances of concern were acceptable The methods provided regarding the residues of the active substances propiconazole, tebuconazole, and ATMAC/TMAC were acceptable. Methods regarding residues of substances of concern were not necessary.

3.5 Efficacy against target organisms

3.5.1 Function and field of use

Wolsit F-15T is used for preventive protection of wood composites, e.g. plywood, oriented strand board (OSB), and particle board, for use in use-class (UC) 2 and UC 3.1 against attack by wood destroying basidiomycetes. Treated plywood always needs to be coated with a phenolic resin.

The application process involves industrial adding of the preservative to the resin binder (glue). For OSB, and particle 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, the preservative is added to the glue line 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 wood layers, respectively.

The ready to use Wolsit F-15T contains 7.5 % Tebuconazole, 7.5 % Propiconazole, 0.105 % ATMAC/TMAC and is added to the resin binder (glue) to finally achieve a 0.75 % to 0.8 % effective concentration of the wood preservative resulting in effective concentrations of active ingredients ranging from 0.0375 % Tebuconazole, 0.0375 % Propiconazole, 0.00053 % ATMAC/TMAC to 0.06 % Tebuconazole, 0.06 % Propiconazole, 0.00084 % ATMAC/TMAC.

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

Wolsit F-15T is a ready for use formulation and is effective against wood destroying basidiomycetes (brown rot and white rot). Wolsit F-15T is suitable for use in UC 2 and UC 3.1. The product is for use as binder (glue) additive for wood composites (e.g. plywood, OSB, and other particle boards).

3.5.3 Effects on target organisms, including unacceptable suffering

Wolsit F-15T protects derived timber products for Use Class 2 (OSB, particle board and plywood coated with a phenolic resin) and 3.1 (plywood coated with a phenolic resin) from infestation of brown rot fungi and white rot fungi, respectively, like for instance the basidiomycetes *Coniophora puteana*, *Pleurotus ostreatus*, *Trametes versicolor*, or *Gloeophyllum trabeum*.

Unacceptable suffering does not apply.

3.5.4 Mode of action, including time delay

Tebuconazole and Propiconazole
Tebuconazole and Propiconazole inhibit in the ergosterol biosynthesis of fungi, thus prohibiting formation of cell walls.

ATMAC/TMAC
ATMAC/TMAC is a quaternary ammonium compound which acts by disruption and leakage of the membranes, leading to cell damage or lysis of the cell content.

3.5.5 Efficacy data

Efficacy of Wolsit F-15T is supported by four key studies (two on OSB and two on coated plywood) following the protocol of DIN V ENV 12038:2002 for wood based panels. Standard protocols were performed in combination with accelerated aging according to DIN EN 84:1997 (leaching) and DIN EN 73:2014 (evaporation) according to efficacy testing requirements for UC 3.1 (also covering UC 2).

According to test report “B 2767b”, industrially manufactured beech plywood containing 0.039 % Tebuconazole, 0.035 % Propiconazole, and 0.0005 % ATMAC/TMAC (formulated as Wolsit F-15T) in the resin binder was protected against wood destroying brown and white rot fungi with average mass losses of below 3 % and with no individual mass loss of greater than 3 %. These active substance concentrations correspond to 3.65 kg Wolsit F-15T /m³ of treated plywood (calculation based on Tebuconazole content). Therefore, the minimum authorised application rate for plywood is set to 3.65 kg/m³ instead of 3 kg/m³ as intended by the applicant.
Furthermore, ENV 12038:2002 describes in section 5.1.1.1 that the test organisms *C. puteana* and *P. ostreatus* are mandatory test organisms in any case, while *T. versicolor* must be tested for wood composites made of pure hardwood and *G. trabeum* must be tested for wood composites made of pure softwood. For mixed wood composites, both additional organisms have to be tested. In test report “B 2767b” only *C. puteana*, *P. ostreatus* and *T. versicolor* were tested and no data are available for efficacy against *G. trabeum* on plywood. Therefore, use of Wolsit F-15T for protection of plywood can only be authorised for plywood made of hardwood only.
Additionally, the tested plywood pieces were coated with a phenol-formaldehyde resin (PFR). As it is likely that a PFR resin coating prevents or slows down fungal attack from the coated surfaces of the test item, passing ENV 12038:2002 with PFR-coated plywood is likely easier than passing with uncoated plywood. As no data is available for uncoated plywood, use of Wolsit F-15T is restricted to plywood coated with phenolic resins both in UC 2 and 3.1.

According to test report “B 2767a”, industrially manufactured OSB-panel Type OS´Brace H3.1 containing 0.048 % Tebuconazole, 0.045 % Propiconazole, and 0.0006 % ATMAC/TMAC (formulated

as Wolsit F-15T) in the glue line was protective against wood destroying brown fungi with average mass losses of below 3 % and with only one individual mass loss greater than 3 % but less than 5 % after leaching (EN 84) and evaporation (EN 73), respectively. These active substance concentrations correspond to 0.64 % Wolsit F-15T /m³ of treated plywood (calculation based on Tebuconazole content). Consequently, the minimum authorised dose is restricted to 0.64 % Wolsit F-15T in the final treated article (OSB), which corresponds to a minimum of 0.75 % Wolsit F-15T relative to oven-dry wood chips used for manufacture.

Furthermore, ENV 12038:2002 describes in section 5.1.1.1 that the test organisms *C. puteana* and *P. ostreatus* are mandatory test organisms in any case, while *T. versicolor* must be tested for wood composites made of pure hardwood and *G. trabeum* must be tested for wood composites made of pure softwood. For mixed wood composites, both additional organisms have to be tested. In test report “B 2767a” only *C. puteana*, *P. ostreatus* and *G. trabeum* were tested and no data are available for efficacy against *T. versicolor* on OSB. Therefore, use of Wolsit F-15T for protection of OSB is restricted to softwood OSB only.

Table 27

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**
Fungicide; Preventive effectiveness against wood destroying basidiomycetes	Wood preservative in use class 2 and 3.1	Wolsit F-15T Tebuconazol 0.048 %; Propiconazole 0.045 %; ATMAC/TMAC 0.0006 % Corresponds to 0.64 % Wolsit F-15T in the OSB composites	*Coniophora puteana* (BAM Ebw. 15); *Pleurotus ostreatus* (FPRL 40 c) HFA 58; *Gloeophyllum trabeum* (BAM Ebw. 109)	DIN V ENV 12038 EN 84 EN 73	**Laboratory method** samples of OSB (3 replicates) **Treatment:** resin binder additive **Ageing** according to EN 84 and EN 73, resectively; **Test period** 16 weeks biotest; **Results** no average mass loss greater than 3 % (only one individual mass loss greater than 3 % but below 5 % in each of EN 84 and EN 73 test series.	Effective prevention of fungal attack at 0.64 % Wolsit F-15T in resin binder	Möller und Chemnitzer 2017 B 2767a

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**
Fungicide; Preventive effectiveness against wood destroying basidiomycetes	Wood preservative in use class 2 and 3.1	Wolsit F-15T Tebuconazol 0.039 %; Propiconazole 0.035 %; ATMAC/TMAC 0.0005 % Corresponds to 3.65 kg Wolsit F-15T / m³ plywood	*Coniophora puteana* (BAM Ebw. 15); *Pleurotus ostreatus* (FPRL 40 c) HFA 58; *Trametes versicolor (*syn. *Coriolus versicolor)* (CTB 863A)	DIN V ENV 12038 EN 84 EN 73	**Laboratory method** samples of beech plywood coated with PFR (3 replicates) **Treatment:** glue line additive **Ageing** according to EN 84 and EN 73, resectively; **Test period** 16 weeks biotest; **Results** no average mass loss greater than 3 % and no individual mass loss greater than 3 %.	Effective prevention of fungal attack at 0.5 % (3.65 kg/m³) Wolsit F-15T in glue line	Möller und Chemnitzer 2018 B2767b

3.5.6 Occurrence of resistance and resistance management

As other triazole fungicides Propiconazol and Tebuconazol inhibit the C 14 demethylation step in the ergosterol biosynthesis of fungi. All demethylation inhibitors have a similar resistance risk but resistance factors may be different. Resistance of target organisms to Propiconazol and Tebuconazol is not officially reported for wood preservatives. Triazoles in plant protection products should be strictly used according to the Fungicide Resistance Action Committee (FRAC) guidelines. However, there are no specific resistance prevention measures for biocides identified. It is therefore only recommended to pay attention to prevention of the evolution of tolerant fungal strains and report to the authorisation holder any new information on development of fungal resistance to Propiconazol and Tebuconazol.
ATMAC/TMAC is a quarternary ammonium compound and targets cell walls and membranes. In the context of Wolsit F-15T, it is likely to have little activity of its own, due to its low in-use concentration, and probably improves efficacy of the triazole fungicides by increasing membrane permeability.
Due to the specific application fields, the nature of the target organisms and the frequency of treatment it is unlikely that resistance to Wolsit F-15T will be developed by the target organisms in a short time.

3.5.7 Known limitations

Wolsit F-15T can only be used for treatment of plywood made of hardwood and OSB or particle boards made of softwood. Plywood treated with Wolsit F-15T always needs to be coated with a phenolic resin. Please also refer to section 3.5.5.

3.5.8 Evaluation of the label claims

Ready to use Wolsit F-15T protects phenolic resin-coated plywood from attack by wood destroying basidiomycetes in UC 2 and UC 3.1 when applied at 3.65 kg/m³ in the glue line.
Ready to use Wolsit F-15T protects OSB from attack by wood destroying basidiomycetes in UC 2 when applied at min. of 0.64 % relative to the finished product in the resin binder (0.75 % relative to oven-dry wood chips).

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

No other use of biocidal products envisaged.

3.5.10 Data waiving and conclusion

No data waiving

Table 28

Conclusion on the efficacy
Ready to use Wolsit F-15T protects hardwood plywood coated with phenolic resins from attack by wood destroying basidiomycetes in UC 2 and UC 3.1 when applied at 3.65 – 4.5 kg product /m³ wood composite in the glue line. Ready to use Wolsit F-15T protects softwood OSB from attack by wood destroying basidiomycetes in UC 2 when applied at min. of 0.64 % in the resin binder (0.75 % relative to oven-dry wood chips).

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 29

Tebuconazole	Value	Study	Safety factor
AEL long-term	0.03 mg/kg bw/d [1]	1-yr dog; Porter et al. (1989 & 1993)	100
AEL medium-term	0.03 mg/kg bw/d [1]	1-yr dog; Porter et al. (1989 & 1993)	100
AEL acute	0.03 mg/kg bw [1]	Developmental mice; Renhof (1988)	300

[1] Based on Assessment-Report for PT 07 (Denmark (2013)

Table 30

Tebuconazole	Value	Reference
Inhalative absorption	100 %	Default value
Oral absorption	100 % [1]	CAR PT 07 (DK, 2013)
Dermal absorption	25 % - concentrate 70 % - application liquid	Default value (EFSA Guidance, 2017)

[1] Based on Assessment-Report for PT 07 (Denmark (2013),

Table 31

Propiconazole	Value	Study	Safety factor
AEL long-term	0.04 mg/kg bw/d [1]	Chronic rat study; Hunter et al., (1982)	100
AEL medium-term	0.08 mg/kg bw/d [1]	2-generation rat study; Borders et al. (1985)	100
AEL acute	0.3 mg/kg bw/day [1]	Developmental study rat; Marcsisin et al. (1987)	100

[1] Based on Assessment-Report for PT 7 (Finland, 2015)

Table 32

Propiconazole	Value	Reference
Inhalative absorption	100 %	Default value
Oral absorption	86 % [1] (100 % for calculation)	Cresswell and Hopkins 1989; Hambock and Maier 1979, Bissig and Maier 1992
Dermal absorption	25 % - concentrate 70 % - application liquid	Default value (EFSA Guidance, 2017)

[1] Based on Assessment-Report for PT 7 (Finland, 2015)

Table 33

ATMAC/TMAC	Value	Study	Safety factor
AEL long-term	Not relevant	Assessment Report (RMS Italy (2016))	-
AEL medium-term	Not relevant	Assessment Report (RMS Italy (2016))	-
AEL acute	Not relevant	Assessment Report (RMS Italy (2016))	-
Local effects			
Dermal NOAEC	0.3 %	2-week skin irritation study with rats, ATMAC/TMAC Assessment Report (RMS Italy (2016))	-
Oral NOAEC	0.03 %	52-week oral gavage study in dogs, ATMAC/TMAC Assessment Report (RMS Italy (2016))	-

Table 34

ATMAC/TMAC	Value	Reference
Inhalative absorption	Inhalation of ATMAC is not considered a potential route of exposure based on use patterns and vapour pressure (1.8 x 10-6 Pa, 20°C).	Assessment Report (RMS Italy (2016))
Oral absorption	It is expected that its oral absorption is limited (around 10 % at non-corrosive concentrations) and that the majority (90 %) of orally administered a.s. is excreted unabsorbed via the faeces.	**ATMAC** Assessment Report (RMS Italy (2016))
Oral absorption	TMAC: ≥ 3.3 % (based on 1.22 % excreted by urine and 2 % in bile). Supporting data. DDAC and C12-16-BKC: 10 %, based the urinary and biliary excretion mean values (3-4 % with a single peak value = 8.3 % and 3.7-4.6 %, respectively as worst case values), in the absence of residues in the carcass.	**TMAC** Assessment Report (RMS Italy (2016))
Dermal absorption	No value derived	For this product

3.6.2 Assessment of effects of the product on human health

3.6.2.1 Skin corrosion and irritation

Table 35

Data waiving was acceptable for the following information requirements	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	Studies on potential skin corrosive or skin irritating properties of the biocidal product are not available and are not required.

Data waiving was acceptable for the following information requirements	
	According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “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 (CLP), and synergistic effects between any of the components are not expected.” The composition of the biocidal product is known (including the identity of the co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components (e.g. surfactants). Additionally, information on the physico-chemical properties of the biocidal product (e.g. pH) are available. Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 36

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to the skin.
Justification for the value/conclusion	Based on the calculation method considering the relevant concentrations of the components classified as Skin Corr. 1, H314 and Skin Irrit. 2, H315, classification of the biocidal product is not required.
Classification of the product according to CLP	Classification for skin corrosion or skin irritation is not required.

3.6.2.2 Eye irritation

Table 37

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	Studies on potential eye irritating properties of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “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 (CLP), and synergistic effects between any of the components are not expected.” The composition of the biocidal product is known (including the identity of the co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components (e.g. surfactants). Additionally, information on the physico-chemical properties of the biocidal product (e.g. pH) are available. Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 38

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Damaging to the eye.
Justification for the value/conclusion	The active substance ATMAC/TMAC and one co-formulant are classified for causing serious eye damage. For details refer to the Confidential Annex.
Classification of the product according to CLP	Classification with Eye Dam. 1, H318 is required.

3.6.2.3 Respiratory tract irritation

Table 39

Data waiving was acceptable for the following information requirements	
Information requirement	8.10. Other tests
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.

Table 40

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the value/conclusion	The biocidal product does not contain components in relevant concentrations classified for respiratory tract irritation.
Classification of the product according to CLP	Classification for respiratory tract irritation is not required.

3.6.2.4 Skin sensitisation

Table 42

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 available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "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 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known (including the identity of the co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components (e.g. surfactants).

	Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 41

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Sensitising to the skin.
Justification for the value/conclusion	The biocidal product contains 7.89 % (w/w) of the active substance propiconazole (CAS-No. 60207-90-1), classified with Skin Sens. 1, H317. Hence, classification of the biocidal product with Skin Sens.1, H317 according to Regulation (EC) No 1272/2008 is necessary due to the generic concentration limit of 1 % (w/w).
Classification of the product according to CLP	Classification with Skin Sens. 1, H317 is required.

3.6.2.5 Respiratory sensitisation (ADS)

Table 42

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 43

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory tract.
Justification for the value/conclusion	The biocidal product does not contain any components that are known to have sensitising properties for the respiratory tract. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 44

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.1. By oral route
Justification	Studies on potential acute toxicity by oral route of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “testing on the product/mixture does not need to be conducted if: there are valid

Data waiving was acceptable for the following information requirements	
	data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known (including the identity of the most co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Table 45

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} (oral) = 984 mg/kg bw
Justification for the selected value	The LD_{50} (oral) is calculated from the acute dermal toxicty data of the single components. All three active substances as well as 2 co-formulants are classified for acute oral toxicity. For details refer to the Confidential Annex.
Classification of the product according to CLP	Classification with Acute Tox. 4, H302 is required.

3.6.2.6.2 Acute toxicity by inhalation

Table 46

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	Studies on potential acute toxicity by inhalation route of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "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 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known (including the identity of the most co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Table 47

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC_{50} (inhalation): > 5 mg/L

Value used in the Risk Assessment – Acute inhalation toxicity	
Justification for the selected value	The LC_{50} (inhalation) is calculated from the acute inhalation toxicty data of the single components. One co-formulant is classified for acute inhalation toxicity. However, its concentration is not sufficient for classification. For details refer to the Confidential Annex.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required.

3.6.2.6.3 Acute toxicity by dermal route

Table 48

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.3. By dermal route
Justification	Studies on potential acute toxicity by dermal route of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "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 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known (including the identity of the most co-formulants). Based on safety data sheets and other information for each of the individual components in the biocidal product, sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components. Consequently, classification of the mixture was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Table 49

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} (dermal): > 2000 mg/kg bw
Justification for the selected value	The LD_{50} (dermal) is calculated from the acute dermal toxicty data of the single components. One of the active substances is classified for acute dermal toxicity. However, its concentration is not sufficient for classification. For details refer to the Confidential Annex.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

3.6.2.7 Information on dermal absorption

Table 50

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	In the absence of reliable dermal absorption data, default values according to EFSA Guidance on Dermal Absorption (2012 or 2017) can be applied.

Table 51

Value(s) used in the Risk Assessment – Dermal absorption				
Substance exposure scenario(s) (e.g. undiluted formulation or 1:100 in-use dilution, etc.)	ATMAC/TMAC	Tebuconazole Propiconazole Concentrate	Tebuconazole Propiconazole Application liquid	Secondary exposure
Value(s)	-	25 %	70 %	70 %
Justification for the selected value(s)	For ATMAC/TMAC a dermal absorption value is not required. According to the CAR only local effects are relevant. Hence, a systemic exposure and risk assessment requiring a dermal absorption value for this active substance is not performed.	Default for organic solvent-based formulations (c > 5 %) according to EFSA Guidance on Dermal Absorption (2017).	Default for organic solvent-based formulations (c ≤ 5 %) according to EFSA Guidance on Dermal Absorption (2017).	Default for organic solvent-based formulations (c ≤ 5 %) according to EFSA Guidance on Dermal Absorption (2017).

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

3.6.2.8.1 Benzyl alcohol (CAS-No. 100-51-6)

Classification	
Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)	Acute Tox. 4 H302 H332

3.6.2.8.2 Isotridecanol, ethoxylated (CAS-No. 69011-36-5)

Classification		
Notified classification and labelling according to CLP criteria	Acute Tox. 4 Eye Dam. 1	H302 H318

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

Refer to the Confidential Annex.

3.6.2.10 Available toxicological data relating to a mixture

Reproductive toxicity

The biocidal product contains 7.89 % (w/w) of the active substance propiconazole, classified with Repr. 1B, H360D. Based on the generic concentration limit of 0.3 % (w/w), the biocidal product is classified with Repr. 1B, H360D according to Regulation (EC) No 1272/2008 (13th ATP).

The biocidal product also contains 7.81 % (w/w) of the active substance tebuconazole, classified with Repr. 2, H361d. Based on the generic concentration limit of 3 % (w/w), the biocidal product is classified with Repr. 2, H361d according to Regulation (EC) No 1272/2008.

In conclusion, classification with Repr. 1B, H360D is required.

3.6.2.11 Other

Not available.

3.6.2.12 Endocrine disrupting properties

Based on the information available from ECHA databases (e.g. SVHC-candidate list) there are no indications for endocrine disrupting properties of the co-formulants in the biocidal product and of the active substance ATMAC/TMAC.

However, the active substances propiconazole and tebuconazole are classified with Repr. 1B (H360D) and Repr. 2 (H360d), respectively. Propiconazole is undergoing an ED assessment under Regulation (EU) No 528/2012 (BPR). No suggestion has been made yet.

3.6.2.13 Summary of effects assessment

Table 52

Endpoint	Brief description
Skin corrosion and irritation	Based on the available toxicological information for the single components, the biocidal product is not classified for skin corrosion and irritation.
Eye irritation	Based on the available toxicological information for the single components, the biocidal product is classified with Eye Dam. 1, H318. Refer to the Confidential Annex.
Respiratory tract irritation	Based on the available toxicological information for the single components, the biocidal product is not classified for respiratory tract irritation.
Skin sensitisation	Based on the available toxicological information for the single components, the biocidal product is classified with Skin Sens. 1, H317.

Endpoint	Brief description
Respiratory sensitization (ADS)	Based on the available toxicological information for the single components, the biocidal product is not classified for respiratory sensitisation.
Acute toxicity by oral route	Based on the available toxicological information for the single components, the biocidal product is classified with Acute Tox. 4, H302. Refer to the Confidential Annex.
Acute toxicity by inhalation	Based on the available toxicological information for the single components, the biocidal product is not classified for acute inhalation toxicity. Refer to the Confidential Annex.
Acute toxicity by dermal route	Based on the available toxicological information for the single components, the biocidal product is not classified for acute dermal toxicity. Refer to the Confidential Annex.
Information on dermal absorption	Tebuconazole and propiconazole: 25 % for concentrated biocidal product (Default EFSA Guidance, 2017) 70 % for application liquid (Default EFSA Guidance, 2017) 70 % for secondary exposure (Default EFSA Guidance, 2017)
Available toxicological data relating to non-active substance(s)	Refer to the Confidential Annex.
Available toxicological data relating to a mixture	Based on the available toxicological information for the single components, the biocidal product is classified with Repr. 1B, H360D.
Other relevant information	Not available.

3.6.3 Exposure assessment

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

Table 53

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	Yes	N.a.	Not relevant	Yes	Yes	Yes	N.a.
Dermal	Yes	N.a.	Not relevant	Yes	Yes	Yes	N.a.
Oral	N.a.	N.a.	Not relevant	N.a.	N.a.	Yes	No

List of scenarios

Table 54

Summary table: scenarios			
Scenario number	**Scenario (e.g. mixing/ loading)**	**Primary or secondary exposure Description of scenario**	**Exposed group (e.g. professionals, non-professionals, bystanders)**

1	Connecting transfer lines (automated transfer)	Primary exposure of workers resulting from loading of the b.p. to the processing plant, all steps being part of a fully automated manufacturing spray process in a closed system (use 1 as intended by the applicant – Glue-line treatment (closed system)).	Industrial user
2	Deluge treatment	Primary exposure of workers resulting from deluge processes (rolling/flow-coating) in industrial scale treatment units including relevant steps of a semi-closed system (use 2 as intended by the applicant – Glue-line treatment (semi-closed system)).	Industrial user
3	Secondary exposure: Mechanical processing of treated wood	Secondary exposure of workers resulting from mechanical processing of treated wood, e.g. sawing or sanding.	Industrial/professional user
4	Post application	Secondary acute exposure, adult - sanding treated wood, inhalation and dermal exposure	General public
5	Post application	Secondary acute exposure, toddler – chewing/mouthing treated wood off-cut, oral exposure	General public
6	Post application	Secondary long-term exposure, toddler - inhalation of volatilised residues indoors, inhalation exposure	General public
7	Post application	Secondary long-term exposure, toddler - playing on treated structure and mouthing of hands, dermal and oral exposure	General public

3.6.3.1.1 Industrial exposure

For a detailed description on this scenario, please see chapter 3.6.3.1.2.

3.6.3.1.2 Professional exposure

Wolsit F-15T is a liquid wood preservative. It is processed in a closed system by spraying and in a semi-closed system by rolling/flow-coating during the manufacturing process of plywood -, particle -, OSB panels. Since spraying of the biocidal product takes place in a closed system, only for mixing and loading an exposure assessment has to be considered (exposure scenario: Mixing with glue and mortar, according to HEAdhoc Recommendation no. 6, version 3; see scenario 1: Connecting transfer lines (automated transfer)).
The applicant described a second application in a semi-closed system. Rolling/flow-coating during the manufacturing process of plywood -, particle -, OSB panels is carried out in a semi-closed system, which corresponds to the scenario "Professional deluging", according to HEAdhoc Recommendation no. 6 (Version 3; see scenario 2: Deluge treatment). Exposure is carried out based on the described scenarios.
In addition, secondary exposure of workers resulting from mechanical processing of treated wood, e.g. sawing or sanding, has to be considered for risk assessment (see scenario 3: Secondary exposure: Mechanical processing of treated wood).

Wolsit F-15T is a ready-to-use wood preservative containing *Propiconazole* (CAS-No.: 60207-90-1, 7.89 %), *Tebuconazole* (CAS-No.: 107534-96-3, 7.81 %) and *Quaternary ammonium compounds, coco alkyltrimethyl, chlorides* (CAS-No.: 61789-18-2, 0.1 %). A semi-quantitative assessment was carried out for *Quaternary ammonium compounds, coco alkyltrimethyl, chlorides*. In addition, the product contains SoC (*Benzyl alcohol* and *Isotridecanol, ethoxylated)* that are not relevant for the quantitative exposure assessment. For details, see chapter 3.6.4.5

The biocidal product is marketed in different package sizes:

- Jerry can, plastic: HDPE 30 L
- IBC, plastic: HDPE 1000 L

The exposure to the a.s. are assessed separately for the different application techniques and will thus be described in individual subsections of the current section. It is usually based on the harmonised document "Biocides Human Health Exposure methodology (BHHEM, October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated where relevant with the corresponding parts from HEEG/HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007.
Due to the local effects resulting from the b.p., a qualitative risk assessment for professional/industrial users is performed. The qualitative risk assessment is described in Chapter 3.6.4.5.
In Annex 4.3.1the details of the exposure calculations to the a.s. for the professional user are laid out.

- **Scenario 1 – Connecting transfer lines (automated transfer)**

Description

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

Wolsit F-15T is a ready-to-use product. It is transferred via hoses to the processing plant (loading phase). In either case, during this process workers are only present for supervision. A direct contact to the wood preservative is only expected during the connection of the transfer lines to the processing plant (loading phase).

The application of the wood preservative is integrated in a fully automatic manufacturing process.

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 automated process is assumed for the cleaning process.

Exposure by inhalation
The technical requirements and installations minimise the amount of the respirable fraction of the b.p. Therefore, inhalation exposure to aerosols is not expected.

Table 55

Details of Scenario 1	
Parameters	Value
Concentration of a.s. *Propiconazole* in b.p.	7.89 %
Concentration of a.s. *Tebuconazole* in b.p.	7.81 %
Concentration of b.p. in application liquid	100 %
Density of the b.p.	1.065 g/cm³ (20 °C)

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 58.
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 3.6.4.5.

Further information and considerations

The classification of the b.p. requires additional assessment of local risks (see chapter 3.6.4.5). Local risk assessment has indicated a risk for eye damages, thus eye protection is required. For all relevant risk mitigation measures see chapter 2.5.2.

- **Scenario 2 – Deluge treatment**

Description

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

Wolsit F-15T is a concentrated wood preservative.

For deluge treatment, it is pumped into the semi-closed processing plant. The operator connects the transfer lines to the dosing system.

During application, timber is passed through the semi-closed processing plant in which the wood preservative is applied from various types of spray jets/rollers. The biocidal product is diluted directly in the processing plant to the application concentration, processing of the concentrate is not intended. It is assumed that there is manual contact with the treated wood during or after processing (e.g. manually lifting onto the deposit station for drying or restacking of treated wood).

Dermal exposure

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

Exposure to hands is expected for the loading phase during connecting transfer lines from the package to the automatic dosing system. An appropriate model is recommended by Human Exposure Expert Group (HEEG) and is used to calculate the hand exposure. This phase has a minor impact on the total dermal exposure.

The application phase covers different steps of manual handling: handling treated timber coming out of the semi-closed processing plant (restacking of treated wood or placing treated wood on the deposit station. Exposure to hand and body is considered to occur. There is no generic model data available for the deluge treatment, however “Dipping model 1” (TNsG on Human Exposure) is used because the tasks described in this model most accurately reflect the procedures listed above. The model provides measurement data of potential body and actual hand exposure (measurements of hand exposure inside gloves). 60 min per day are taken into account for the deluge treatment, including cleaning. This is based

on experience of the reference member state collected during an onsite visit of a deluge treatment plant and on the assumption that much more treated wood is handled for deluge treatment than for manual dipping; furthermore this approach is in accordance with the *Biocides Human Health Exposure methodology document* (October 2015, version 1). The application process significantly contributes to the total dermal exposure.

Exposure by inhalation

Exposure to aerosols cannot be excluded for the worker operating next to the semi-closed processing plant. Therefore, inhalation exposure to aerosols has been calculated for the application phase using indicative values of “Dipping model 1”. Exposure to aerosols during loading and post-application are not expected to occur.

Table 56

Details of Scenario 2	
Parameters	Value
Concentration of a.s. *Propiconazole* in b.p.	7.89 %
Concentration of a.s. *Tebuconazole* in b.p.	7.81 %
Concentration of b.p. in application liquid	3.95 %
Concentration of a.s. *Propiconazole* in application liquid	0.31%
Concentration of a.s. *Tebuconazole* in application liquid	0.31%
Density of the b.p.	1.065 g/cm³ (20 °C)

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in table Table 58.
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 3.6.4.5.

Further information and considerations

The classification of the b.p. require additional assessment of local risks (see chapter 3.6.4.5). Local risk assessment has indicated a risk for eye damages, thus eye protection is required. For all relevant risk mitigation measures see chapter 2.5.2.

- **Scenario 3 – Secondary exposure: Mechanical processing of treated wood**

Description

Secondary exposure due to mechanical processing of treated wood produced by application via mixing with glue line and mortar cannot be excluded. Therefore, the inhalation exposure to wood dust and dermal exposure during handling of treated wood and resulting from transfer of wood preservative to the skin are estimated here.

Inhalation exposure for mechanical processing of treated wood is assessed taking the limit value for wood dust concentration of 2 mg/m^3 into account - according to the German Hazardous Substances Ordinance “Gefahrstoffverordnung” and the Technical Rules for Hazardous Substances (TRGS 553). For calculation of the concentration of the a.s. within the wood dust, it is assumed that the applied application liquid is distributed within a thin layer at the wood surface. Sanding, as a worst case, releases wood dust created entirely from this layer. The density of the wood is taken from the Technical Agreements for Biocides (TAB, 2016, version 1).

Since the a.s. are not chemically fixed to the wood it cannot be ruled out that the substances can be released when the surface is wet, for instance. Therefore, it is reasonable that during the mechanical processing of treated wood dermal exposure could occur due to transfer of wood preservative to the hand. For exposure assessment, it is assumed that the inner surface of both hands is exposed.

Table 57

Details of Scenario 3	
Parameters	Value
Concentration of a.s. *Propiconazole* in b.p.	7.89 %
Concentration of a.s. *Tebuconazole* in b.p.	7.81 %
Application amount b.p.	75 g/m^2
Concentration b.p. in treated wood surface*	37.5 kg/m^3
Concentration b.p. in treated wood	4.5 kg/m^3
Exposed hand area	410 cm^2
Transfer coefficient	3 %

* assumed penetration depth (outer layer): 0.002 m; expert judgement

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 58.
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 3.6.4.5.

Further information and considerations

The classification of the b.p. require additional assessment of local risks (see chapter 3.6.4.5). Local risk assessment has indicated a risk for eye damages, thus eye protection is required. For all relevant risk mitigation measures see chapter 2.5.2.

- **Summary of professional exposure**

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

Table 58

Summary table: estimated exposure from professional/industrial uses. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.					
Exposure scenario	**Tier/RMM**	**a.s. no. 1: Propiconazole**		**a.s. no. 2: Tebuconazole**	
		Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**	**Estimated external inhalation exposure [mg/m³]**	**Estimated external dermal exposure [mg/day]**
Scenario 1: Connecting transfer lines (automated transfer)	Tier 1: • Automatic dosing system	Not applicable	0.77	Not applicable	0.77
	Tier 2: • Automatic dosing system • Protective gloves (EN 374)	Not applicable	7.73×10^{-2}	Not applicable	7.65×10^{-2}
Scenario 2: Deluge treatment	Tier 1: • Automatic dosing system • Protective gloves (EN 374; included in data used for assessing application phase)	3.90×10^{-4}	38.86	3.86×10^{-4}	38.47
	Tier 2: • Automatic dosing system • Protective gloves (EN 374) • Protective coverall (type 6)	3.90×10^{-4}	8.21	3.86×10^{-4}	8.13
Scenario 3: Mechanical processing of treated wood	Tier 1: • No RMM	1.48×10^{-2}	7.28	1.46×10^{-2}	7.20
	Tier 2: • Protective gloves (EN 374)	1.48×10^{-2}	0.73	1.46×10^{-2}	0.72

- **Combined scenarios**

Please refer to Table 58

3.6.3.1.3 Non-professional exposure

Not relevant. The biocidal product is intended for industrial use only.

3.6.3.1.4 Secondary exposure of the general public

The biocidal product Wolsit F-15T is used with maximum application rates of 4.28 kg/m³ of OSB plates and 4.5 kg/m³ of plywood plates. Hence, the plywood application is considered a worst-case exposure for the risk assessment of the general public.
A systemic exposure and risk assessment is performed for the active substances tebucolazole and propiconazole. For ATMAC/TMAC systemic reference values are not available. The observed systemic effects can be considered secondary in comparison to the local ones. Therefore, the AEL approach is not performed for this substance. A local exposure assessment for ATMAC/TMAC based on the same scenarios as for systemic exposure assessment is performed after the section on systemic exposure assessment.

- **Scenario 4**

Table 59

Description of Scenario 4		
Secondary acute exposure, adult - sanding treated wood, inhalation and dermal exposure The exposure estimates for the general public to the active substances of this biocidal product in treated wood by sanding, is based on the recommendations of the TNsG on Human Exposure (2002). Some parameters have been adapted due to more recent guidances. It is assumed that an adult sands a wooden post with a dimension of 4 cm x 4 cm x 250 cm. It is assumed that the biocidal product is evenly distributed in the treated material. The transfer coefficient and the percentage of the hand getting in contact have not been adopted from the TNsG on Human Exposure (2002), but amended in accordance with the HEAdhoc recommendation No. 5 Non-professional use of antifouling paints: exposure assessment for a toddler (2015). Although these parameters are for exposure of toddlers to antifouling paints, it is expected that they also represent a worst case for adults getting in contact to wood preservatives.		
	Parameters	Value
Tier 1	Application rate (applicant)	4500 g/m³
	Concentration a.s. (applicant)	Tebuconazole: 7.81 % (w/w) Propiconazole: 7.89 % (w/w)
	Dimension of wooden post to be sanded (TNsG on Human Exposure (2002) Part 3)	4 cm x 4 cm x 250 cm = 4000 cm³
	Volume of wood treated with biocidal product (biocidal product is evenly distributed in the whole wood) (TNsG on Human Exposure (2002) Part 3)	4000 cm³

	Concentration a.s. in the treated wood: (application rate x density x concentration a.s. in the b.p.)	Tebuconazole: 0.35145 mg a.s./cm^3 Propiconazole: 0.35505 mg a.s./cm^3
	Hand inner surface (both hands), adult (HEAdhoc recommendation No.14, 2017), half of both hands	410 cm^2
	Percentage of hand surface getting in contact to the biocidal product (HEAdhoc recommendation No. 5, 2015)	40 %
	Transfer coefficient, rough sawn wood, dried fluid (Biocides Human Health Exposure Methodology, 2015 and HEAdhoc recommendation No. 5, 2015)	3 %
	Dermal absorption (default for all a.s., EFSA Guidance on Dermal Absorption, 2017)	70 %
	Body weight, adult (HEAdhoc recommendation No.14, 2017)	60 kg
	Wood dust concentration in the air during sanding (EU, OEL, 2004)	5 mg/m^3
	Exposure duration (TNsG on Human Exposure (2002) part 3)	1 h
	Inhalation rate adult, short-term (HEEG opinion No. 17, 2013)	1.25 m^3/h
	Wood density (MOTA, 2013 from TM III, 2008)	0.4 g/cm^3
	Inhalation absorption (default for a.s., CAR of all a.s.)	100 %

Calculations for Scenario 4 – Tier 1

Systemic exposure

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

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

Tebuconazole

$Exposure_{dermal}$ = 0.35145 mg a.s./cm^3 x 410 cm^2 x 40 % x 3 % x 70 % / 60 kg

= 0.020173 mg a.s./kg bw

$Exposure_{inhalation}$ = 0.35145 mg a.s./cm^3 x (5 mg/m^3 / 0.4 g/cm^3) x 1 h x 1.25 m^3/h / 60 kg

= 0.000092 mg a.s./kg bw

Total systemic exposure = 0.02026 mg a.s./kg bw

Propiconazole

$Exposure_{dermal}$ = 0.35505 mg a.s./cm^3 x 410 cm^2 x 40 % x 3 % x 70 % / 60 kg

= 0.02038 mg a.s./kg bw

$Exposure_{inhalation}$ = 0.35505 mg a.s./cm^3 x (5 mg/m^3 / 0.4 g/cm^3) x 1 h x 1.25 m^3/h / 60 kg

= 0.000092 mg a.s./kg bw

Total systemic exposure = 0.02047 mg a.s./kg bw

- **Scenario 5**

Table 60

Description of Scenario 5		
Secondary acute exposure, toddler - chewing treated wood off-cut, oral exposure The exposure estimates are based on the recommendations of the TNsG on Human Exposure (2002) Part 3. It is based on the assumption that a toddler mouthes and chews a piece of wood of 4 cm x 4 cm x 1 cm, which can be considered as 1 cm-off-cut of a wooden post. Following this approach, a human health risk cannot be excluded for tebuconazole. Therefore, exposure assessment was refined for this active substance considering the specific saliva content for calculations. To that purpose, the respective exposure assessment for ATMAC/TMAC was adopted and slightly modified (for details refer to Table 66). It is assumed that the water solubility of tebuconazole is comparable to the solubility of this active substance in saliva, because saliva is consisting of >99 % water. The typical saliva pH ranges from 6.2-7.6, whereas the pH of stimulated saliva is supposed to be >7. Hence, a rounded solubility value of 0.03 g/l for tebuconazole was considered for the calculation (AR tebuconazole PT08, 2007).		
	Parameters	Value
Tier 1	Application rate (applicant)	4500 g/m^3
	Concentration a.s. (applicant)	Tebuconazole: 7.81 % (w/w) Propiconazole: 7.89 % (w/w)
	Concentration a.s. in the treated wood (application rate x density x concentration a.s. in the b.p.)	Tebuconazole: 0.35145 mg a.s./cm^3 Propiconazole: 0.35505 mg a.s./cm^3
	Dimension of the wood off-cut (TNsG Human Exposure to Biocidal Products (2002) Part 3, Infant acute, Chewing wood off-cut)	4 cm x 4 cm x 1 cm = 16 cm^3
	Total amount a.s. in the treated wood off-cut (= a.s. in the treated wood x volume of wood off-cut)[1)]	Tebuconazole: 5.62 mg a.s. Propiconazole: 5.68 mg a.s.
	Extraction coefficient (TNsG Human Exposure to Biocidal Products (2002) Part 3)	10 %

	Oral absorption (CAR/AR, default for all a.s.)	100 %
	Body weight, toddler (HEAdhoc recommendation No.14, 2017)	10 kg
Tier 2 (for tebuconazole only)	Solubility of a.s. in water (AR tebuconazole PT08, 2007)	Tebuconazole: pH 7: 0.029 g/l at 20ºC, rounded to 30 mg /l
	Amount of saliva produced by an infant (stimulated saliva flow) (Watanabe S. et al, 1995, CAR ATMAC/TMAC 2016)	3.6 ml/minute
	Duration of chewing of off-cut (Watanabe S. et al, 1995, CAR ATMAC/TMAC 2016)	1 minute
	Max. attainable concentration of a.s. in saliva (water solubility x amount of saliva produced/ min)	0.108 mg a.s./min

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

Calculations for Scenario 5 – Tier 1

Systemic exposure

$Exposure_{oral}$ = Total amount a.s. in the treated wood off-cut x extraction coefficient x oral absorption / body weight toddler

Tebuconazole

$Exposure_{oral}$ = 5.62 mg a.s. x 10 % x 100 % / 10 kg

= 0.056 mg/kg bw

Propiconazole

$Exposure_{oral}$ = 5.68 mg a.s. x 10 % x 100 % / 10 kg

= 0.057 mg/kg bw

Calculations for Scenario 5 – Tier 2

Tebuconazole

$Exposure_{oral}$ = Concentration a.s. in saliva x oral absorption / body weight toddler

= 0.108 mg x 100 % / 10 kg

= 0.0108 mg/kg bw

- **Scenario 6**

Table 61

Description of Scenario 6		
Secondary long-term exposure, toddler - inhalation of volatilised residues indoors, 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. This exposure assessment for toddlers represents also a worst case for other members of the general public.		
Tier 1	Parameters	Value
	Molecular weight Tebuconazole (CAR/AR, 2008)	307.8 g/mol
	Vapour pressure Tebuconazole (20 °C, CAR/AR, 2008)	0.0000017 Pa
	Molecular weight Propiconazole (CAR/AR, 2008)	342.2 g/mol
	Vapour pressure Propiconazole (25 °C, CAR/AR, 2008)	0.000056 Pa
	Gas constant (Atkins Physical Chemistry, 5th Edition)	8.31451 J/mol/K
	Temperature (assumed room temperature = 20 °C HEEG opinion No. 13, 2011)	293 K
	Saturated vapour pressure (calculated acc. to HEEG opinion No. 13, 2011)	Tebuconazole: 2.148×10^{-4} mg/m³ Propiconazole: 7.866×10^{-3} mg/m³
	Exposure duration (worst case, HEEG opinion No. 13, 2011)	24 h
	Inhalation rate, toddler (HEAdhoc recommendation No.14, 2017, long-term exposure)	8 m³/24 h
	Inhalation absorption (CAR/AR of all a.s., default)	100 %
	Body weight, toddler (HEAdhoc recommendation No.14, 2017)	10 kg

Calculations for Scenario 6 – Tier 1

Systemic exposure

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

Tebuconazole

$Exposure_{inhalation}$ = 2.148×10^{-4} mg/m³ x 8 m³/d x 1 d x 100 % / 10 kg

= 0.0001718 mg a.s./kg bw/d

Propiconazole

$Exposure_{inhalation}$ = 7.866×10^{-3} mg/m³ x 8 m³/d x 1 d x 100 % / 10 kg

= 0.006293 mg a.s./kg bw/d

- **Scenario 7**

Table 62

Description of Scenario 7
Secondary long-term exposure, toddler - playing on treated structure and mouthing, dermal and oral exposure According to the use description provided by the applicant, the biocidal product Wolsit F-15T is intended for the preservative treatment of timber-derived products, such as plywood-, particle- and OSB-panels. These panels are mainly used for exterior cladding of facades and sub-roof, as well as for scaffolding (Use classes 2 and 3.1). According to the applicant, the treated wood is not intended to be used as part of playground structures or other structures, to which the general public has a prolonged contact. Hence, a regular direct contact and exposure of the general public to treated surfaces is very unlikely, if the biocidal product is used as described in the instruction for use. Therefore, assessment of chronic exposure in scenario 7 (Secondary long-term exposure of a toddler playing on treated structures) is considered not relevant. However, in the absence of a relevant risk assessment, the implementation of a respective risk mitigation measure ('Do not use the biocidal product on wood, which is intended to be used as part of playground structures and other indoor/ outdoor structures (e.g. flooring, furniture), to which persons of the general public and pets may have prolonged contact.') is necessary to assure safety of the general public and children in particular.

Table 63 Tebuconazole

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw(/d)]**	**Estimated dermal uptake [mg/kg bw(/d)]**	**Estimated oral uptake [mg/kg bw(/d)]**	**Estimated total uptake [mg/kg bw(/d)]**
Scenario 4	1	0.000092	0.020173	-	0.02026
Scenario 5	1	-	-	0.056	0.056
Scenario 5	2	-	-	0.0108	0.0108
Scenario 6	1	0.0001718	-	-	0.0001718
Scenario 7	1	n.a.	n.a.	n.a.	n.a.

Table 64 Propiconazole

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake [mg/kg bw(/d)]**	**Estimated dermal uptake [mg/kg bw(/d)]**	**Estimated oral uptake [mg/kg bw(/d)]**	**Estimated total uptake [mg/kg bw(/d)]**
Scenario 4	1	0.000092	0.02038	-	0.02047
Scenario 5	1	-	-	0.057	0.057
Scenario 6	1	0.006293	-	-	0.006293
Scenario 7	1	n.a.	n.a.	n.a.	n.a.

- **Combined scenarios**

Not applicable. According to the use description provided by the applicant, the assessment of scenario 7 is considered not relevant.

Local Exposure Assessment for ATMAC/TMAC

- **Scenario 4**

Table 65

Description of Scenario 4		
Secondary acute exposure, adult - sanding treated wood, inhalation and dermal exposure Inhalation and dermal exposure: based on the assumptions for scenario 4 in the systemic exposure assessment, the aerial concentration of the active substance and the concentration of the active substance in wood dust getting in contact to the skin can be calculated as presented below:		
	Parameters	Value
Tier 1	Application rate (applicant)	4500 g/m^3
	Concentration a.s. (applicant)	ATMAC/TMAC: 0.105 % (w/w)
	Dimension of wooden post to be sanded (TNsG on Human Exposure (2002) Part 3)	4 cm x 4 cm x 250 cm = 4000 cm^3
	Volume of wood treated with biocidal product (biocidal product is evenly distributed in the whole wood) (TNsG on Human Exposure (2002) Part 3)	4000 cm^3
	Concentration a.s. in the treated wood: Application rate x concentration a.s. in the b.p.	ATMAC/TMAC: 0.0047 mg a.s./cm^3
	Wood dust concentration in the air during sanding (EU, OEL, 2004)	5 mg/m^3
	Wood density (MOTA, 2013 from TM III, 2008)	0.4 g/cm^3 = 400 mg/cm^3

For inhalation exposure:

Aerial concentration of ATMAC/TMAC = Concentration a.s. in the treated wood / wood density x wood dust concentration
= 0.0047 mg/cm^3 / 400 mg/cm^3 x 5 mg/m^3

Aerial concentration of ATMAC/TMAC = 0.000059 mg/m^3

For dermal exposure:

Concentration of ATMAC/TMAC in the treated wood = Concentration a.s. in the treated wood / wood density x conversion factor to %
= 0.0047 mg/cm^3 / 400 mg/cm^3 x 100

Concentration of ATMAC/TMAC in the treated wood = 0.00118 %

- **Scenario 5**

Table 66

Description of Scenario 5

Secondary acute exposure, toddler - chewing treated wood off-cut, oral exposure
The assessment was adopted from the CAR. The biocidal product in the CAR was applied in an amount of 0.168 mg ATMAC/TMAC/cm^2. The application rate of the biocidal product Wolsit F-15T is 0.0047 mg ATMAC/TMAC/cm^3. Hence, the estimated oral exposure from the biocidal product submitted for application is expected to be lower.

Extract from the CAR:
Secondary exposure: Infants chewing wood off-cut - ingestion route

Watanabe et al (1995) informs that in 15 boys and 15 girls of five years old, the mean flow of unstimulated saliva was 0.26 (+0.16 SD) ml/min and that of saliva while chewing was 3.6 (+0.8 SD) ml/min. The Watanabe study measured saliva flow when chewing foodstuffs. It can be assumed that this stimulated saliva flow would be similar for any chewing action. Dawes (2008) found that taste also stimulated saliva flow. In adults infusion of 5 % citric acid into the mouth elicited a flow rate of 7.07 ml/min compared to 4.94 ml/min. Thus, the taste of the active substance could also add to the rate of saliva flow. Information taken from a study on leachability of ATMAC/TMAC in the fate and behaviour data supporting the assessment of this substance can be used to determine the amount of active substance released from a treated wood off-cut. Section 3.3.2 of Doc IIB gives details of a study in which wooden blocks (19 x 19 x 19 mm) were vacuum pressure treated at 3 different concentrations. The ATMAC/TMAC retention levels were calculated to be 3.5, 7.0 and 14.0 kg/m^3. The blocks were then suspended in water and measurements of ATMAC/TMAC concentration in the leachate water were taken at various time points up to 14 days after initiation of leaching. The shortest interval was 6 hours after initiation of leaching. For the 6 hour time-point the level of leaching, expressed as a percentage of the original amount, was 0.63 %, 1.08 % and 1.97 % for the 3.5, 7.0 and 14.0 kg/m^3 respectively. Whilst there appears to be some uncertainty over the value derived for the highest concentration, these data suggest less than 2.0 % of ATMAC/TMAC was removed from the treated wood after soaking in water for 6 hours. Considering a retention rate of 150 g treatment solution/m^2 and an in-use treatment solution with a maximum active substance content of 1.12 %, the worst case loading is 0.168 mg a.s./cm^2 (150g b.p./m^2 x 1.12/100 = 1.68 g a.s./m^2 = 0.168 mg a.s./cm^2). The total surface area of wood off-cut is 48 cm^2 (= 2 x [4cm x 4cm + 4cm x 1cm + 4cm x 1cm]) with a volume of 16 cm^3 (4 cm x 4 cm x 1 cm). Using an extraction factor of 2.0 % for human health risk assessment, the concentration of active substance in saliva of an infant chewing/mouthing a 4 x 4 x 1 cm wood off-cut treated by dipping application can be calculated as follows.

Estimation of exposure to infant mouthing wood off-cut treated by dipping application

Concentration of a.s. in treated wood	*0.168 mg a.s./cm^2 (TMAC dossier)*
total surface of wood off- cut	*48 cm^2*
Amount of a.s. released from off-cut – assuming 2.0 % extraction	*0.16 mg*
Amount of saliva produced by an infant (stimulated saliva flow)	*3.6 ml/minute*
Duration of chewing of off-cut	*1 minute*
Concentration of a.s. in saliva	*0.04 mg a.s./ml*

For wood treated by dipping application, the predicted exposure concentration is 0.04 mg a.s./ml.

Extrapolating the environmental fate data to an infant mouthing treated wood involves a degree of uncertainty, as the treated wooden blocks used were soaked and not sucked or chewed. However, it is of note that the blocks were soaked for 360 minutes compared to 1 minute for the infant mouthing the off-cut.

Using the same approach for the biocidal product, the following active substance concentration in saliva can be estimated:

Concentration of a.s. in treated wood	0.0047 mg a.s./cm^3
Total volume of wood off-cut	16 cm^3
Amount of a.s. released from off-cut – assuming 2.0 % extraction =(Concentration of a.s. in treated wood x total volume of wood off-cut) x 0.02	0.0015 mg
Amount of saliva produced by an infant (stimulated saliva flow)	3.6 ml/min
Duration of chewing of off-cut	1 minute

Concentration of a.s. in saliva	0.00042 mg a.s./ml = 0.000042 %

Concentration of ATMAC/TMAC in saliva = (Amount of a.s. released from off-cut / stimulated saliva flow) x conversion factor to %
= (0.0015 mg / 3.6 ml/min) x 0.1
Concentration of ATMAC/TMAC in saliva =0.00042 mg/ml = 0.000042 %

- **Scenario 6**

Table 67

Description of Scenario 6		
Secondary long-term exposure, toddler - inhalation of volatilised residues indoors, inhalation exposure The air concentration of volatilised residues is determined by the calculation of the saturated vapour concentration (SVC). This is a conservative but very simple approach to estimate the potential concentration of a substance in the air. This estimate is based on parameters laid down in the HEEG opinion No. 13 “Assessment of Inhalation Exposure of Volatilised Biocide Active Substance”.		
Tier 1	Parameters	Value
	Molecular weight ATMAC/TMAC (CAR/AR, 2016)	278 g/mol (278000 mg/mol)
	Vapour pressure ATMAC/TMAC (20°C, CAR/AR, 2016)	0.0000018 Pa
	Gas constant (Atkins Physical Chemistry, 5th Edition)	8.31451 J/mol/K
	Temperature (assumed room temperature = 20°C HEEG opinion No. 13, 2011)	293 J/mol/K

Saturated vapour concentration = molecular weight x vapour pressure / (gas constant x temperature)
= 278 g/mol x 0.0000018 Pa / (8.31451 J/mol/K x 293 K)
= 0.000205 mg/m^3

- **Scenario 7**

Table 68

Description of Scenario 7
Secondary long-term exposure, toddler - playing on treated structure and mouthing, dermal and oral exposure. With respect to dermal exposure of toddlers playing on weathered structures the following statement from the CAR is adopted: The handling of treated wet wood, where exposure was to the diluted product, posed only a “low” hazard. When the treated wood has dried, the release of the active substance is not expected to reach a concentration that could lead to irritative effects during dermal exposure. Therefore, the potential of local effects during child playing on weathered structure is negligible. No risk to the child playing on weathered structure is identified. Furthermore, according to the use description provided by the applicant, a regular direct contact and exposure of the general public to treated surfaces is very unlikely. Therefore, assessment of chronic exposure in scenario 7 (Secondary long-term exposure of a toddler playing on treated structures) is considered not relevant. (For details refer to Table 62) In the absence of a relevant risk assessment, the implementation of a respective risk mitigation measure (‘Do not use the biocidal product on wood, which is intended to be used as part of playground structures and other indoor/ outdoor structures (e.g. flooring, furniture), to which persons of the general public and pets may have prolonged contact.’) is necessary to assure safety of the general public and children in particular.

Dermal and oral exposure from contact to treated surfaces = not relevant

Exposure assessment for substances of concern

According to Regulation (EC) No. 1272/2008, the co-formulants isotridecanol, ethoxylated (CAS-No. 69011-36-5) and benzyl alcohol (CAS-No. 100-51-6) contribute to the classification of the biocidal product with Acute Tox. 4, H302. In line with the banding evaluation scheme, specified in Annex A of the Guidance on the Biocidal Products Regulation Volume III Human Health – Assessment and Evaluation (Part B+C), 2017, both substances of concern are assigned to Band A. Thus, no quantitative risk assessment is required. Instead, potential risks should be addressed by the application of appropriate risk mitigation measures, such as precautionary (P)-statements associated with the corresponding H-statements.

The co-formulant isotridecanol, ethoxylated (CAS-No. 69011-36-5) further contributes to the classification of the biocidal product with Eye Dam 1, H318 according to Regulation (EC) No. 1272/2008, which would include this substance of concern in Band B of the evaluation scheme according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Assessment and Evaluation (Part B+C), 2017. However, the in-use concentration of the biocidal product is classified with Eye Irrit. 2, H319. This classification is also assigned to Band A and the above mentioned requirements still apply for this substance of concern. Assuming a worst case application rate of 0.84 % Wolsit F-15T/m³ (= 4.5 kg/m³), the concentration of this substance of concern in the wood is approximately 0.26 % isotridecanol, ethoxylated/m³ and below any concentration limit for classification.

According to the method described by the applicant, the biocidal product is added fully automated to the glue by a dilution factor of approximately 25. The glue containing the diluted biocidal product is then incorporated in the derived timber products for use class 2 and 3.1.

Therefore, the general public may only be exposed to the diluted biocidal product when touching and sanding the treated wood. Exposure to benzyl alcohol is considered not relevant, for it is likely to have evaporated during the drying/hardening process. In addition, the concentration of this substance of concern in the wood is about 0.31 % benzyl alcohol/m³ (assuming an application rate of 0.84 % Wolsit F-15T/m³) even if no evaporation is expected. This is below the cut-off value of 1 % defined in Regulation (EC) No. 1272/2008.

Note, that benzyl alcohol (CAS-No. 100-51-6) is currently being evaluated as new biocidal active substance for PT06 by eCA NL. Upon approval, a full quantitative risk assessment for this substance of concern will be required.

3.6.3.2 Dietary exposure

The intended use descriptions of the ATMAC/TMAC-, propiconazole- and tebuconazole-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 applied for the preservation of wood that is used for exterior cladding (panels) of facades and sub-roof as well as scaffolding. Consequently treated wood is not expected to come into direct contact with food, feedstuff or livestock animals.

Information on non-biocidal use of the active substance

- Tebuconazole is approved as pesticide (Reg. (EU) 2020/1160) and MRLs have been set (Reg. (EU) 2018/1514).
- Propiconazole is not approved as pesticide (Reg. (EU) 2018/1865) but MRLs have been set (Reg. (EU) 2017/626, SANTE/10482/2020 (not applicable yet))
- Quaternary ammonium compounds like ATMAC/TMAC are not approved as pesticides (2004/129/EC) but a default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg 396/2005 has been set.

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

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

3.6.3.4 Aggregated exposure

Not relevant.

3.6.3.5 Summary of exposure assessment

Table 69

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/d]**
Scenario 1: Connecting transfer lines (automated transfer)	Industrial user	Tier 1: • Automatic dosing system Tier 2: • Automatic dosing system • Protective gloves (EN 374)	Propiconazole Tier 1: 3.22×10^{-3} Tier 2: 3.22×10^{-4} Tebuconazole Tier 1: 3.19×10^{-3} Tier 2: 3.19×10^{-4}
Scenario 2: Deluge treatment	Industrial user	Tier 1: • Automatic dosing system • Protective gloves (EN 374) Tier 2: • Automatic dosing system • Protective gloves (EN 374) • Protective coverall (type 6)	Propiconazole Tier 1: 0.45 Tier 2: 0.10 Tebuconazole Tier 1: 0.45 Tier 2: 0.09
Scenario 3: Mechanical processing of treated wood	Professional/industrial user	Tier 1: -/- Tier 2: • Protective gloves (EN 374)	Propiconazole Tier 1: 0.09 Tier 2: 0.01 Tebuconazole Tier 1: 0.09 Tier 2: 0.01

Table 70 Tebuconazole

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake [mg/kg bw (/d)]**
4	General public	1	0.02026
5	General public	1	0.056
5	General public	2	0.0108
6	General public	1	0.0001718
7	General public	1	n.a.*

** Acute dermal exposure is covered in scenario 4 – sanding treated wood*

Table 71 Propiconazole

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake [mg/kg bw (/d)]**
4	General public	1	0.02047
5	General public	1	0.057
6	General public	1	0.006293
7	General public	1	n.a.*

** Acute dermal exposure is covered in scenario 4 – sanding treated wood*

3.6.4 Risk characterisation for human health

3.6.4.1 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 see in chapter 3.6.1. Assessment of effects of the active substance on human health.

3.6.4.2 Maximum residue limits or equivalent

Table 72

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL (quaternary ammonium compounds)	Reg 396 / 2005 (Default acc. to Art 18(1)(b))	all	0.01 mg/kg
MRL (DDAC, decyldimethylammonium chloride (mixture of alkyl-quaternary ammonium salts with alkyl chain lengths of C8, C10 and C12))	Reg. (EU) No 1119/2014	all	0.1 mg/kg
MRL (Propiconazole (sum of isomers))	Reg. (EU) 2017/626 SANTE/10482/2020 (not yet applicable)	all	variable
MRL (Tebuconazole)	Reg. (EU) 2018/1514	all	variable

3.6.4.3 Specific reference value for groundwater

No specific reference values for ground water were derived.

3.6.4.4 Risk for industrial users

For some scenarios, more than one group of exposed users with identical exposure patterns exist. For clarity, the risk assessment of all scenarios is only described in detail in the section 3.6.4.5 Risk for professional users.

3.6.4.5 Risk for professional users

The occupational risk assessment for the biocidal product Wolsit F-15T takes into account systemic and local effects of the active substances propiconazole, tebuconazole and ATMAC/TMAC as well as systemic and local effects of the substances of concern. In the biocidal product isotridecanol, ethoxylated is identified as a substance of concern based on self-classification with H318 (Causes serious eye damage) in the safety data sheet submitted by the applicant (see section Local risk in this chapter).

Furthermore, benzyl alcohol is identified as a substance of concern based on its contribution to the classification of the biocidal product with H302 (Harmful if swallowed) due to its classification according to Annex VI of Regulation (EC) No 1272/2008. In line with the banding evaluation scheme, specified in Annex A of the Guidance on the Biocidal Products Regulation Volume III Human Health – Assessment and Evaluation (Part B+C), 2017, benzyl alcohol is assigned to Band A and appropriate risk mitigation measures in the form of the precautionary (P)-statements should be applied. It is assumed that the application of the precautionary statements associated with the concerned H302 and the provisions described in chapter 2.5.2 are sufficient to minimize the risk for professional users. Moreover the oral uptake of the biocidal product is considered not relevant and thus not further assessed for the professional user.

Propiconazole

The primary toxic effect of the active substance propiconazole in long-term studies is liver toxicity. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to propiconazole resulting from use of the biocidal product.

Details of risk characterisation

Reference values

As systemic reference value the $AEL_{long\text{-}term}$ of 0.04 mg propiconazole/kg bw/d derived from the $AEL_{medium\text{-}term}$ of 0.08 mg propiconazole/kg bw/d is used.

Calculation of total uptake and AEL exhaustion (%)

For inhalation route 100 % is assumed as default absorption for the active substance propiconazole.

The calculation of the dermal uptake significantly depends on the methodology used for the calculation of dermal absorption. Valid data are not available. Therefore, the default value of 25 % for active substance concentration above or equal to 5 % and the default value of 70% for active substance concentration below 5% (secondary exposure) has to be taken into consideration for risk assessment (according to the EFSA Guidance on Dermal Absorption, 2017).

The inhalation uptake and dermal uptake referring to the active substance propiconazole resulting from use of the biocidal product Wolsit F-15T are determined according to the following equations:

> Inhalation uptake (mg/kg bw/d) = inhalation exposure to propiconazole (mg/m^3) x 10 m^3/d breathing volume / 60 kg body weight / 100 % x 100 % inhalation absorption
>
> Dermal uptake (mg/kg bw/d) = dermal exposure to propiconazole (mg/kg bw/d) / 100 % x 25% or 70 %-dermal absorption

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

The summation of inhalation uptake and dermal uptake within a scenario gives the total uptake.

A risk for professional users referring to the active substance propiconazole resulting from the use of the biocidal product Wolsit F-15T is unlikely if the AEL exhaustion (%) for each scenario is below the value of 100 %.

Table 73 gives a detailed overview of the risk assessment results referring to the active substance propiconazole in the biocidal product Wolsit F-15T. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places in Table 73. However, the underlying calculations are based on unrounded values.

As shown in Table 73, for the scenarios ‘connecting transfer lines (automated transfer)’ a risk for the professional user is unlikely already in Tier 1. By contrast, for the scenarios ‘deluge treatment’ as well as from secondary exposure (‘Mechanical processing of treated wood’) inacceptable risks are identified after Tier 1 consideration. However, when additional risk mitigation measures are implemented a risk for the professional user is unlikely in Tier 2 for the secondary exposure scenario. No acceptable risk could be identified for the scenario “deluge treatment” even when risk mitigation measures were applied.

Table 73: Overview of detailed risk assessment results referring to the active substance propiconazole in the biocidal product Wolsit F-15T

Scenario no.	Scenario		$AEL_{long-term}$	Estimated inhalation uptake	Inhalation uptake / AEL	Estimated dermal uptake	Dermal uptake / AEL	Estimated total uptake	Estimated total uptake / AEL AEL exhaustion	Acceptable	HQ[1]
			mg/kg bw/d	mg/kg bw/d	%	mg/kg bw/d	%	mg/kg bw/d	%	(yes/no)	
1	Connecting transfer lines (automated transfer)	Tier 1	0.04	-	-	3.22×10^{-3}	8.1	3.22×10^{-3}	8	yes	0.08
2	Deluge treatment	Tier 1	0.04	6.49×10^{-5}	0.16	0.45	1134	0.45	1134	no	11
		Tier 2	0.04	6.49×10^{-5}	0.16	0.10	240	0.10	240	**no**	2.4
3	Mechanical processing of treated wood	Tier 1	0.04	2.47×10^{-3}	6.2	0.08	212	0.09	218	no	2.2
		Tier 2	0.04	2.47×10^{-3}	6.2	8.49×10^{-3}	21	0.01	27	**yes**	0.27

[1]: Hazard Quotient (HQ) for assessment of cumulative/combined exposure (see chapter 3.6.4.9). HQ: estimation of internal exposure/AEL

Combined scenarios

We considered the combination of the scenarios 1+3 and 1+2+3 but did not display them as already the scenario 2 (deluge treatment) leads to unacceptable risks even after tier 2 consideration. Thus also the combined scenarios will lead to unacceptable risks.

Conclusion

Based on the risk assessment of the active substance propiconazole via the inhalation and dermal route, a risk for professional users resulting from the uses 'connecting transfer lines (automated transfer)' as well as from secondary exposure ('Mechanical processing of treated wood') with the biocidal product Wolsit F-15T is unlikely at the latest in Tier 1. An unacceptable risk for the professional user was identified for the use "deluge treatment".

Tebuconazole

The primary toxic effects of the active substance tebuconazole in a one-year dog study were unspecific effects like histopathological alterations in the adrenal cortex. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to tebuconazole. As reference value the AEL of 0.03 mg/kg bw/day is used.

Details of risk characterisation

Reference values

As systemic reference value the $AEL_{long\text{-}term}$ of 0.03 mg tebuconazol/kg bw/d is used.

Calculation of total uptake and AEL exhaustion (%)

For inhalation route 100 % is assumed as default absorption for the active substance tebuconazole.

The calculation of the dermal uptake significantly depends on the methodology used for the calculation of dermal absorption. Valid data are not available. Therefore, the default value of 25 % for active substance concentration above or equal to 5 % and the default value of 70% for active substance concentration below 5% (secondary exposure) has to be taken into consideration for risk assessment (according to the EFSA Guidance on Dermal Absorption, 2017).

The inhalation uptake and dermal uptake referring to the active substance tebuconazole resulting from use of the biocidal product Wolsit F-15T are determined according to the following equations:

> Inhalation uptake (mg/kg bw/d) = inhalation exposure to tebuconazole (mg/m^3) x 10 m^3/d breathing volume / 60 kg body weight / 100 % x 100 % inhalation absorption x
>
> Dermal uptake (mg/kg bw/d) = dermal exposure to tebuconazole (mg/kg bw/d) / 100 % x 25% or 70 %-dermal absorption

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

The summation of inhalation uptake and dermal uptake within a scenario gives the total uptake.

A risk for professional users referring to the active substance tebuconazole resulting from the use of the biocidal product Wolsit F-15T is unlikely if the AEL exhaustion (%) for each scenario is below the value of 100 %.

Table 74 gives a detailed overview of the risk assessment results referring to the active substance tebuconazole in the biocidal product Wolsit F-15T. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places in Table 74. However, the underlying calculations are based on unrounded values.
As shown in Table 74, for the scenarios ‘connecting transfer lines (automated transfer)’ a risk for the professional user is unlikely already in Tier 1. By contrast, for the scenarios ‘deluge treatment’ as well as from secondary exposure (‘Mechanical processing of treated wood’) inacceptable risks are identified after Tier 1 consideration. However, when additional risk mitigation measures are implemented a risk for the professional user is unlikely in Tier 2 for the secondary exposure scenario. No acceptable risk could be identified for the scenario “deluge treatment” even when risk mitigation measures were applied.

Table 74: Overview of detailed risk assessment results referring to the active substance tebuconazole in the biocidal product Wolsit F-15T

Scenario no.	**Scenario**		**$AEL_{long-term}$**	**Estimated inhalation uptake**	**Inhalation uptake / AEL**	**Estimated dermal uptake**	**Dermal uptake / AEL**	**Estimated total uptake**	**Estimated total uptake / AEL** AEL exhaustion	**Acceptable**	**HQ[1]**
			mg/kg bw/d	mg/kg bw/d	%	mg/kg bw/d	%	mg/kg bw/d	%	(yes/no)	
1	Connecting transfer lines (automated transfer)	Tier 1	0.03	-	-	$3.19x10^{-3}$	11	$3.19x10^{-3}$	11	**yes**	0.11
2	Deluge treatment	Tier 1	0.03	$6.43x10^{-5}$	0.2	0.45	1496	0.45	1496	no	15
		Tier 2	0.03	$6.43x10^{-5}$	0.2	0.09	316	0.09	316	**no**	3.2
3	Mechanical processing of treated wood	Tier 1	0.03	$2.44x10^{-3}$	8.1	0.08	280	0.09	288	no	2.9
		Tier 2	0.03	$2.44x10^{-3}$	8.1	$8.41x10^{-3}$	28	0.01	36	**yes**	0.36

[1]: Hazard Quotient (HQ) for assessment of cumulative/combined exposure (see chapter 3.6.4.9). HQ: estimation of internal exposure/AEL

Combined scenarios

We considered the combination of the scenarios 1+3 and 1+2+3 but did not display them as already the scenario 2 (deluge treatment) leads to unacceptable risks even after tier 2 consideration. Thus also the combined scenarios will lead to unacceptable risks.

Conclusion

Based on the risk assessment of the active substance tebuconazole via the inhalation and dermal route, a risk for professional users resulting from the uses 'connecting transfer lines (automated transfer)' as well as from secondary exposure ('Mechanical processing of treated wood') with the biocidal product Wolsit F-15T is unlikely at the latest in Tier 1. An unacceptable risk for the professional user was identified for the use "deluge treatment".

Local effects – semi-quantitative
ATMAC/TMAC

The primary toxic effect of the active substance ATMAC/TMAC is skin corrosion (severe and irreversible). The semi-quantitative risk characterisation for professional users takes into account the dermal exposure concentration of ATMAC/TMAC resulting from use of the biocidal product Wolsit F-15T. For the assessment the dermal NOAEC (no observed adverse effect concentration) of 0.3 % ATMAC/TMAC, is used.

Details of risk characterisation

Dermal effect concentration

For the purpose of risk characterisation for professional users the dermal exposure concentration of ATMAC/TMAC is compared with the dermal NOAEC of 0.3 % ATMAC/TMAC. It is important to keep in mind that this comparison is meant to provide only an approximation of the magnitude of the risks rather than a precise, quantitative measure of the risks involved.

However, if the dermal exposure concentration is below the dermal NOAEC no risk mitigation measures are applied. In contrast, if the dermal exposure concentration exceeds the NOAEC a risk for professional users referring to the active substance ATMAC/TMAC resulting from the use of the biocidal product Wolsit F-15T can not be excluded. Here, appropriate risk mitigation measures (RMMs) have to be applied to avoid contact with the biocidal product Wolsit F-15T.

Table 75 gives a detailed overview of the semi-quantitative risk assessment results referring to the active substance ATMAC/TMAC in the biocidal product Wolsit F-15T. For the scenarios 'connecting transfer lines (automated transfer)' and 'deluge treatment' as well as from secondary exposure ('Mechanical processing of treated wood') the dermal exposure concentration does not exceed the NOAEC. Regarding

ATMAC/TMAC no risk mitigation measures for the use or due to secondary exposure of the product Wolsit F-15T are considered necessary.

Table 75: Overview of semi-quantitative risk assessment results for dermal route and the active substance ATMAC/TMAC in the biocidal product Wolsit F-15T

Scenario	**Dermal NOAEC**	**Concentration ATMAC/TMAC (max.) in application solution**	**Concentration ATMAC/TMAC higher/lower than dermal NOAEC?**	**RMM**
	%	%		
Connecting transfer lines (automated transfer)	0.3	0.1	lower	-
Deluge treatment	0.3	0.1	lower	-
Mechanical processing of treated wood	0.3	0.1	lower	-

Combined scenarios

Due to the local nature of the effects of ATMAC/TMAC a consideration of combined scenarios is not necessary.

Conclusion

Based on the semi-quantitative risk assessment of the local effects of the active substance ATMAC/TMAC via the dermal route, for the scenarios ‘connecting transfer lines (automated transfer)’ and ‘deluge treatment’ as well as from secondary exposure (‘Mechanical processing of treated wood’) the dermal exposure concentrations are below the NOAEC. Thus, risk mitigation measures are not considered to be necessary regarding the active substance ATMAC/TMAC in the product Wolsit F-15T.

Local effects – qualitative

The local toxicity profiles of the active substances propiconazole and ATMAC/TMAC as well as the substance of concern Isotridecanol, ethoxylated are considered. These substances contribute to the classification of the biocidal product Wolsit F-15 T with H317 (May cause an allergic skin reaction) and H318 (Causes serious eye damage).

Qualitative risk characterisation for local effects

The active substance propiconazole contributes to the classification of the biocidal product with H317. The active substance ATMAC/TMAC and the substance of concern Isotridecananol, ethoxylated contribute to the classification of the biocidal product with H318. Therefore a qualitative risk assessment for local effects regarding contact with skin and eye is necessary. The qualitative risk assessment for local effects takes into account the concentrated biocidal product as well as the different dilutions thereof. The Table 76 gives an overview of the relevant classifications for the qualitative risk assessment for local effects of biocidal product Wolsit F-15 T. Furthermore, the allocated hazard categories according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) are plotted against the respective classification.

Table 76: 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 (December 2017)**
100	Skin Sens. 1, H317 Eye Dam. 1, H318	high

For the concentrated biocidal product local risk assessment is triggered by the skin sensitisation (Skin Sens. 1, H317) and eye corrosion effect (Eye Dam. 1, H318) as these classifications are allocated to the hazard category high (Table 76).

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 (December 2017) the following tables are prepared to carry out the qualitative risk assessment for local effects regarding contact with the skin and eye of the biocidal product Wolsit F-15 T for the intended uses ‘connecting transfer lines (automated transfer)’, ‘deluge treatment’ as well as from secondary exposure (‘mechanical processing of treated wood’) (Table 77, Table 78 Table 80). With the proposed risk mitigation measures the reduction of dermal and eye contact minimises the anticipated health risk to an acceptable level for the intended uses and for secondary exposure.

Table 77: Summary of qualitative conclusions for local risk assessment for scenario ‘Connecting transfer lines (automated transfer)

No.	**Task, uses, processes**	**Concentration b.p. (max.)**	**Local effects in terms of C&L**	**Hazard category**	**Potential degree of exposure**	**Necessary RMM & PPE <u>for acceptable risk</u>**

1	Connecting transfer lines (automated transfer)	100%	Skin Sens. 1, H317 Eye Dam. 1, H318	High	Skin: Contact to hands expected Eyes: Incidental contact possible	Technical Measure: - Automated processing Organisational measure: 1) PPE: - Protective gloves (EN 374) - Eye protection

1) At the workplace a good standard of occupational hygiene is assumed.

Table 78: Summary of qualitative conclusions for local risk assessment for scenario 'Deluge treatment'

No.	Task, uses, processes	Concentration b.p. (max.)	Local effects in terms of C&L	Hazard category	Potential degree of exposure	Necessary RMM & PPE for acceptable risk
1	Connecting transfer lines (automated transfer)	100%	Skin Sens. 1, H317 Eye Dam. 1, H318	High	Skin: Incidental contact to hands likely Eyes: Incidental contact possible	Technical Measure: - Automated processing Organisational measure: 1) PPE: - Protective gloves (EN 374) - Eye protection
2	Deluge treatment (incl. Cleaning)	100%	Skin Sens. 1, H317 Eye Dam. 1, H318	High	Skin: Incidental contact to hands likely Eyes: Incidental contact possible	Technical Measure: - Automated processing Organisational measure: 1) PPE: - Protective gloves (EN 374) - Protective coverall - Eye protection

Table 79: Summary of qualitative conclusions for local risk assessment for scenario 'Mechanical processing of treated wood'

No.	Task, uses, processes	Concentration b.p. (max.)	Local effects in terms of C&L	Hazard category	Potential degree of exposure	Necessary RMM & PPE for acceptable risk

1	Sawing/sanding of treated wood	100%	Skin Sens. 1, H317 Eye Dam. 1, H318	High	Skin: Incidental contact to hands likely Eyes: Incidental contact possible	Technical Measure: - Automated processing Organisational measure: 1) PPE: - Protective gloves (EN 374) - Protective coverall - Eye protection

1) At the workplace a good standard of occupational hygiene is assumed.

Conclusion

Concerning the corrosive and sensitising properties of the biocidal product Wolsit F-15 T exposure should be minimised with risk mitigation measures. If the proposed risk mitigation measures are implemented, the intended uses (‘connecting transfer lines (automated transfer)’, ‘deluge treatment’) as well as secondary exposure resulting from ‘mechanical processing of treated wood’ do not lead to concern for professional users.

Overall conclusion

In summary, a risk for professional users of substance by substance assessment resulting from the use of the biocidal product Wolsit F-15T is unlikely for the intended uses ‘connecting transfer lines (automated transfer)’ as well as from secondary exposure (‘Mechanical processing of treated wood’). Risk mitigation measures described in chapter 2.5.2 have to be taken into account in order to ensure safe use of the biocidal product Wolsit F-15T.

An unacceptable risk for the professional user was identified for the use ‘deluge treatment’.

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

For the component Lutensol TO 89 contained in the biocidal product Wolsit F-15 T the composition is not fully known. The risk assessment is based on the assumption that the biocidal product contains no further substances relevant for evaluation.

3.6.4.6 Risk for non-professional users

Not relevant. Non-professional use of the biocidal product is not intended.

3.6.4.7 Risk for the general public

Table 80: Systemic effects tebuconazole

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 4, Sanding treated wood	1	3	0.03	0.02026	67.5	yes
Scenario 5, Mouthing treated wood	1	3	0.03	0.056	187	no
Scenario 5, Mouthing treated wood	2	3	0.03	0.0108	36	yes
Scenario 6, inhalation volatilised residues	1	3	0.03	0.0001718	0.57	yes
Scenario 7, Contact to treated surfaces	1	3	0.03	n.a.	n.a.	n.a.

Table 81: Systemic effects propiconazole

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 4, Sanding treated wood	1	30	0.3	0.02047	6.8	yes
Scenario 5, Mouthing treated wood	1	30	0.3	0.057	19	yes
Scenario 6, inhalation volatilised residues	1	8	0.04	0.006293	15.7	yes
Scenario 7, Contact to treated surfaces	1	8	0.04	n.a.	n.a.	n.a.

Combined scenarios are not applicable. According to the use description provided by the applicant, the assessment of scenario 7 is considered not relevant.

Table 82: Local effects ATMAC/TMAC

Task/ Scenario	Tier	NOAEC/DNEL	Exposure concentration	Margin of exposure	Acceptable (yes/no)
Scenario 4, Sanding treated wood	1	Inhalation DNEL: 1 mg/m³ 1) Dermal NOAEC: 0.3 %	0.000059 mg/m³ 0.00118 %	16949 254	yes yes
Scenario 5, Mouthing treated wood	1	Oral NOAEC: 0.03 %	0.000042 %	714	yes
Scenario 6, inhalation volatilised residues	1	Inhalation DNEL: 1 mg/m³ 1)	0.000205 mg/m³	4878	yes
Scenario 7, Contact to treated surfaces	1	Dermal NOAEC: 0.3 % Oral NOAEC: 0.03 %	Not relevant	n.a.	yes

1) A NOAEC for inhalation exposure has not been derived during biocidal active substance evaluation to Regulation (EU) 528/2012. However, from the REACH registration report an inhalation DNEL of 1 mg/m³ is available.

Conclusion

In the relevant scenarios [1-3] for secondary exposure, no human health risk neither for systemic nor for local effects is identified for the general public from exposure to the active substances ATMAC/TMAC and propiconazole, if the biocidal product is used as intended.

For tebuconazole, human health risk is identified in Tier 1 for the secondary exposure scenario 5 (toddler chewing treated wood off-cut). However, in Tier 2 of the respective scenario, an acceptable health risk can be demonstrated.

According to the use description provided by the applicant, the assessment of scenario 7 is considered not relevant. According to the applicant, the treated wood is not intended to be used as part of playground structures or other structures, to which the general public has a prolonged contact. This constraint has to be specified by the implementation of a respective risk mitigation measure to ensure safety of the general public and children in particular.

For the substances of concern no human health risk was identified.

3.6.4.8 Risk for consumers via residues in food

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

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

Professional user
Risk characterisation for professional users from combined exposure takes into account the dermal and inhalation exposure of the active substances with systemic effects in the biocidal product Wolsit F-15T. Thus, the risk characerisation considers the active substances propiconazole and tebuconazole in the biocidal product Wolsit F-15T.

First, each active substance is assessed individually for all scenarios relevant to the biocidal products use (Tier 1). Secondly, the combined exposure of the active substances is assessed by considering the effects used to establish the AELs as dose-additive regardless of the specific target organs or mode of actions (Tier 2). If necessary, Tier 3 is carried out which further refines the assessment by either confirming or refuting the assumption of dose-additivity of Tier 2.

Tier 1: Risk assessment of substance by substance of the mixture/the biocidal product
The hazard quotients (HQs) and the conclusions for the risk assessment substance by substance are presented in chapter 3.6.4.5 (Table 73, Table 74).

Tier 2: Risk assessment of combined exposure to the mixture/the biocidal product by dose addition

Calculation of the Hazard Index (HI) for each scenario
The HI is the sum of the HQs.

A risk for professional users resulting from the use of the biocidal product Wolsit F-15T is unlikely if the HI for each scenario is below or equal to the value of 1. If the HI for a scenario exceeds the value of 1, the risk related to the mixture will be considered unacceptable and further refinement is needed. The

refinement may consider further risk mitigation measures beyond the Tier 1 assessment or a Tier 3 assessment.

As shown in Table 83, for the scenario ‘connecting transfer lines (automated transfer)’ a risk for the professional user for the combined exposure is unlikely, regarding all active substances already without exposure/HQ refinement in Tier 1 (HI < 1). By contrast, for the scenarios ‘deluge treatment’ and secondary exposure ‘Mechanical processing of treated wood’ the exposure estimates/HQs for all active substances were refined in Tier 1. Therefore, only when additional risk mitigation measures are implemented a risk for the professional user from the combined exposure to the two active substances is unlikely for the secondary exposure scenario ‘Mechanical processing of treated wood’ because the HI of the Tier 2 assessment is below the value of 1. As concluded already in the risk assessmente susbtance by substance (chapter 3.6.4.5) an unacceptable risk was identified for the scenario ‘deluge treatment’.

Table 83: Combined exposure to the mixture of and propiconazole and tebuconazole in the biocidal product Wolsit F-15T by dose addition

Scenario		**HI[1]**	**Acceptable** (yes/no)
Connecting transfer lines (automated transfer)	Tier 1	0.19	**yes**
Deluge treatment	Tier 1	26	no
	Tier 2	5.6	**no**
Mechanical processing of treated wood	Tier 1	5.1	no
	Tier 2	0.64	**yes**

[1]Sum of the HQs (Hazard Quotients) for each substance. HQ: estimation of internal exposure/AEL. Acceptable: HI≤1

Tier 3: Confirmation or refutation of dose addition

A refinement of the cumulative Tier 2 assessment is not performed as both active substances exert liver toxicity and exceed the respective AELs by 20 to 30 fold already in the substance by substance risk assessment even when risk mitigation measures are applied (Tier 2) (see chapter 3.6.4.5 (Table 73, Table 74)). While the AEL of tebuconazol is based on kidney effects and may be adjusted, the AEL of propiconazol is already based on liver effect. Thus, a further refinement attempt appears meaningless.

Overall conclusion

Based on the risk assessment of combined exposure to the mixture of the active substances propiconazole and tebuconazole via the inhalation and dermal route, a risk for professional users resulting from the uses ‘connecting transfer lines (automated transfer)’ and ‘secondary exposure (‘Mechanical processing of treated wood’) with the biocidal product Wolsit F-15T is unlikely at the latest

when RMMs are applied. Regarding occupational safety, there are no objections against the use as well as secondary exposure taking into account the provisions described in chapter 2.5.2 of this PAR.

An unacceptable risk for professional users was identified for the use “deluge treatment”.

Non-professional user

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

General Public

A quantitative cumulative exposure estimate is performed for the active substances tebucolazole and propiconazole. They belong to the group of triazole-fungicides. Hence, the same mode of action is expected for these substances and additivity of effects is assumed, using the hazard index approach. The active substance ATMAC/TMAC has not been included, because there are no systemic reference values available and only local effects are reported.

In line with the banding evaluation scheme, specified in Annex A of the Guidance on the Biocidal Products Regulation Volume III Human Health – Assessment and Evaluation (Part B+C), 2017, a quantitative assessment is also not required for Band A substances of concern. Hence, none of the co-formulants of concern (isotridecanol, ethoxylated (CAS-No. 69011-36-5) and benzyl alcohol (CAS-No. 100-51-6)) have been considered for cumulative exposure estimation.

Table 84: Systemic effects

Task/ Scenario	Tier	Exposure [mg/kg bw(/d)]	AEL [mg/kg bw(/d)]	Hazard index	Acceptable (yes/no)
Scenario 4, Sanding treated wood	1	Tebuconazole: 0.02026 Propiconazole: 0.02047	Tebuconazole: 0.03 Propiconazole: 0.3	0.75	yes
Scenario 5, Mouthing treated wood	1	Tebuconazole: 0.056 Propiconazole: 0.057	Tebuconazole: 0.03 Propiconazole: 0.3	2.06	no
	2	Tebuconazole: 0.0108 Propiconazole: 0.057	Tebuconazole: 0.03 Propiconazole: 0.3	0.55	yes
Scenario 6, inhalation volatilised residues	1	Tebuconazole: 0.0001718 Propiconazole: 0.006293	Tebuconazole: 0.03 Propiconazole: 0.04	0.16	yes
Scenario 7, Contact to treated surfaces	1	Tebuconazole: n.a. Propiconazole: n.a.	Tebuconazole: 0.03 Propiconazole: 0.04	n.a.	yes

In conclusion, no risk is identified for the general public by cumulative exposure to the active substances propiconazole and tebuconazole from use of the biocidal product.

3.6.4.10 Summary of risk characterisation

3.6.4.10.1 Summary of risk characterisation for industrial user

For clarity, the risk assessment of all scenarios is only described in detail in the section 3.6.4.5 Risk for professional users.

3.6.4.10.2 Summary of risk characterisation for professional user

Please refer to Table 73and Table 74in section 3.6.4.5.

3.6.4.10.3 Summary of risk characterisation for non-professional user

Not relevant.

3.6.4.10.4 Summary of risk characterisation for indirect exposure

Table 85 Tebuconazole

Scenario, Tier	Relevant reference value	Estimated uptake mg/kg bw/d	Estimated uptake/reference value (%)	Acceptable (yes/no)
Scenario 4, Sanding treated wood, Tier 1	0.03	0.02026	67.5	yes
Scenario 5, Mouthing treated wood, Tier 1	0.03	0.056	187	no
Scenario 5, Mouthing treated wood, Tier 2	0.03	0.0108	36	yes
Scenario 6, inhalation volatilised residues, Tier 1	0.03	0.0001718	0.57	yes
Scenario 7, Contact to treated sur-faces, Tier 1	0.03	n.a.	n.a.	n.a.

Table 86 Propiconazole

Scenario, Tier	Relevant reference value	Estimated uptake mg/kg bw/d	Estimated uptake/reference value (%)	Acceptable (yes/no)
Scenario 4, Sanding treated wood, Tier 1	0.3	0.02047	6.8	yes
Scenario 5, Mouthing treated wood, Tier 1	0.3	0.057	19	yes
Scenario 6, inhalation volatilised residues, Tier 1	0.04	0.006293	15.7	yes
Scenario 7, Contact to treated surfaces, Tier 1	0.04	n.a.	n.a.	n.a.

Table 87: Local effects ATMAC/TMAC

Task/ Scenario	NOAEC/DNEL	Exposure concentration	Margin of exposure	Acceptable (yes/no)
Scenario 4, Sanding treated wood, Tier 1	Inhalation DNEL: 1 mg/m³ Dermal NOAEC: 0.3 %	0.000059 mg/m³ 0.00118 %	16949 254	yes yes
Scenario 5, Mouthing treated wood, Tier 1	Oral NOAEC: 0.03 %	0.000042 %	714	yes
Scenario 6, inhalation volatilised residues, Tier 1	Inhalation DNEL: 1 mg/m³	0.000205 mg/m³	4878	yes
Scenario 7, Contact to treated surfaces, Tier 1	Dermal NOAEC: 0.3 % Oral NOAEC: 0.03 %	not relevant	n.a.	yes

3.7 Risk assessment for animal health

Due to the lack of an appropriate guidance, a specific exposure and risk assessment for pets and domestic animals is not performed.

However, it is expected that animals can be exposed to the active substance after treatment, particularly by contact to treated surfaces. It is assumed that the health risk for these animals is comparable to those of toddlers and children and covered by the corresponding assessment. Therefore, pets are implemented of a respective risk mitigation measure (‘Do not use the biocidal product on wood, which is intended to be used as part of playground structures and other indoor/ outdoor structures (e.g. flooring, furniture), to which persons of the general public and pets may have prolonged contact.’), which is necessary to assure safety of the general public and children in particular.

3.8 Risk assessment for the environment

3.8.1 General information

Wolsit F-15T is a wood preservative containing the active substances ATMAC/TMAC (0.105%; CAS: 61789-18-2), Propiconazole (7.89%; CAS: 60207-90-1) and Tebuconazole (7.81%, CAS: 107534-96-3). The fungicidal product is intended to be added to the glue-line during the production of derived timber products (plywood -, particle -, OSB panels). It is applied industrially.

Since no substances of concern were identified for the environment, the environmental risk assessment of Wolsit F-15T is based on the active substances, only.
Regarding the leaching behaviour of Wolsit F-15T, a semi-field study was submitted by the applicant. No further studies regarding environmental effects, fate and behaviour or exposure were submitted for this product. Therefore, the assessment is based on the information provided in the respective CA reports of the active substances.

3.8.2 Effects assessment

No ecotoxicological effect studies with the biocidal product Wolsit F-15T were provided by the applicant. Therefore, the environmental effects assessment for the product is based on the effect values for the active substances. All data were taken from the respective active substance AR (ATMAC/TMAC: eCA IT, final AR, 2016; Propiconazole: eCA FI, final AR 2015; Tebuconazole: eCA DK, final AR, 2013).

3.8.2.1 Mixture toxicity

Screening step

- **Screening Step 1**:

The biocidal product affects both, aquatic and terrestrial environment. For further information on the release pathway and the relevant compartments for the assessment of the product, see chapter 3.8.4.

- **Screening Step 2:**

Besides the active substances no other substances, which trigger the classification of the product are included in the product composition.

- **Screening Step 3: Screen on synergistic interactions**

There is no indication of synergistic interactions for the product or its constituents.

Table 88

Screening step	
Y	Significant exposure of environmental compartments? (Y/N)
Y	Number of relevant substances >1? (Y/N)
N	Indication for synergistic effects for the product or its constituents in the literature? (Y/N)

Conclusion on screening for mixture toxicity

Mixture toxicity assessment is required, as more than one ecotoxicologically relevant component was identified. The mixture toxicity assessment was performed by PEC/PNEC summation and will be provided in the Risk assessment chapter for the environment (3.8.5).

3.8.2.2 Aquatic compartment (including sediment and STP)

ATMAC/TMAC

The hazard assessment of coco alkyltrimethylammonium chloride to aquatic organisms relies on read across data, mostly to DDAC. While on acute toxicity basis, fish appear to be less sensitive than invertebrates and algae, the sensitivity of the three taxa is very similar when chronic endpoints are compared.

Considering the chronic endpoints selected as most reliable among all those available in the ATMAC and TMAC dossier, a PNECwater for coco alkyltrimethylammonium chloride can be derived from the lowest of the chronic endpoints available for the three trophic levels, which is the algae 96h NOEC of 0.011 mg/L (mean measured) corrected for difference in molecular weight (MW) (96h NOErC = 0.008 mg/L, mean measured), hence:

PNECwater = 0.008 mg a.s./L / AF 10 = 0.8 µg a.s./L

PNECsediment = 397.5 mg/kg dw /100= 3.98 mg/kg dw, equivalent to 2.67 mg/kg ww (based on read across to DDAC and correction for MW).

PNEC in sewage treatment plant is 0.122 mg a.i./L.

Propiconazole

Propiconazole is very toxic to aquatic invertebrates and toxic to algae and fish. PNEC in surface water is 6.8 µg a.i./L based on the NOEC from marine fish. The $PNEC_{sediment}$ is 0.054 mg a.i./kg wet sediment based on the NOEC from *Chironomus*.

PNEC in sewage treatment plant is 100 mg a.i./L.

Tebuconazole

The toxicity to aquatic organisms is documented by acute and long-term studies. Long-term NOEC values are available for all three trophic levels in the aquatic compartment: The lowest NOEC from the 21-day daphnia study of 0.01 mg/l was taken as the basis for the PNEC derivation in water (PNECwater = 1 µg a.i./L).

From the dose-related test on *Chironomus riparius* the NOEC (= EC10) of 2.45 mg/L is used for the PNEC derivation in sediment. Calculation of a related concentration of Tebuconazole in suspended sediment gave a NOEC of 54.5 mg a.i./kg suspended sediment (PNECsed = 550 µg a.i./kg suspended sediment). PNEC in sewage treatment plant is 0.32 mg a.i./L.

3.8.2.3 Terrestrial compartment (including groundwater)

ATMAC/TMAC

Based on the lowest of the two chronic endpoints available for earthworms and micro-organisms, i.e. 28d EC10 of 70 mg/kg ww (79.1 mg/kg dw) for microorganisms for the DDAC data (recalculated as 28d EC10 = 52.5 mg/kg ww and 59.3 mg/kg dw, upon correction for MW), the PNEC soil for coco alkyltrimethylammonium chloride is derived as follows:

PNEC soil = 52.5 mg/kg ww/ 50 = 1.05 mg/kg ww equivalent to 1.19 mg/kg dw (based on read across to DDAC).

Propiconazole
Toxicity to terrestrial species was studied in three trophic levels (microorganisms, plants and earthworms). $PNEC_{soil}$ is 0.1 mg a.i./kg wet soil.

Tebuconazole
The toxicity to terrestrial organisms is documented by acute and long-term studies. Tests are available for test on earthworm reproduction, terrestrial micro-organisms and terrestrial plants. The 56 days NOEC of 5.7 mg a.i./kg dry weight soil from the earthworm reproduction test was taken as the basis for the terrestrial PNEC (PNECsoil = 100 µg a.i./kg wet weight soil).

For the relevant soil metabolite **1,2,4-triazole** a PNECsoil is calculated on the basis of NOEC to microorganisms using AF 100. PNECsoil is 0.01 mg/kg ww soil at 3.4% organic matter.

3.8.2.4 Atmosphere

Exposure to the atmosphere is not considered relevant for the biocidal product Wolsit F-15T, due to low vapour pressures of the three active substances.

ATMAC/TMAC
Due to the low vapour pressure, ATMAC/TMAC is not expected to partition into the atmosphere. Furthermore, the substance is not expected to contribute to global warming, ozone depletion in the stratosphere, or acidification on the basis of its physical and chemical properties (CAR 2014).

Propiconazole
Based on the vapour pressure (5.6×10^{-5} Pa*m³/mol) and the Henry's Law constant (9.2×10^{-5} Pa*m³/mol), volatilisation of Propiconazole is considered to be negligible. Calculations of the chemical lifetime in the troposphere resulted in a half-life between 10.2 h and 42 h. According to these results (DT_{50} < 2d), Propiconazole is rapidly degraded by photochemical processes and no accumulation of Propiconazole in the air is expected (CAR 2014).

Tebuconazole
Calculations of the chemical lifetime in the troposphere resulted in a half-life of 3.8 days. Although according to these results (DT_{50} > 2d), Tebuconazole could be suspect of accumulation in the atmosphere, air will not be an environmental compartment of concern for use in PT 8. Based on the vapour pressure (1.7E-06 Pa) and the Henry's Law constant (1E-05 Pa×m³/mol), volatilisation of Tebuconazole is considered to be negligible.

3.8.2.5 Summary of effects assessment

Table 89

Summary table on calculated PNEC values		
Compartment	**Active substance**	**PNEC**
STP	ATMAC/TMAC	0.122 mg/L
	Propiconazole	100 mg/L
	Tebuconazole	0.32 mg/L
Surface water	ATMAC/TMAC	0.8 µg/L
	Propiconazole	6.8 µg/L
	Tebuconazole	1 µg/L
Sediment	ATMAC/TMAC	2.67 mg/kg wwt
	Propiconazole	0.054 mg/kg wwt
	Tebuconazole	0.55 mg/kg wwt
Soil	ATMAC/TMAC	1.05 mg/kg wwt
	Propiconazole	0.1 mg/kg wwt
	Tebuconazole	0.1 mg/kg wwt
	1,2,4-triazole	0.01 mg/kg wwt

3.8.3 Fate and behaviour

For a detailed assessment of the environmental fate and behaviour of the active substances, please refer to the respective Assessment reports:

- ATMAC/TMAC (CAS: 61789-18-2): Assessment Report PT 8, April 2016, Italy
- Propiconazole (CAS: 60207-90-1): Assessment Report PT 7, 2015, Finland
- Tebuconazole (CAS: 107534-96-3): Assessment Reports PT 7+10, September 2013, Denmark

Fate and behaviour of the active substances are summarised briefly below:

ATMAC/TMAC

ATMAC/TMAC is a quaternary ammonium compound with a fungistatic mode of action. It was shown to be readily biodegradable. Hence, according to the Guidance on BPR, Vol IV ENV Parts B+C, a half-life in surface water of 15 d can be assumed. In soil, considering the Kpsoil of 22,000 L/kg. it was decided that a DT50 of 30,000 d should be used.

Regarding abiotic degradation, ATMAC/TMAC is hydrolytically stable at pH 5, 7 or 9 at 25 °C and photolytically stable. Estimation of photodegradation in air via the assessment tool AOPWIN showed a half-life in air of 13.505 hours.

The results of an adsorption/desorption study conducted with a structural analogue substance indicated that ATMAC/TMAC is adsorbed in soil and has little or no potential for mobility in soil. Hence, it should not pose an environmental risk for contamination of groundwater. A Koc value of 562314 L/Kg was agreed to be used for the risk assessment of the active substance.

Propiconazole

Propiconazole is not readily biodegradable. In soil studies the geometric mean DT_{50} (12 °C) value was determined to be 82 days. The decomposition of Propiconazole in aerobic soil proceeds via the formation of CGA 118245 (DT_{50} (12 °C) value = 1.9 days) and 1,2,4-triazole, both occurring at amounts > 10%. CGA 118245 is degrading more rapidly and being slightly less mobile than 1,2,4-triazole. It is covered by the assessment of 1,2,4-triazole and not further assessed. In the trilateral discussions on CAR of propiconazole in PT 7 it was raised that the UK RMS made a PPPD review on propiconazole in January 2014 indicating that the DT_{50} of the metabolite 1,2,4-triazole in soil at 20 °C should be 60.5 days. Due to the metabolite's behaviour in soil (fast and slow degradation phases) the DT_{50} is 1.68 d for the fast fraction (48.9%) and 60.5 days for the slow fraction (51.1%). BPC Working Group on environmental issues decided that the DT_{50} of 60.5 days corresponding to a DT_{50} of 115 days at 12 °C from the slow fraction should be used for worst case PECsoil calculations. For groundwater assessment a bi-phasic approach including a fast phase as well as a slow phase degradation should be employed according to FOCUS guidance.
In the water-sediment system a first order $DegT_{50}$ value at 12 °C of 1206 days was assessed and no metabolites exceeded 10% of applied radioactivity in the study.
Regarding abiotic degradation, Propiconazole is hydrolytically and photolytically stable. Estimation of photodegradation in air showed a half-life between 10.2 and 42 hours.
Propiconazole adsorbs to soil and sediment (arithmetic mean Koc of 944 ml/g from 9 soils). Hence, mobility is limited.

Tebuconazole
Tebuconazole is not readily biodegradable. In soil studies the geometric mean DT_{50} (12 °C) value was determined to be 77 days and this value was subsequently used for calculation of PECsoil. The decomposition of tebuconazole in aerobic soil proceeds via the formation of 1,2,4-triazole. According to DOC IIB (CAR tebuconazole PT 7) 1,2,4-triazole was identified as a relevant metabolite of tebuconazole in soil, because it was found in soil degradation studies at concentrations up to 9%, which is close to the limit value of 10%. The metabolite 1,2,4-triazole is also a metabolite of the a.s. propiconazole. Due to high mobility, the groundwater is a compartment of concern regarding exposure to 1,2,4-triazole.
For risk refinement purposes in the aquatic compartment the whole water/ sediment system first order $DegT_{50}$ value at 12 °C of 198 days was used for Tebuconazole.
Regarding abiotic degradation, Tebuconazole is hydrolytically and photolytically stable.
Tebuconazole has a low mobility in soil, the arithmetic mean Koc is 992 ml/g.

3.8.3.1 Leaching behaviour (ADS)

A leaching test with the product was performed to estimate the released amount of the active substances into the environment during service life of treated plywood.

The leaching of ATMAC/TMAC, Propiconazole and Tebuconazole from treated plywood was investigated in a semi-field study for a period of 386 days at Holzforschung Austria. A summary of the test report is included in the IUCLID dossier. The test design is in accordance with NT Build 509, but the exposed surface was lower (0.5904 m² including edges of plywood). Plywood boards made from beech wood with Wolsit F-15T incorporated in the glue-line were tested. The tested plywood contains 3 kg Wolsit F-15T per m³.
Three treated test sets with top-coating and tree treated test-sets without top-coating as well as one untreated test set were established. The vertically oriented timber panels were exposed to the weather. Run-off leachates were continuously collected and analysed for the active substances after each major rain event. Leachates were collected from 04 July 2017 to 24 July 2018.

The calculated cumulative leached quantities ($Q^*_{leach,time}$) which have been used for risk assessment are summarised below. The detailed calculations are presented in chapter 4.3. A correction factor of 1.5 was applied to calculate the cumulative leached quantities and leaching rates, since the product retention of 3 kg/m³ in the study is lower than the maximum intended retention rate of the product of 4.5 kg/m³.
The leaching rates were derived from the test-set without topcoat because the mathematical models did not fit well to the results of the test sets with top-coating. However, the leached quantities from the test set with topcoat have been significantly lower throughout the test period. Furthermore, plywood in use class 3 has always to be topcoated. Thus, the derived leaching rates should be considered as very conservative.

Table 90

Leaching of Wolsit F-15T			
Active substance	**TIME 1 (30 days)**	**TIME 1b (1 year)**	**TIME 2 (15 years)**
Cumulative leaching $Q^*_{leach,time}$ (mg/m²)			
ATMAC/TMAC	0.226	1.515	22.722
Propiconazole	0.334	1.914	2.255
Tebuconazole	0.382	1.967	2.333
Leaching rate FLUX (mg/(m²*d))			
ATMAC/TMAC	0.008	0.004	0.004
Propiconazole	0.011	0.005	0.0004
Tebuconazole	0.013	0.005	0.0004

3.8.3.2 Bioconcentration

The bioaccumulation potential of the active substances of Wolsit F-15T is low:

ATMAC/TMAC
A bioconcentration test with fish exposed to the read-across substance DDAC provided a $BCF_{whole\ fish}$ of 81 L/kg. In addition, experimental $BCF_{whole\ fish}$ of 79 L/kg measured for the other quaternary ammonium compound Alkyl (C12-16) dimethylbenzyl ammonium chloride (C12-16-BKC/ADBAC) shows the same low bioaccumulation potential.

Propiconazole
In the bioaccumulation study the mean steady-state BCF of Propiconazole was 180 and depuration half-life was 0.4 days for the whole fish. The estimated BCF of Propiconazole for bioconcentration to soil dwelling species is 64. Therefore, the bioaccumulation potential is assumed to be low.

Tebuconazole
The experimentally derived BCF_{fish} value considered in the risk assessment is 78 L/kg. Tebuconazole is therefore not considered as bioaccumulative.

3.8.4 Exposure assessment

3.8.4.1 General information

The biocidal product Wolsit F-15T is a ready-to-use product which is added to the glue-line during production of derived timber products (plywood, particle boards, OSB panels). It contains the active substances ATMAC/TMAC (0.105%), Propiconazole (7.89%) and Tebuconazole (7.81%).
Treated particle and OSB panels are intended for use class 2 (UC2), only. Treated plywood may also be used in use class 3 (UC3). The maximum application rate in plywood is 4.5 kg/m³.
According to the Revised ESD PT8 (2013), an exposure assessment for the service life of wood in use class 2 ("Situation in which the wood or wood-based product is under cover and fully protected from the weather but where occasional but not persistent wetting may occur".) needs not to be carried out. An exposure of the environment is not expected for UC2. Hence, the following exposure assessment of wood in service focusses on the use of plywood in UC3. In UC3 exposed wood is not in contact with the ground, but either continually exposed to the weather or subject to frequent wetting.

Table 91

Assessed PT	PT 8
Assessed scenarios	Wood in service (UC3), house Wood in service (UC3), noise barrier Wood in service (UC3), bridge over pond
ESD(s) used	OECD Emission Scenario Documents, Number 2, Revised Emission Scenario Document for Wood Preservatives, September 2013
Approach	Average consumption (all scenarios)
Distribution in the environment	Calculated based on Guidance on BPR, Vol. IV ENV, Parts B + C
Groundwater simulation	FOCUS Pearl version 4.4.4
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use (application): Yes (qualitative) Storage: Yes (qualitative) Service life: Yes (quantitative)
Remarks	-

3.8.4.2 Fate and distribution in exposed environmental compartments

In the following table, the environmental compartments are summarized, which might potentially be exposed to the active substances ATMAC/TMAC, Propiconazole and Tebuconazole due to the use of plywood containing Wolsit F-15T in use class 3.

Table 92

Identification of relevant receiving compartments based on the exposure pathway						
Scenario	**Freshwater**	**Freshwater sediment**	**STP**	**Soil**	**Groundwater**	**Air**
House	-	-	-	++	+	-
Noise barrier	+	+	++	++	+	-
Bridge over pond	++	++	-	-	-	-

++ direct release to receiving compartment
+ indirect release to receiving compartment
- no release to receiving compartment

Direct and indirect emissions from service-life of plywood treated with Wolsit F-15T to the affected receiving compartments are assessed in chapter 3.8.4.2.

Input parameters - active substances

A summary of the relevant parameters used in the risk assessment is given in the following table:

Table 93

Input parameters of the active substances used for calculating the fate and distribution in the environment				
Parameter	**Unit**	**ATMAC/TMAC**	**Propiconazole**	**Tebuconazole**
Molecular weight	g/mol	275.35 (mean)	342.2	307.8
Vapour pressure	Pa	$1.8*10^{-6}$ (at 20 °C)	$5.6*10^{-5}$ (at 25 °C)	$1.7*10^{-6}$ (at 20 °C)
Henry's law constant	$Pa \cdot m^3 \cdot mol^{-1}$	$1.38*10^{-9}$	$9.2*10^{-5}$	$1*10^{-5}$
Water solubility	g/L	346 (at 20 °C, pH 7)	0.1 (at 20 °C, pH 6)	0.029 (at 20 °C, pH 7)
Sorption coefficient (Koc)	L/kg	562314	944	992
Log Pow		0	3.72 (at 25 °C)	3.49 (at 20 °C)
Hydrolysis		stable	stable	stable
Aqueous photolysis		stable	stable	stable
Readily biodegradable		Yes, fulfilling 10-day window	no	no
DT50 soil (12 °C)	d	30000	82	77
DT_{50} surface water (12 °C)	d	15	1206	198
DT_{50} air	hr	13.505	10.2 – 42	91.2

Distribution in the STP

For the environmental exposure assessment, the distribution in the STP according to the respective CA Reports was used:

Table 94

Distribution in STP			
	ATMAC/TMAC	Propiconazole	Tebuconazole
To water	7.7 %	90 %	89.1 %

To sludge	88.8 %	10 %	10.9 %
To air	0 %	0 %	0 %
degraded	3.5 %	0 %	0 %

Input parameters - relevant metabolite

1,2,4-triazole is both a relevant metabolite of Propiconazole and Tebuconazole. For the environmental exposure and risk assessment, emissions resulting from both parent substances should be summed up. 1,2,4-triazole is a relevant metabolite for soil and groundwater compartment. The input parameters for the environmental risk assessment in the table below are based on the Propiconazole AR and CAR (2014) and a PAR from UK already agreed.

Table 95

Input parameters of the relevant metabolite used for calculating the fate and distribution in the environment			
Parameter	**Unit**	**1,2,4-triazole**	**Remarks**
Molecular weight	g/mol	69.1	
Vapour pressure	Pa	0.22 (25 °C)	
Water solubility	g/L	700 (20 °C)	
Sorption coefficient (K_{oc})	L/kg	69	
Hydrolysis		stable	
Aqueous photolysis		stable	
DT50 soil (12 °C)	d	115 (fast fraction: 3.19 slow fraction: 115)	Due to the 1,2,4-triazole's behaviour in soil (fast and slow degradation phases) the BPC Working Group on environmental issues decided that the DT_{50} of 60.5 days corresponding to a DT_{50} of 115 days at 12 °C from the slow fraction should be used for worst case PECsoil calculations. For groundwater assessment a bi-phasic approach including a fast phase as well as a slow phase degradation should be employed according to FOCUS guidance.

The concentrations of 1,2,4-triazole were calculated by correcting the amount of active substance leached over the assessment period for the differences in molar weight.

3.8.4.1 Formulation, industrial application and storage

Wolsit F-15T is intended for industrial application, only. Application takes place in a closed or semi-closed system, where the product is added directly to the glue-line during the production process of derived timber products (plywood, particle boards, OSB panels). The product containing the active substances ATMAC/TMAC, Propiconazole and Tebuconazole is supposed to prevent fungi on derived timber products.

The following qualitative assessment evaluates potential emission of Wolsit F-15T or single product components to the environment during the life cycle steps formulation, production and application of the product and storage of treated wood-products:

Formulation/ production of the biocidal product

Environmental emission estimation for production of the active substances and formulation of the biocidal product has not been performed as the active substances as well as the product are manufactured in a closed system and unacceptable emissions to the environment are not expected. Furthermore, other EU legislation already cover this step.

Industrial application of the biocidal product

The product is used for the industrial treatment of derived timber products. The ready-to-use biocidal product is incorporated in derived timber products in a closed or semi-closed system by addition to the glue-line. According to the applicant it is applied automatically by spraying, rolling or flow-coating to the basic materials (wood chips, veneer) of the derived timber products.

In ESD PT8, sentence 100 and 101, following is stated for automated spraying: “The treatment apparatus is typically established in a contained or bunded area fabricated from materials resistant to the wood preservative product. Provision is made for the collection, recycling and reuse of wood preservative collected from the conveyor or drip dry area. The release of wood preservatives from the treating installation or where the treated timber is stored into a surface water drain or drain connected to a Sewage Treatment Plant (STP) is not permitted and so any installation where this occurs is in contravention of environmental protection legislation and the licence to operate the treatment process.” and “Even though release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore in EU member state countries, the corresponding emission pathway (facility drain to STP to surface water) is nevertheless a worst case the assessment of which can be of relevance outside the EU.” The same applies to the other application methods.

Authorisation of Wolsit F-15T within EU member state countries is sought after in this product application process. Since emissions from the treatment process of the wood to the environment are not allowed within the EU, a quantitative emission estimation is not needed. 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, e.g. as given in the European Code of Practice EWPM (2011[14]).

Safety measures regarding the application process are also demanded in the Implementation Directive (IR) of the active substance ATMAC/TMAC (2016) and apply to the application of Wolsit F-15T as well. Following risk mitigation measure (RMM) has to be added to the SPC:

- *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).*

In addition, the following instruction for use is required to ensure the safe use of Wolsit F-15T and is part of the authorisation:

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

- *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 derived timber products

Emissions to the environment could potentially occur during storage of derived timber products after industrial application of Wolsit F-15T.

In ESD PT8, sentence 90, the following is stated “On European level, where the industrial application of wood preservatives is regulated by local authorities, it can be assumed that most storage places are sealed to prevent any direct release to soil. In the case that the storage place is sealed and run-off from storage places will be collected and disposed of by save means, the storage place scenario does not need to be considered.”

As stated in the respective Inclusion Directives of the three active substances, storage of treated timber exposed to wetting poses a risk to the environment unless RMM (storage under shelter or on impermeable hard standing) are undertaken. Considering this RMM, only negligible emissions to the environment are expected. Therefore, according to the Inclusion Directives, the following RMM is part of the authorisation of Wolsit F-15T:

- “*Freshly treated derived timber products shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water. Any losses of the product shall be collected for reuse or disposal.”*

Because of the information provided and the required RMM, no quantitative emission and exposure calculation is performed for the assessment of storage of wood after industrial application.

3.8.4.2 Service life of treated wood

Emissions to the environment may take place due to leaching from constructions being built from industrially treated wood. As stated above, the following assessment focussed on the use of treated plywood in UC3.
During the Arona Leaching Workshop in June 2005 (EC, 2005[15]), it was agreed that besides a short-term assessment (30 days, TIME1) a long-term assessment should be carried out which is linked to the service life of the treated wood. For wood treated industrially with no pressure methods a service life of 15 years (TIME2) should be taken into account.
The PECs in the environmental compartments derived in the following sections are calculated on the basis of the emission scenarios available for Product Type 8, taking into account degradation processes and/or dilution (where applicable). The PEC values presented in the following tables are rounded values, whereas the calculations for the different PECs are always carried out with unrounded values.

3.8.4.2.1 Aquatic compartment (including sediment and STP)

According to ESD PT8, the aquatic compartment is considered a relevant receiving compartment during service life of plywood treated with Wolsit F-15T for the following scenarios:

- Scenario 2: noise barrier
- Scenario 3: bridge over pond

[15] European Commission (2005): Report of the Arona Leaching Workshop (open session). Arona, Italy, 13 and 14 June 2005. European Commission Joint Research Centre, EUR 21878.

The emission estimation was conducted according to ESD PT8 (2013), chapter 4.3.3.3 and 4.3.3.4.

Emission to STP

Emissions to the STP are calculated for plywood treated with Wolsit F-15T, which is used for the construction of noise barriers.
The STP effluent concentrations do represent the PECs of the active substances of Wolsit F-15T for this compartment. The distribution of the compounds to air, water and sludge is listed in Table 94.
The following tables contain the PEC values for STPs.

Table 96

PECs for the active substances of Wolsit F-15T in the STP				
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Propiconazole	Tebuconazole
		PEC_{STP} in µg/L		
Noise barrier	30 days	6.16E-04	0.010	0.012
	15 years	3.36E-04	3.89E-04	3.99E-04

Emission to surface water

Emissions to surface water are assessed either for indirect emissions via the STP with the noise barrier scenario or direct emissions with the bridge over pond scenario. The calculated PEC values for surface water are presented in the table below. Unless otherwise stated the values include degradation (acc. eq. 3.16 and 3.17 of ESD PT 8 (2013)).

Table 97

PECs for the active substances of Wolsit F-15T in surface water				
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Propiconazole	Tebuconazole
		$PEC_{surfacewater}$ in µg/L		
Noise barrier	30 days	3.34E-05*	0.001*	0.001*
	15 years	1.82E-05*	3.89E-05*	3.98E-05*
Bridge over pond	30 days	7.48E-04	0.002	0.002
	15 years	8.95E-04	0.005	0.001

*without degradation

Emission to sediment

Emissions to sediment are assessed either for indirect emissions to surface water via the STP with the noise barrier scenario or direct emissions to surface water with the bridge over pond scenario. The predicted concentration in sediment is deduced from the $PEC_{surfacewater}$ by a partition of the active substance between suspended matter and the water phase. The sediment values are derived from initial surface water concentrations without considering biodegradation.

Table 98

PECs for the active substances of Wolsit F-15T in sediment

Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Propiconazole	Tebuconazole
		$PEC_{sediment}$ in µg/kg		
Noise barrier	30 days	0.408	0.022	0.027
	15 years	0.223	8.29E-04	8.89E-04
Bridge over pond	30 days	27.60	0.071	0.085
	15 years	2780	0.490	0.514

3.8.4.2.2 Terrestrial compartment (including groundwater)

According to ESD PT8, the terrestrial compartment is considered a relevant receiving compartment during service life of plywood treated with Wolsit F-15T for the following scenarios:

- House
- Noise barrier

No PECs were calculated for release to soil and groundwater via sewage sludge for the noise barrier scenario, since direct emission to soil is considered the worst case.

Emission to soil

The emission estimation was conducted according to ESD PT8 (2013), chapter 4.3.3.1 and 4.3.3.3. The values stated consider degradation (acc. eq. 3.11 and 3.12 of ESD PT 8 (2013)). PEC values were also derived for 1,2,4-triazole, which is considered a relevant metabolite in soil.

Table 99

PECs for the active substances of Wolsit F-15T in soil				
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Propiconazole	Tebuconazole
		PEC_{soil} in mg/kg_{wwt}		
Noise barrier	30 days	4.78E-04	6.25E-04	7.09E-04
	15 years	0.045	1.03E-04	1.00E-04
House	30 days	0.001	0.002	0.002
	15 years	0.121	2.76E-04	2.68E-04

Table 100

PECs for the relevant metabolite of Wolsit F-15T in soil				
Scenario	Assessed period of leaching (TIME)	1,2,4-triazole from parent Propiconazole	1,2,4-triazole from parent Tebuconazole	Sum of 1,2,4-triazole
		PEC_{soil} in g/L		
Noise barrier	30 days	1.3E-04	1.67E-04	2.97E-04
	15 years	2.93E-05	3.36E-05	6.29E-05
House	30 days	3.47E-04	4.45E-04	7.92E-04
	15 years	7.8E-05	8.98E-05	1.68E-04

Emission to groundwater

According to Guidance on BPR, Vol. IV ENV, Part B+C the predicted porewater concentration is an indicator for concentrations in groundwater. In Table 101 and Table 102 the predicted porewater concentrations for the active substances of Wolsit F-15T and the relevant metabolite are shown.

Table 101

PECs for the active substances of Wolsit F-15T in porewater				
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Propiconazole	Tebuconazole
		$PEC_{porewater}$ in µg/L		
Noise barrier	30 days	4.82E-05	0.037	0.04
	15 years	0.005	0.006	0.006
House	30 days	1.29E-04	0.0995	0.107
	15 years	0.012	0.016	0.015

Table 102

PECs for the relevant metabolite of Wolsit F-15T in porewater		
Scenario	Assessed period of leaching (TIME)	Sum of 1,2,4-triazole
		$PEC_{porewater}$ in µg/L
Noise barrier	30 days	0.222
	15 years	0.047
House	30 days	0.593
	15 years	0.126

3.8.4.2.3 Atmosphere

Due to the low vapour pressure, ATMAC/TMAC is not expected to partition into the atmosphere. Based on the vapour pressure (5.6 x 10^{-5} Pa at 25 °C) and the Henry`s Law constant (9.2 x 10^{-5} Pa×m³/mol), volatilisation of propiconazole can be regarded as negligible. For tebuconazole the volatilization is considered to be negligible based on the vapour pressure (1.7E-06 Pa) and the Henry's Law constant (1E-05 Pa×m³/mol).
Therefore, the calculation of PEC values for the atmosphere (PEC_{air}) is of no relevance and air is not regarded as a compartment of concern for this product type and proposed use patterns.

3.8.4.3 Non-compartment specific effects

Primary poisoning

Not relevant for PT 8.

Secondary poisoning

According to the BPR guidance Vol IV part B+C (2017) for substances with a log K_{ow} ≥ 3, the uptake through the food chains eventually leading to secondary poisoning should be considered. This is the case for Propiconazole (log K_{ow} = 3.72) and Tebuconazole (log K_{ow} = 3.49).

Although the log Kow of Propiconazole (log Kow = 3.7) reveals a slight potential for bioaccumulation, the assessment of secondary poisoning is not requested according to the Assessment Report for the use of Propiconazole in wood preservatives.
For Tebuconazole, the BCF_{fish} is 78 L/kg and the estimated $BCF_{earthworm}$ is 28 L/kg. Hence, the potential for bioaccumulation is low with the BCF_{fish} below the trigger value of 100.

No further assessment of secondary poisoning via the food chain is considered necessary and no PECs were derived.

3.8.4.4 Aggregated exposure (combined for relevant emission sources)

Biocidal active substances are used in various applications and are often contained in many different products. The environmental exposure assessment of single uses may therefore underestimate the actual concentrations of active substances to be found in the environment.
However, currently a guideline on how an aggregated exposure assessment shall be performed is in development. Therefore, in this PAR the aggregated exposure has not yet been assessed.

3.8.5 Risk characterisation

The environmental risk characterisation for biocidal active substances in the context of Annex VI of the Biocidal Products Regulation (Regulation (EU) No 528/2012) involves the comparison of PEC and PNEC values for each relevant environmental compartment as well as for non-target organisms. For this purpose, Risk Characterisation Ratios (PEC/PNEC) are derived for the use of the wood preservative Wolsit F-15T. If the PEC/PNEC ratio is equal or below 1, this is interpreted as an acceptable risk to the environment. Exceptions are the assessments of industrial application of the biocidal product and the storage of treated derived wood products, which were done qualitatively.

PEC values were calculated for TIME1 and TIME2. It was agreed at WG ENV I 2014 that, if TIME1 results in unacceptable risks for the environment, an intermediate time period (365 days, TIME1b) can be considered in the risk assessment. In future TIME1b might be relevant for the authorisation decision. In the following risk assessment of Wolsit F-15T, TIME1b is considered if TIME1 resulted in unacceptable risks for the environment.

3.8.5.1 Industrial application and storage

Application (industrial)
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.

No unacceptable risk for the environment is expected during industrial application of Wolsit F-15T.
The following risk mitigation measure, as requested in the Inclusion Directive of ATMAC/TMAC (2016) 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 instruction for use is part of the authorisation:

- *Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer.*

Storage of treated derived timber products

No risk quotients for the environment were derived. As it can be concluded from the respective Inclusion Directives of the three active substances, storage of treated derived timber products may pose a risk to the environment unless risk mitigation measures are undertaken.

Therefore, the following risk mitigation measure is part of the authorisation and reduces potential risks to the environment to an acceptable level, as emission to the environment is prevented:

- *Freshly treated derived timber products shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water. Any losses of the product shall be collected for reuse or disposal.*

3.8.5.2 Service life of treated wood

3.8.5.2.1 Aquatic compartment (including sediment and STP)

STP

Losses to STPs are calculated for the in-service leaching from the surface of the noise barriers.
The following table contains the PEC/PNEC ratios for the substances as well as a mixture toxicity assessment, comprising the addition of the PEC/PNEC values for ATMAC/TMAC, Propiconazole and Tebuconazole.

Table 103

PEC/PNEC values of the active substances of Wolsit F-15T in the STP					
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Propiconazole	Tebuconazole	Mixture Toxicity
		$PEC/PNEC_{STP}$			
Noise barrier	30 days	5.05E-06	1.00E-07	3.75E-05	4.26E-05
	15 years	2.75E-06	3.89E-09	1.25E-06	4.00E-06

Conclusion: The requirements for acceptable risks according to the BPR guidance Vol IV part B (2017) are met for the STP for the representative noise barrier scenario for each active substance and the mixture of all active substances for Wolsit F-15T.

Surface water

The following table contains the PEC/PNEC ratios for the active substances as well as a mixture toxicity assessment for the “bridge over pond” and “noise barrier” scenarios, which represent exposure of surface water to Wolsit F-15T.

Table 104

PEC/PNEC values of the active substances of Wolsit F-15T in surface water

Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Propiconazole	Tebuconazole	Mixture Toxicity
		$PEC/PNEC_{surfacewater}$			
Noise barrier	30 days	4.18E-05	1.51E-04	0.001	0.001
	15 years	2.28E-05	5.72E-06	3.98E-05	6.83E-05
Bridge over pond	30 days	9.35E-04	2.44E-04	0.002	0.003
	15 years	0.001	7.34E-04	0.001	0.003

Conclusion: Both scenarios yield PEC/PNEC ratios below one for surface water for the single substances as well as the mixture of active substances, indicating an acceptable risk for surface water organisms.

Sediment

The PEC/PNEC values for the active substances as well as the mixture toxicity assessment are summarized below for the representative scenarios “bridge over pond” and “noise barrier”. A PEC/PNEC > 1 is shown in bold letters.

Table 105

PEC/PNEC values of the active substances of Wolsit F-15T in sediment					
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Propiconazole	Tebuconazole	Mixture Toxicity
		$PEC/PNEC_{sediment}$			
Noise barrier	30 days	1.53E-04	4.07E-04	4.91E-05	6.09E-04
	15 years	8.35E-05	1.54E-05	1.62E-06	1.00E-04
Bridge over pond	30 days	0.01	0.001	1.55E-04	0.012
	15 years	**1.04**	0.009	9.35E-04	**1.05**

Conclusion: Acceptable risks for the sediment compartment were found for the “noise barrier” scenario as well as for TIME1 of the “bridge over pond” scenario for the three active substances and the mixture toxicity assessment.
TIME2 of the “bridge over pond” scenario resulted in a PEC/PNEC ratio of 1.04 for ATMAC/TMAC and, thus, a slight exceedance of the trigger value of 1. Consequently, the PEC/PNEC for the mixture toxicity assessment was also slightly higher than 1.

However, as explained in detail in chapter 4.3 the leaching rate for ATMAC/TMAC is an extreme worst-case: ATMAC/TMAC was not measured in any sample of the leaching test. For the detection of ATMAC/TMAC, the samples were tested for its individual compounds (TMAC C_8, C_{10}, C_{12}, C_{14}, C_{16}, C_{18}) with a limit of quantification of 5 µg/L, each. None of those compounds were detected in any of the samples. As agreed at PT 8 EG meeting (March 2019), the limit of quantification was used for the calculation of leaching. For the calculation of leaching, the sum of the limits of quantification (6 x 5 µg/L) of these compounds of 30 µg/L was used to derive the leaching rate and the quantity leached over TIME. The approach chosen is an extreme worst-case approach and it is unlikely that the amounts of all compounds of ATMAC/TMAC in the samples are close to the limit of quantification to result in an unacceptable risk for sediment.

Therefore, acceptable risks for the sediment compartment can be expected and RMM are not deemed necessary.

3.8.5.2.2 Terrestrial compartment (including groundwater)

Soil

The calculated PEC/PNEC ratios for the soil compartment for the active substances and the relevant metabolite 1,2,4-triazole and the mixture toxicity assessment are shown in the tables below. The PEC/PNEC ratios for the metabolite 1,2,4-triazole are based on the total expected concentrations in soil, resulting from both parent substances Propiconazole and Tebuconazole.

Table 106

PEC/PNEC values of the active substances of Wolsit F-15T in soil					
Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Propiconazole	Tebuconazole	Mixture Toxicity
		$PEC/PNEC_{soil}$			
Noise barrier	30 days	4.55E-04	0.006	0.007	0.014
	15 years	0.043	0.001	0.001	0.045
House	30 days	0.001	0.017	0.019	0.037
	15 years	0.115	0.003	0.003	0.121

Table 107

PEC/PNEC values of the relevant metabolite of Wolsit F-15T in soil		
Scenario	Assessed period of leaching (TIME)	1,2,4-triazole
		$PEC/PNEC_{soil}$
Noise barrier	30 days	0.030
	15 years	0.006
House	30 days	0.079
	15 years	0.017

Conclusion: Acceptable risks for the soil compartment were identified for the active substances of Wolsit F-15T and the relevant metabolite. The mixture toxicity assessment resulted in acceptable risks for soil organisms, too.

Groundwater

The predicted concentration in groundwater is represented by the porewater concentration as a first tier approach. The maximum permissible concentration for biocides and their metabolites in groundwater is 0.1 µg/L according to Directive 2006/118/EC for drinking water. In Table 108 and Table 109 porewater concentrations above the trigger value of 0.1 µg/L are shown in bold letters.

Table 108

PECs for the active substances of Wolsit F-15T in porewater

Scenario	Assessed period of leaching (TIME)	ATMAC/TMAC	Propiconazole	Tebuconazole
		$PEC_{porewater}$ in µg/L		
Noise barrier	30 days	4.82E-05	0.037	0.040
	15 years	0.005	0.006	0.006
House	30 days	1.29E-04	0.0995	**0.107**
	15 years	0.012	0.016	0.015

Table 109

PECs for the relevant metabolite of Wolsit F-15T in porewater		
Scenario	Assessed period of leaching (TIME)	Sum of 1,2,4-triazole
		$PEC_{porewater}$ in µg/L
Noise barrier	30 days	**0.222**
	15 years	0.047
House	30 days	**0.593**
	15 years	**0.126**

Conclusion: As a first tier approach, porewater concentration were derived from $PEC_{soil,}$ which represent concentrations in groundwater according to Guidance on BPR, Vol IV ENV, Part B+C. As shown in Table 108 porewater concentrations of ATMAC/TMAC and Propiconazole are below the trigger value for the relevant scenarios. Therefore, no further assessment of $PEC_{groundwater}$ is needed for those active substances.
For Tebuconazole the trigger value of 0.1 µg/L is exceeded slightly ($PEC_{porewater}$ = 0.107 µg/L) in TIME1 of the house scenario. For the relevant metabolite 1,2,4-triazole the trigger value is exceeded in three of the four soil scenarios. Hence, for Tebuconazole and 1,2,4-triazole the groundwater assessment needs to be refined with FOCUS PEARL 4.4.4.

For the refinement the scenario with the highest $PEC_{porewater}$ is considered, which is TIME1 of the house scenario. However, TIME 1 (30 days) is currently not relevant for the authorisation decision of the product and would result in an extreme overestimation of leaching, as the leaching rate during the first 30 days would be considered. As stated above, in future, TIME1b (365 days) is relevant for the authorisation decision. Hence, the FOCUS modelling was already done on the basis of $Q^*_{leach\_time1b}$ (refer to chapter 3.8.3.1). By this approach the leached amounts from day 1 to day 30 and from day 30 to 365 are summed up. This allows a realistic modelling of leaching in the first year of the service life of treated wood. As the annual leached amount for TIME 2 is lower than for TIME 1b, this means that FOCUS modelling for TIME 2 would result in lower groundwater concentrations. Therefore, the conducted modelling for TIME1b on basis of $Q^*_{leach\_time1b}$ covers also emissions to groundwater in TIME2.

The groundwater exposure scheme according to the supplement to Appendix 4 of the ESD for PT 8 (2013) was taken into account. A density of 16 treated houses per ha and a leachable area of 125 m² per house, resulting in a total leachable area of 2000 m² per ha with a weatherside fraction ($F_{weatherside}$) of 0.5 was considered. As application scheme 10 application events are considered (10 January, 15 February, 24 March, 29 April, 5 June, 11 July, 17 August, 22 September, 29 October, 4 December) with the application mode “to the soil surface” (no plant uptake). The crop type is alfalfa/grass.

Relevant input parameters for the substances are shown in chapter 3.8.4.2. Modelling for all substances was run with a Freundlich coefficient of 1 by default.

The results of the refined groundwater assessment of Tebuconazole are shown in the following table:

Table 110

$PEC_{groundwater}$ of Tebuconazole after refinement with FOCUS PEARL	
Scenario	**PECgw (µg/L)**
	Tebuconazole
Chateaudun	<0.0001
Hamburg	<0.0001
Joikoinen	<0.0001
Kremsmuester	<0.0001
Okehampton	<0.0001
Piacenza	<0.0001
Porto	<0.0001
Sevilla	<0.0001
Thiva	<0.0001

Since 1,2,4-triazole is both a metabolite of Propiconazole and Tebuconazole, FOCUS modelling was conducted for both active substances. Groundwater concentrations of 1,2,4-triazole were summed up for slow and fast phase and for release from both parent substances:

Table 111

$PEC_{groundwater}$ of 1,2,4-triazole (from Propiconazole and Tebuconazole) after refinement with FOCUS PEARL	
Scenario	**PECgw (µg/L)**
	1,2,4-triazole
Chateaudun	0.013
Hamburg	0.021
Joikoinen	0.019
Kremsmuester	0.013
Okehampton	0.016
Piacenza	0.013
Porto	0.009
Sevilla	0.007
Thiva	0.008

Conclusion refinement: The $PEC_{groundwater}$ is below the quality standard of 0.1 µg/L for pesticides and biocidal products according to Directive 2006/118/EC for drinking water for all active substances as well as the metabolite 1,2,4-triazole for all scenarios. Therefore, acceptable risks for groundwater can be expected for service life of plywood treated with Wolsit F-15T.

3.8.5.2.3 Atmosphere

Due to the physicochemical properties of the active substances air is not regarded as a compartment of concern. The risk to the air compartment is considered acceptable.

3.8.5.3 Non-compartment specific

Primary poisoning

Not relevant for PT8.

Secondary poisoning

The risk of secondary poisoning via the food chain is considered low (see chapter 3.8.4.3).

3.8.5.4 PBT assessment

ATMAC/TMAC
ATMAC/TMAC is not considered to be persistent. The B criterion is not fulfilled with a BCF fish of 81. The T criterion is fulfilled with a NOEC for algae of 0.008 mg/L.
Hence, ATMAC/TMAC is not considered to be a PBT or vPvB substance.

Propiconazole
Propiconazole fulfils the criterion for persistence (P) in the water-sediment system with the worst-case whole system degradation half-life of 1206 days at 12 °C as well as in the soil compartment with the worst-case degradation half-life of 137 days at 12 °C. Furthermore, it fulfils the vP criterion in the water-sediment system but not in the soil compartment.
According to AR (PT 7, 2015), Propiconazole does not fulfil the B- or the T-criterion with the BCF of 180 for fish and NOEC of 0.068 mg/l for fish. However, according to the Regulation (EU) 2018/1480[16] the active substance Propiconazole shall be classified with Repr. 1B, H360D from 1 May 2020. A substance fulfils the T-criterion when it meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), toxic for reproduction (category 1A, 1B or 2) or specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation 1272/2008. In conclusion, Propiconazole should be regarded as fulfilling the criterion for toxicity.
Propiconazole is considered to be persistent (P) and toxic (T) but not bioaccumulative (B) and therefore meets two of the criteria for being PBT.

Tebuconazole
Tebuconazole fulfils the criterion to be very persistent (vP).

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16 Regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776

It does not fulfil the B criterion. Tebuconazole fulfils the T criterion as it meets the criteria for classification as toxic for reproduction, category 2 according to the CLP Regulation (CAR PT 7 & 10, 2013). Hence, Tebuconazole is regarded as candidate for substitution because it fulfils the vP and T criterion.

3.8.5.5 Endocrine disrupting properties

According to the Assessment Report for the QUATS (April 2016, eCA: IT) the substance ATMAC/TMAC is not considered to have endocrine disrupting properties. According to the Assessment Reports for tebuconazol (November 2009, eCA: DK) and propiconazol (November 2018, eCA: FI) there might be a potential to cause endocrine disruption based on suspected properties of the azole group. However, a comprehensive ED-assessment for all three active substance according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine disruptors will need to be performed at the renewal stage.

The full composition of the product is listed in the confidential annex. There are no indications that a non-active substance of the product may have endocrine disrupting properties on environmental non-target organisms 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 or ECHA's endocrine disruptor assessment list. For none of the co-formulants indications on potential ED effects on environmental non-target organisms were found in scientific literature.

3.8.5.6 Summary of risk characterisation

The biocidal product Wolsit F-15T is a ready-to-use product containing the active substances ATMAC/TMAC, Propiconazole and Tebuconazole. It is added to the glue-line during industrial production of derived timber products. Whereas Wolsit F-15T treated OSB panels and particle boards may only be used in UC2, treated plywood may also be used in UC3.
During industrial application of Wolsit F-115T 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. Additionally, the following RMM shall ensure safe application of the product: "*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).*"
For the storage of treated derived timber products no exposure/risk assessment was conducted. Potential emissions to the environment during storage of treated derived timber products can be controlled by implementation of the risk mitigation measure "*Freshly treated derived timber products shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water. Any losses of the product shall be collected for reuse or disposal.*"
The assessment of service life of treated plywood used in UC3 resulted in acceptable risks for all environmental compartments.
Therefore, it can be concluded that for the biocidal product Wolsit F-15T acceptable risks for the environment are assessed if the imposed risk mitigation measures according to chapter 2.5.2 are considered and the instructions for use according to chapter 2.5.1 are followed.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

3.10.1 Background

The biocidal product (BP) Wolsit F-15T is a wood preservative containing the three active substances ATMAC/TMAC, tebuconazole and propiconazole. ATMAC/TMAC does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 (BPR) and is not a candidate for substitution. Tebuconazole does meet the conditions laid down in Article 10(1)(d) of BPR and is therefore a candidate for substitution by being very persistent (vP) and toxic (T). Tebuconazole is not considered as meeting the exclusion criteria according to Article 5(1) of BPR. Propiconazole is considered to be persistent (P) and toxic (T), meeting the conditions laid down in Article 10(1)(d) of BPR. Additionally, propiconazole meets the criteria for exclusion under Article 5(1) of BPR as it is classified as toxic for reproduction category 1B.

Therefore, in line with Article 23 (1) of the BPR, the German CA has conducted a comparative assessment for the product family according to the “Technical Guidance Note on comparative assessment of biocidal products” (document: CA-May-15-Doc-4.3a-Final-TNG on comparative assessment.doc).

In accordance with the Technical Guidance Note on comparative assessment of biocidal products (CA-May-15-Doc-4.3a-final), the products were only compared to the alternatives authorised in Germany as the R4BP3 is not yet populated with searchable SPCs and no search tool has been provided by ECHA yet.

3.10.2 Application administrative details

Procedure: National Authorisation (NA)
Purpose: Authorisation
Case Number in R4BP: BC-YH039264-29
Evaluating Competent Authority: Germany (BAuA)
Applicant: Wolman Wood and Fire Protection GmbH
(Prospective) Authorisation holder: Wolman Wood and Fire Protection GmbH

3.10.3 Administrative information of the BP

Trade name: Wolsit F-15T
Product type: 08 (Wood preservatives)
Active substances: Tebuconazole, ATMAC/TMAC, Propiconazole.

3.10.4 Uses appropriate for authorisation of the relevant BP and the properties of the active substances

The biocidal product Wolsit F-15T is a wood preservative (PT 08) which contains the active substances ATMAC/TMAC, tebuconazole and propiconazole. The product is used by industrial users for preventive wood protection of derived timber products in use class 2 and 3 against wood destroying fungi.
The product is a solvent-base liquid that is mixed with glue and mortar during application. The fungicidal product is intended to be added to the glue-line (glue-line treatment in semi-closed systems) during the production of derived timber products (plywood -, particle -, OSB panels).

Table 112 lists the uses appropriate for authorisation of the biocidal product, which determines the focus of the comparative assessment.

Table 112: Uses appropriate for authorisation of the biocidal product

Product type(s)	Wood preservative (PT 08)
Where relevant, an exact description of the authorised use	Fungicide used in derived timber products for Use Class (UC) 2 (OSB + particle board and uncoated plywood) and 3.1 (coated plywood) according to EN 335-1. Ready-to-use product.
Target organism (including, where relevant) development stage)	Wood destroying fungi
Field(s) of use	Plywood -, particle -, OSB panels (only derived timber products). It is mainly used for exterior cladding (panels) of facades and sub-roof. Also for scaffolding. Especially for non-resistant hardwood. Treatment is done indoors. Treated wood will be used in areas protected or exposed to weathering sporadically but not in contact with soil. Use classes (UC) 2 and 3.1.

Application method(s)	Direct addition into the glue-line (mixing with glue and mortar), direct application in closed systems.
Category(ies) of users	industrial

The active substances tebuconazole and propiconazole inhibit in the ergosterol biosynthesis of fungi, thus prohibiting formation of cell walls.
The active substance ATMAC/TMAC is a quaternary ammonium compound which acts by disruption and leakage of the membranes, leading to cell damage or lysis of the cell content.

3.10.5 Mapping of existing alternatives to the relevant BP in Germany

Identified eligible alternative BPs[17]

As of 12.05.2020, there are only three products authorised in Germany that have a similar use to the relevant biocidal product, i.e. the addition of the biocidal product in the glue line for manufacturing of derived timber products for use in use class 2 and the target organism wood destroying fungi.
Two products contain boric acid and disodiumtetraborate pentahydrate as active substances. As boric acid and disodium tetraborate pentahydrate are themselves candidates for substitution that fulfil the exclusion criteria, products containing these active substances are not included in this comparative assessment.
The remaining product Xyligen 30 F containing the active substance K-HDO is an eligible alternative biocidal product available on the german market and therefore it is included in this comparative assessment.

Identified eligible non-chemical alternatives

In Germany, wood preservation is guided by the DIN 68800 standards. According to DIN 68800-1, constructional measures, which constitute non-chemical alternatives, are preferable over treatment with chemical wood preservatives. In many scenarios, including the intended uses for the relevant biocidal product, such constructional measures however are not sufficient to reduce risk of infestation by wood-destroying fungi to a level where no further protection is required. For wood composites made of common, susceptible wood types, there are no preventive non-chemical treatments when protection against wood-rotting fungi is concerned, so they can only be protected with appropriate wood preservatives.

[17] In accordance with the Technical Guidance Note on comparative assessment of biocidal products (CA-May-15-Doc-4.3a-final) the biocidal product was only compared to the alternative biocidal products authorised in Germany as the R4BP3 is not yet populated with searchable SPCs and no search tool has been provided by ECHA yet.

3.10.6 Screening phase

Table 113 lists the mode of action of the active substances and the risk of resistance development.

Table 113: Mode of action and risk of resistance development for PT 8 (Wood protection)

Active Substance	Mode of action	Resistance reported
Propiconazole Tebuconazole	Propiconazole and tebuconazole inhibit in the ergosterol biosynthesis of fungi, thus prohibiting formation of cell walls.	No
ATMAC/TMAC	ATMAC/TMAC is a quaternary ammonium compound which acts by disruption and leakage of the membranes, leading to cell damage or lysis of the cell content	No
K-HDO	K-HDO inhibits enzymatic activity in fungi, likely via electrophilic and radical reactions with thiol-containing enzymes	No

The mode of action of the active substance K-HDO in the eligible alternative is distinct from the mode of action of the active substances in the relevant biocidal product. However, to ensure an adaequate chemical diversity, at least three different and independent “active substance/mode of action” combinations should be available. Without the relevant biocidal product, only a single active substance is available for the relevant uses.

Conclusion of the screening phase

The German CA concludes that there is currently no adequate chemical diversity to minimise the occurrence of resistance in the target organisms of the relevant biocidal product. Therefore, the condition set out in Article 23 3. (b) of the BPR is not met.

However, the active substance propiconazole is classified as Repr. 1B and therefore meets one of the exclusion criteria listed in Article 5(1) of the BPR. As described in the the “Technical Guidance Note on comparative assessment of biocidal products”, a quantitative comparatative assessment (Tier I-B) with the eligible alternative biocidal product is necessary, wether there is adequate chemical diversity or not.

3.10.7 Tier I-B

The Tier I B assessement focuses on the main concerns posed by the candidates for substitution. The key element for comparison in Tier I-B are the CMR properties resulting from the classification of propiconazol as Repr. 1B. Additionally, the PBT properties are assessed, as propiconazole ist considered persistent and toxic and tebuconazole is considered very persistent and toxic.

3.10.7.1 Hazard-based assessment for human health considering classification and labelling of the relevant products

Table 114: Classification of Xyligen 30 F and Wolsit F-15T

Wolsit F-15T	Xyligen 30 F
Acute Tox. 4, H302	Acute Tox. 4, H302
Skin Sens. 1, H317	Skin Irrit. 2, H315
Eye Dam. 1, H318	Eye Dam. 1, H318
Repr 1B, H360D	

Both Xyligen 30 F and Wolsit F-15T are classified as Acute Tox. 4 (oral) and as Eye Dam. 1. Wolsit F-15T is additionally classified as Skin Sens. 1 and Repr. 1B whereas Xyligen 30 F is classified as Skin Irrit. 2.

According to the guidance for comparative assessment only the classification for respiratory sensitization, ED or CMR properties are considered.

Xyligen 30 F is not classified for such an effect or known to have ED properties, whereas Wolsit F-15T is classified as Repr. 1B.

Hence, the alternative product differs significantly from Wolsit F-15T in its classification. The different classifications lead to additional precautionary statements and risk mitigation measures for Wolsit F-15T.

Conclusion

In conclusion, the alternative product Xyligen 30 F has a significantly lower hazard with respect to classification and labelling. However, the risk regarding human health is not significantly lower (see chapter 3.10.7.2 and 3.10.7.3)

3.10.7.2 Assessment of risks for professional users

For Tier I B the results of the risk assessment of same application methods (taking into account risk mitigation measures (TIER 2 approach)) are compared. This is necessary to ensure that equivalent model approaches for exposure assessment are used.

For professional use of the product Wolsit F-15T and the alternative biocidal product Xyligen 30 F the use ‘glue-line treatment in closed systems’ and the following relating scenarios are compared:

The addition of the biocidal product in the glue line for manufacturing of derived timber products is performed in a closed system. In the use ‘glue-line treatment in closed systems’ authorised for both products Wolsit F-15T and Xyligen 30 F the worker is exposed during the scenario mixing and loading

(connecting of transfer lines) of the biocidal product into the system and by the scenario handling of treated wood (mechanical processing of treted wood).

For the following comparative assessment (Tier I B) the substance specific risk indices (RI) or Hazard Quotients (HQ) (total uptake / AEL) are compared for the scenario ‘mixing and loading (connectig transfer lines) and ‘mechanical processing of treated wood’. The comparative assessment is limited to the active substances.

1. Mixing and Loading (connecting transfer lines)

The following Table 115 gives a detailed overview of the risk assessment results in TIER 2 (with risk mitigation measures) for the scenario mixing and loading (connecting transfer lines) for the relvant biocidal product Wolsit F-15T and the alternative biocidal product Xyligen 30 F.

Table 115: Overview of risk assessment results in TIER 2 for the scenario mixing and loading (connecting transfer lines)

Product	Active substance (CAS)	Reference Value (RV)	Hazard Class and Hazard Statement b.p.	RMM (Tier 2)
Wolsit F-15T	Propiconazole (60207-90-1) Tebuconazole (107534-96-3) ATMAC/TMAC (61789-18-2)	AELlongterm: 0.04 mg/kg bw/d 0.03 mg/kg bw/d NOAEC: 0.3%	Acute Tox. 4; H302 Skin Sens. 1;H317 Eye Dam. 1; H318 Repr. 1B; H360D	• Protective gloves • Eye protection • Automatic dosing system
Xyligen 30F	K-HDO (66603-10-9)	AELlongterm: 0.021 mg/kg bw/d	Acute Tox. 4; H 302 Skin Irrit. 2; H315 Eye Damage 1; H318	• Protective gloves • Protective coverall • Eye protection

In Table 116 the substance specific risk indices regardless of the nature of the effect per biocidal product is listed.
It can be concluded that for the scenario mixing and loading Wolsit F15-T has a better profile than the alternative product Xyligen 30F.

Table 116: Overview of the most critical substance specific risk index for systemic effects per biocidal product for the mixing and loading (connecting transfer lines)

Product	Active substance (CAS)	RI/HQ Total uptake/AEL (Tier 2)	HI (sum of RIs/HQs) (Tier 2)
Wolsit F-15T	Propiconazole (60207-90-1) Tebuconazole (107534-96-3) ATMAC/TMAC (61789-18-2)	Propiconazole: 8.05×10^{-3} Tebuconazole: 0.01 ATMAC/TMAC: n.a.	0.02
Xyligen 30F	K-HDO (66603-10-9)	KHDO: 0.055	Not applicable

2. Mechanical Processing of treated wood

The following Table 117gives an overview of the risk assessment results in TIER 2 with risk mitigation measures for the scenario mechanical processing of treated wood for the relvant biocidal product Wolsit F-15T and the alternative biocidal Product Xyligen 30 F.

Table 117: Overview of risk assessment results in TIER 2 for the scenario mechanical processing of treated wood

Product	Active substance (CAS)	Reference Value (RV)	Hazard Class and Hazard Statement b.p.	RMM (Tier 2)
Wolsit F-15T	Propiconazole (60207-90-1) Tebuconazole (107534-96-3) ATMAC/TMAC (61789-18-2)	AELlongterm: 0.04 mg/kg bw/d 0.03 mg/kg bw/d NOAEC: 0.3%	Acute Tox. 4; H302 Skin Sens. 1;H317 Eye Dam. 1; H318 Repr. 1B; H360D	• Protective gloves • Protective coverall • Eye protection
Xyligen 30F	K-HDO (66603-10-9)	AELlongterm: 0.021 mg/kg bw/d	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Damage 1; H318	• Protective gloves • Protective coverall • Eye protection

In Table 118 the substance specific risk index regardless the nature of the effect per biocidal product is listed.

It can be concluded that for the scenario mechanical processing of treated wood the alternative product Xyligen 30F has not a significantly better profile than the relevant biocidal product Wolsit F-15T.

Table 118: Overview of the most critical substance specific risk index for systemic effects per biocidal product for mechanical processing of treated wood

Product	Active substance (CAS)	Total uptake/AEL (Tier 2)	HI (sum of RIs/HQs) (Tier 2)
Wolsit F-15T	Propiconazole (60207-90-1) Tebuconazole (107534-96-3) ATMAC/TMAC (61789-18-2)	Propiconazole: 0.27 Tebuconazole: 0.36 ATMAC/TMAC: n.a.	0.64
Xyligen 30F	K-HDO (66603-10-9)	KHDO: 0.212	Not applicable

Conclusion

Hazard indices for all relevant scenarios are in the same order of magnitude. Hence, no significant differences are identified. Considering the risk mitigation measures Wolsit F15-T has a better profile than the alternative product Xyligen 30F for the scenario Mixing & Loading (connecting transfer lines) and a similar profile for the scenario 'Mechanical processing of treated wood'.
In conclusion, the alternative product Xyligen 30 F has no significantly lower risk with respect to human health risk assessment for the professional user.

3.10.7.3 Human Health Risk assessment for the general public

As the identification of hazards based on the classification as presented above does not allow conclusions on the exposure-based risk, the next step includes a comparative exposure and risk assessment for the active substances in Wolsit F-15T and Xyligen 30 F to the general public. An assessment for the non-professional user is not relevant since the products are for professional application only.
The exposure and risk assessment for the active substance KHDO in Xyligen 30 F as presented in the PAR was performed in 2011. Therefore, for comparative assessment exposure of the general public to KHDO in Xyligen 30 F was re-assessed similar to propiconazole and tebuconazole in Wolsit F-15T.
The dermal absorption value in the PAR of Xyligen 30 F used for the assessment was 8 % and derived from a dermal absorption study evaluated in the CAR. However, the evaluation of this study was not performed according to the recent guidance. As the study is not available to us and for a better comparability default values from EFSA Guidance on Dermal absorption (2017) are also used for this

product. As Xyligen 30 F is a water-based product, the dermal absorption value of 50 % is applied for exposure assessment of the general public.

Wolsit F-15T contains two active substances relevant for systemic risk assessment. The risks for these active substances are cumulated. The potential risks are expressed as the hazard index for Xyligen 30 F and Wolsit F-15T.

The scenario 5 (mouthing of wood by smaller children) leads to a non-acceptable risk in the PAR for Xyligen 30 F. However, this exposure scenario was considered as not relevant in the PAR since contact to treated wood does normally not occur or could be avoided by appropriate risk mitigation measures. For tebuconazole in Wolsit F-15T also a non-acceptable risk was identified in Tier 1. However, specific leaching data are available resulting in a safe scenario for Tier 2. Such data are not available for Xyligen 30 F. Therefore, only Tier 1 of scenario 5 are compared although both lead to a non-acceptable risk.

Scenario 7 was not assessed for Wolsit F-15T since the intended use the biocidal product excludes the corresponding exposure of the general public. Also for Xyligen 30 F this scenario was not assessed. No justification was provided in the PAR.

Table 119: Risk assessment for the general public exposed to tebuconazole and propiconazole in Wolsit F-15T

Task/ Scenario	Tier	Exposure [mg/kg bw(/d)]	AEL [mg/kg bw(/d)]	Hazard index	Acceptable (yes/no)
Scenario 4, Sanding treated wood	1	Tebuconazole: 0.02026 Propiconazole: 0.02047	Tebuconazole: 0.03 Propiconazole: 0.3	0.75	yes
Scenario 5, Mouthing treated wood	1	Tebuconazole: 0.056 Propiconazole: 0.057	Tebuconazole: 0.03 Propiconazole: 0.3	2.06	no
	2	Tebuconazole: 0.0108 Propiconazole: 0.057	Tebuconazole: 0.03 Propiconazole: 0.3	0.55	yes
Scenario 6, inhalation volatilised residues	1	Tebuconazole: 0.000172 Propiconazole: 0.006293	Tebuconazole: 0.03 Propiconazole: 0.04	0.16	yes
Scenario 7, Contact to treated surfaces	1	Tebuconazole: n.a. Propiconazole: n.a.	Tebuconazole: 0.03 Propiconazole: 0.04	n.a.	yes

Table 120: : Risk assessment for the general public exposed to KHDO in Xyligen 30 F

Task/ Scenario	Tier	Exposure [mg/kg bw(/d)]	AEL [mg/kg bw(/d)]	Hazard index	Acceptable (yes/no)
Scenario 4, Sanding treated wood	1	KHDO: 0,09284	KHDO: 0,1	0.93	yes
Scenario 5, Mouthing treated wood	1	KHDO: 0.360	KHDO: 0,1	3.60	no
	2	KHDO: n.a	KHDO: 0,1	n.a.	n.a.
Scenario 6, inhalation volatilised residues	1	KHDO: 0.00006	KHDO: 0,021	0.003	yes

Task/ Scenario	Tier	Exposure [mg/kg bw(/d)]	AEL [mg/kg bw(/d)]	Hazard index	Acceptable (yes/no)
Scenario 7, Contact to treated surfaces	1	KHDO: n.a.	KHDO: 0,021	n.a.	Not necessary

Hazard indexes for all relevant scenarios are in the same order of magnitude. Hence, no significant differences are identified. This refers also for potentially resulting risk mitigation measures for protection of the general public. Scenario 6 is based on saturated vapour concentrations. This approach is very conservative and normally linked to a strong overestimation of human exposure and a high uncertainty. Therefore, a quantitative comparison of the corresponding hazard index is not appropriate.

Conclusion

In conclusion, the alternative product Xyligen 30 F has no significantly lower risk with respect to human health risk assessment for the general public.

3.10.7.4 Comparative assessment regarding the environment

According to the "Technical Guidance Note on comparative assessment of biocidal products", chapter 6.2.2.1.1, point (82), the key element for comparison regarding the environment are the PBT properties of the active substances in the considered products. This comparison of Wolsit F-15T and the alternative product is shown in the table below:

Table 121

PBT properties of the active substances of Wolsit F-15T and of the alternative product				
	Wolsit F-15T			Alternative product
	ATMAC/TMAC	Propiconazole	Tebuconazole	K-HDO
PBT criteria fulfilled	no	no	no	no
Two out of three PBT criteria fulfilled	no	**yes**	**yes**	no

Wolsit F-15T contains two active substances which fulfil two out of three PBT properties and, hence, are candidates for substitution. In the alternative BP no candidate for substitution is contained. These observed differences are not marginal and are relevant in terms of biological significance for the safety to animals or the environment. Thus, it is assumed that the alternative biocidal product has a significantly better profile with regard to the environment.

This is underlined if the classification and labelling regarding the environment is considered:

Table 122

Classification and labelling of Wolsit F-15T and of the alternative product regarding the environment		
	Wolsit F-15T	Alternative product
Hazard category	Aquatic chronic 1	Aquatic chronic 2
Hazard statement	H410 (Very toxic to aquatic life with long lasting effects.)	H411 (Toxic to aquatic life with long lasting effects.)

Regarding the hazard statement, the alternative product, which is classified as H411, is less harmful to aquatic organisms than Wolsit F-15T, which is classified as H410.

A more detailed quantitative comparison of the two products according to “Technical Guidance Note on comparative assessment of biocidal products”, chapter 6.2.2.1.1, point (83), by comparison of PEC/PNEC ratios should be approached with particular attention.
According to the PARs of Wolsit F-15T and the alternative product, emissions to the environment during service-life of treated timber products result in acceptable risks to the considered environmental compartments.
However, the alternative product was authorised in 2011 whereas the assessment of Wolsit F-15T was done in 2020. In the meantime, the evaluation criteria have changed as the Emission Scenario Document for PT 8 was revised in 2013 and additional technical agreements for environmental exposure assessment were introduced. For example, emission to STP is assessed with the ‘noise barrier’ scenario for Wolsit F-15T whereas for the alternative product the scenario ‘multi-storey building in the city’ was assessed. Consequently, a quantitative comparison of the two products based on PEC/PNEC ratios is not meaningful as the two assessments are based on different evaluation criteria.

As an overall consequence, the alternative product has a significantly better environmental profile regarding PBT properties and classification and labelling.
A quantitative comparison of PEC/PNEC values is not feasible.

3.10.8 Tier II

Not applicable, as no preventive non-chemical treatment of wood-composites against wood destroying fungi is available.

3.10.9 Conclusion

For the comparative assessement, the relevant biocidal product Wolsit F-15T was compared to one eligible alternative. No non-chemical alternative is available for the intended use of the product.

The quantitative comparative assessment regarding the CMR properties as the key element for comparison revealed that the overall risk for human health posed by the alternative biocidal product cannot be regarded as significantly lower compared to the risk of Wolsit F-15T.

The qualitative comparative assessment regarding the PBT properties showed that the alternative biocidal product has a better profile regarding the environment. As the environmental assessment concerned substitution criteria, the chemical diversity has to be considered for a conclusive assessment. The screening phase showed that there is currently no adequate chemical diversity to minimise the occurrence of resistance in the target organisms of the relevant biocidal product.

Consequently, no alternative product to substitute Wolsit F-15T was identified. The product can be authorised for a period not exceeding 5 years in accordance with Article 23 (6) BPR.

4 Annexes

4.1 List of studies for the biocidal product

Table 123

Author(s)	Year	Annex II/III requirements and IUCLID section	Title and Report number	Owner company
Wittenzellner, J.	2018	Appearance (at 20°C and 101.3 kPa) **IUCLID Section No.** 3.1	Title: Odour, physical state and ph value of Wolsit® F-15T Report no. 17-WD-030	BASF Wolman GmbH
Wittenzellner, J.	2018	Acidity, alkalinity **IUCLID Section No.** 3.2	Title: Odour, physical state and ph value of Wolsit® F-15T Report no. 17-WD-030	BASF Wolman GmbH
Wittenzellner, J.	2018	Relative density (liquids) and bulk, tap density (solids) **IUCLID Section No.** 3.3	Title: Density of Wolsit® F-15T Report no. 17-WD-031	BASF Wolman GmbH
Wittenzellner, J.	2017	Storage stability tests **IUCLID Section No.** 3.4.1	Title: Accelerated storage test by heating of Wolsit® F-15T Report no. 17-WD-039	BASF Wolman GmbH
Wittenzellner, J.	2018	Storage stability tests **IUCLID Section No.** 3.4.1	Title: Long term stability of Wolsit® F-15T Report no. 17-WD-040	BASF Wolman GmbH
Sebastian Riedl	2019	Surface tension	Title: Determination of Surface Tension	BASF Wolman GmbH

		IUCLID Section No. 3.8	Report no. 190130BT / CPT18561	
Sebastian Riedl	2019	Surface tension **IUCLID Section No.** 3.8	Title: Determination of Surface Tension Report no. 190130BT / CPT18561	BASF Wolman GmbH
Wittenzellner, J.	2018	Viscosity **IUCLID Section No.** 3.9	Title: Viskosity of Wolsit® F-15T Report no. 17-WD-032	BASF Wolman GmbH
Möller, M.	2017	Explosives **IUCLID Section No.** 4.1	Title: Determination of physico-chemical properties according to UN Transport Regulation and Regulation (EC) No. 440/2008 Report no. CSL-17-0618.01	BASF Wolman GmbH
Önem-Siakou, E.	2017	Corrosive to metals **IUCLID Section No.** 4.16	Title: Corrosive to metal for Wolsit® F-15T Report no. 17-WD-017	BASF Wolman GmbH
Möller, M.	2017	Additional physical indicators for hazards **IUCLID Section No.** 4.17	Title: Determination of physico-chemical properties according to UN Transport Regulation and Regulation (EC) No. 440/2008 Report no. CSL-17-0618.01	BASF Wolman GmbH
Möller, M.	2017	Auto-ignition temperature (liquids and gases) **IUCLID Section No.** 4.17.1	Title: Determination of physico-chemical properties according to UN Transport Regulation and Regulation (EC) No. 440/2008 Report no. CSL-17-0618.01	BASF Wolman GmbH
Möller, M.	2017	Oxidising properties **IUCLID Section No.** 4.4	Title: Determination of physico-chemical properties according to UN Transport Regulation and	BASF Wolman GmbH

			Regulation (EC) No. 440/2008 Report no. CSL-17-0618.01	
Möller, M.	2017	Flammable liquids **IUCLID Section No.** 4.6	Title: Determination of physico-chemical properties according to UN Transport Regulation and Regulation (EC) No. 440/2008 Report no. CSL-17-0618.01	BASF Wolman GmbH
Möller, M.	2017	Self-reactive substances and mixtures **IUCLID Section No.** 4.8	Title: Determination of physico-chemical properties according to UN Transport Regulation and Regulation (EC) No. 440/2008 Report no. CSL-17-0618.01	BASF Wolman GmbH
Wittenzellner, J.	2017	METHODS OF DETECTION AND IDENTIFICATION **IUCLID Section No.** 5	Title: UPLC method for the determination of Propiconazole and Tebuconazole in Wolsit® F-15T Report no. 17-WD-013	BASF Wolman GmbH
Wittenzellner, J.	2018	METHODS OF DETECTION AND IDENTIFICATION **IUCLID Section No.** 5	Title: Validation of a Gas Chromatography Method for the Determination of TMAC in Wolsit® F-15T Report no. 17-WD-038	BASF Wolman GmbH
Bacher, Reiner	2018	METHODS OF DETECTION AND IDENTIFICATION **IUCLID Section No.** 5	Title: Analysis of Benzyl Alcohol in Stored Wood Preservative Samples Report no. P 04740 G	BASF Wolman GmbH
Bacher, R.	2019	METHODS OF DETECTION AND IDENTIFICATION	Title: Analysis of Benzyl Alcohol and Lutensol TO 89 in Wolsit F-15T	BASF Wolman GmbH

		IUCLID Section No. 5	Report no. ID P 05234 G	
Möller, R.	2017	Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	Title: Determination of the resistance of wood-based panels against wood-destroying basidiomycetes according to FIN V ENV12038:2002-07 Report no. B2767a	BASF Wolman GmbH
Möller, R.	2018	Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant **IUCLID Section No.** 6.7	Title: Determination of the resistance of wood-based panels against wood-destroying basidiomycetes according to FIN V ENV12038:2002-07 (b) Report no. B2767b	BASF Wolman GmbH
Pfabigan, N.; Grüll, G.	2018	Leaching behaviour **IUCLID Section No.** 10.3	Title: Investigation according to prCEN/TR 16663 and NT Build 509 respectevely, to determine the emissions of preservative treated wood to the environment - wood products for use class 3 - semi-field testing beech plywood boards Report no. F466/2016/2-HH	BASF Wolman GmbH

4.2 List of studies for the active substance(s)

4.2.1 Tebuconazole

- 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 Tebuconazole for use in wood preservatives (product-type 08). Please, refer to the corresponding Assessment Report for a reference list.

4.2.2 Propiconazole

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

4.2.2.1 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[19]) of the active substance Propiconazole for use in wood preservatives (product-type 08). Please, refer to the corresponding Assessment Report for a reference list.

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.
19 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.

4.2.3 ATMAC/TMAC

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

4.2.3.1 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[20]) of the active substance ATMAC/TMAC for use in wood preservatives (product-type 08). Please, refer to the corresponding Assessment Report for a reference list.

4.3 Output tables from exposure assessment tools

Output tables from <u>human health</u> exposure assessment tools

4.3.1 Safety for professional users

exposure assessment.xlsx

Risk assessment

Riskassessment_ Wolsit_F-15T.xlsx

Output tables from <u>environmental</u> exposure assessment tools

Derivation of the leaching rates used for the environmental risk assessment

The leaching test of plywood treated with Wolsit F-15T was conducted with three uncoated test-sets and three test-sets with top-coat.

20 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.

The surface area of the plywood was 0.532 m² (70 cm x 76 cm) and the boards were 2 cm thick. The edges of the boards with top-coat were treated with a sealant, which influence on the leaching is unknown. Hence, the following surface areas were considered for the evaluation of the leaching study:

- Boards without top-coat: 0.5904 m² (including surface of edges)
- Boards with top-coat: 0.532 m² (excluding surface of edges)

The measured concentration in the eluate was below the limit of quantification in several samples (see Table 124). As agreed at PT 8 EG meeting (March 2019), the limit of quantification was used for the calculation of leaching in those cases. For the detection of ATMAC/TMAC, the samples were tested for its individual compounds (TMAC C_8, C_{10}, C_{12}, C_{14}, C_{16}, C_{18}) with a limit of quantification of 5 µg/L, each. None of those compounds was detected in any of the samples. For the calculation of leaching, the sum of the limits of quantification (6x5 µg/L) of these compounds of 30 µg/L was used as a very conservative approach.

The detailed results of the semi-field leaching study described in chapter 3.8.3.1 are shown in the table below:

Table 124

Leaching values (mean values of 3 test-sets)							
Exposure period (days)	Cumulated precipitation (mm)	Concentration in leachate [mg/m² wood]					
		ATMAC/TMAC		Propiconazole		Tebuconazole	
Top-coat		no	yes	no	yes	no	yes
04/07/17-17/07/17 14 days)	56	0.160[3]	0.171[3]	0.258	0.101[1]	0.298	0.086[3]
17/07/17-17/08/17 (31 days)	127	0.173[3]	0.233[3]	0.288	0.132	0.282	0.117[3]
17/08/17-26/09/17 (40 days)	245	0.135[3]	0.179[3]	0.338	0.101[2]	0.351	0.090[3]
26/09/17-27/04/18 (213 days)	471	0.309[3]	0.497[3]	0.289	0.313[2]	0.284	0.276[2]
27/04/18-24/07/18 (88 days)	731	0.278[3]	0.370[3]	0.140[2]	0.233[1]	0.141[2]	0.236[1]

[1,2,3] Number of test sets with concentrations in eluate below limit of quantification

Limits of quantification of active substances:

- TMAC: 5 µg/L per compound, 30 µg/L as sum of the 6 compounds
- Propiconazole: 15 µg/L
- Tebuconazole: 5 µg/L

For determination of the leaching rates used for the risk assessment, the experimental leaching rate was normalized to a yearly precipitation of 700 mm as recommended in the revised ESD for PT8 (OECD, 2013). The normalized FLUX is presented in Table 125.

Table 125

FLUX values (mg/m²/d) normalized to a precipitation of 700 mm / year					
Cumulative sampling time (d)	Cumulative precipitation (mm)	Cumulative normalized sampling time (d)	Normalized FLUX ATMAC/TMAC (mg/m²/d)	Normalized FLUX Propiconazole (mg/m²/d)	Normalized FLUX Tebuconazole (mg/m²/d)

Top-coat			no	yes	no	yes	no	yes
14	56	29	0.005	0.006	0.009	0.003	0.010	0.003
45	127	66	0.005	0.006	0.008	0.004	0.008	0.003
85	245	128	0.002	0.003	0.005	0.002	0.006	0.001
298	471	246	0.003	0.004	0.002	0.003	0.002	0.002
386	731	381	0.002	0.003	0.001	0.002	0.001	0.002

The experimental data of each active substance were fitted by a polynomial regression of second order:

$$Log_{10}FLUX(t) = a + b \cdot Log_{10}(t) + c \cdot Log_{10}(t)^2$$

The trend lines with the corresponding regression equations and coefficients of variation are shown in the following figures:

Figure 1

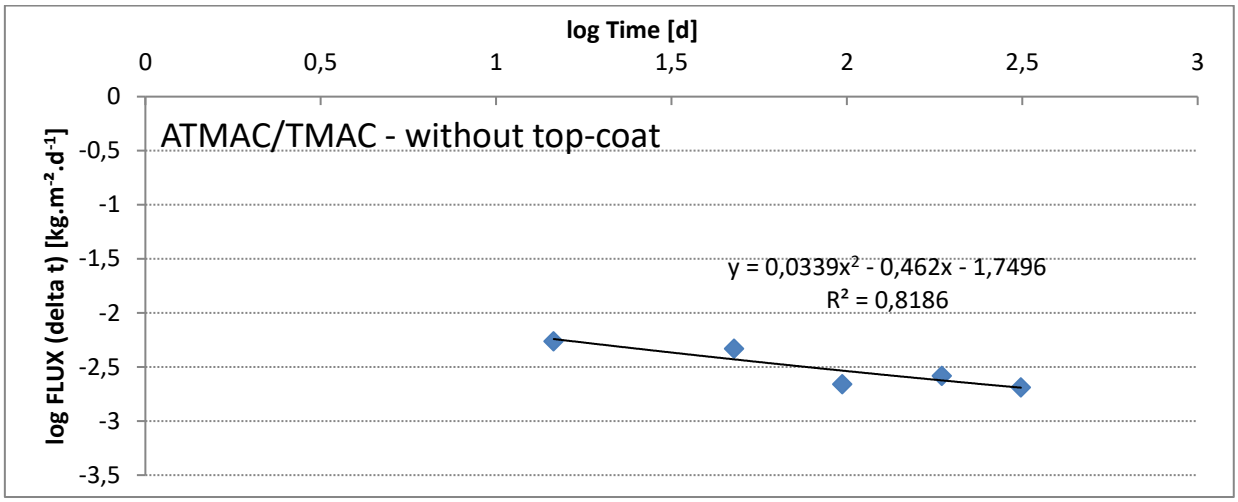


Figure 2

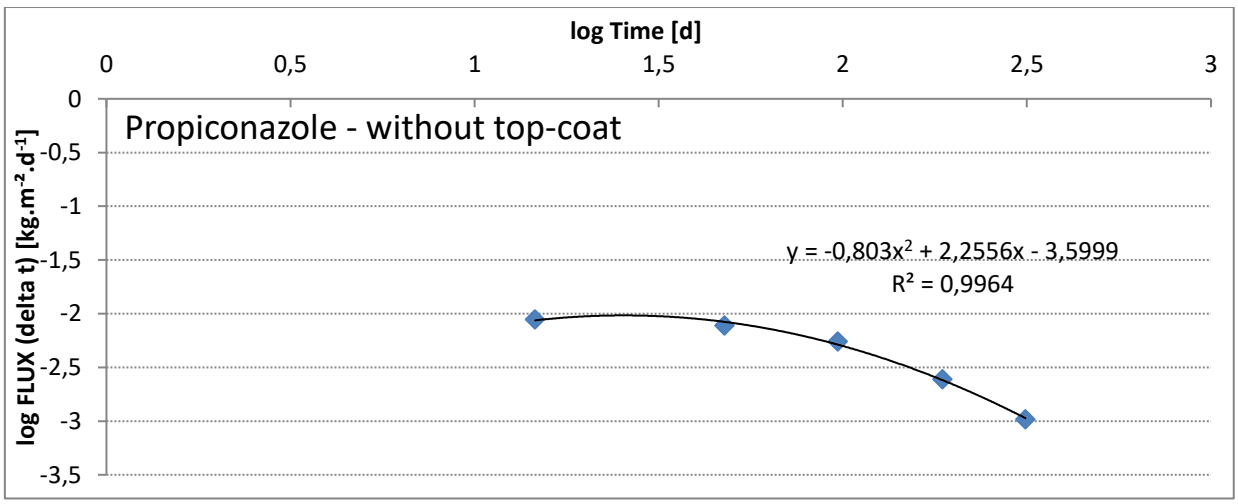
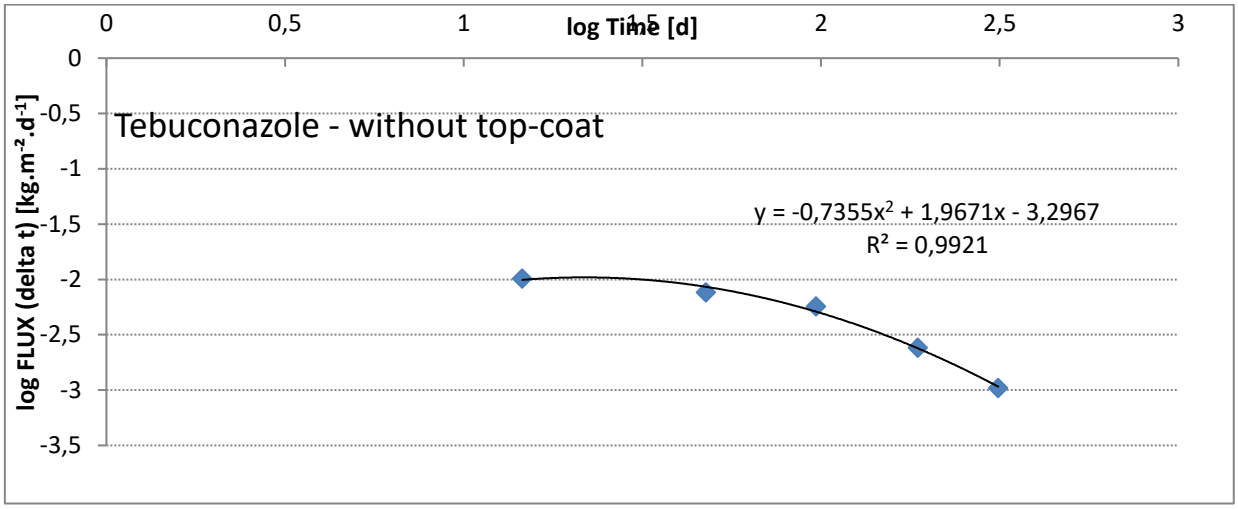


Figure 3



For Propiconazole and Tebuconazole (Figure 2 and Figure 3) the fitting suits the measured data points well, also underlined by a R^2 of 0.99. The parameters a, b and c (see equation above) of the trendlines were used.to calculate the daily FLUX. The FLUX for each day of the respective assessment period was calculated according to equation A2_2 of ESD PT 8 (2013) and summed up to derive the cumulative leaching. The leaching in TIME2 can be extrapolated with this approach (see Table 126 for the results).

For ATMAC/TMAC, the logarithmic FLUX curve (Figure 1) is not suitable to extrapolate to TIME2, as it can be visually assessed that the data points are not fitted well by a polynomic curve. The approach in Appendix 2 point 519 of the ESD for PT 8 (OECD, 2013), where the cumulative quantities leached out were plotted in a diagram and fitted with a logarithmic curve, resulted in an underestimation of leaching at the last datapoint. Therefore, the leaching of ATMAC/TMAC is calculated by using the cumulative leaching during the first period for TIME1 and extrapolated to TIME2 by using the cumulative quantity leached during the whole test.

e.g. for TIME2:
1.055 mg/m² / 381.16 d = 0.03 mg/m²/d ($Q^*_{leach,testperiod}$ / $TIME_{normalized,testperiod}$ = $FLUX_{testperiod}$)
0.03 mg/m²/d x 5475 d = 15.148 mg/m² ($FLUX_{testperiod}$ x TIME2 = $Q^*_{leach,TIME2}$)

Regarding the test-sets with top-coat, the derived flux rates and cumulative leaching were not used for the environmental risk assessment for the following reasons:

- At the 2nd EU Leaching Workshop in Varese, Italy on 12 June 2013 it was concluded for the evaluation of leaching tests with top coat that: “For the assessment of Time 1, no AF needs to be applied on the leaching rate. For the assessment of Time 2, an AF of 2 needs to be applied if the service life is lower or equal to 5 years and an AF of 5 needs to be applied if the service life is longer than 5 years.” Consequently, with an AF of 5 the resulting values for $Q^*_{leach,time}$ in TIME2 exceed the values derived for the test-sets without top-coat significantly. In this case it is appropriate to use the results from the test set without topcoat.
- For Propiconazole and Tebuconazole the leaching rate in TIME 1 and TIME 1b (365d) is higher in the test-sets without top-coat. These more conservative data should be used for the extrapolation to TIME2 and for environmental risk assessment in the first tier. For ATMAC/TMAC the calculated leaching for the test-sets with top-coat is slightly higher, but this is because the quantity of eluate was lower and the limit of quantification was assumed in the calculations as no active substance was detected.

Furthermore, as shown in the test report, the top-coat is of a very dark colour. It can be assumed that the fate and behaviour of the active substances is influenced by this top-coat, e.g. as a higher adsorption of sunlight can be expected due to the dark surface. There are indications in literature that pigmented top-coats can increase photodegradation of the active substances and thus reduce leaching. Consequently, the test set without topcoat is worst-case.

The derived values for $Q^*_{leach,time}$ for the testing with and without top-coat are summarized in the following table:

Table 126

Cumulative leached quantities							
Time	Days [d]	Cumulative leaching $Q^*_{leach,time}$ (mg/m²)					
		ATMAC/TMAC		Propiconazole		Tebuconazole	
Top-coat		no	yes	no	yes	no	yes
TIME1	30	0.151	0.183	0.223	0.106	0.254	0.092
TIME1b	365	1.010	1.389	1.276	0.843	1.311	0.770
TIME2	5475	15.148	60 (100% leaching) 104.184* (calculated)	1.503	63.250*	1.555	57.755*

*including AF=5 for top-coat stability

As stated above, the leaching values of the tests without top-coat were used for the environmental risk assessment. An additional correction factor of 1.5 needs to be applied as the product retention rate in the study (3 kg/m³) is lower than the maximum intended retention rate (4.5 kg/m³). This leads to the following leaching values used for the environmental risk assessment:

Table 127

Leaching of Wolsit F-15T			
Active substance	**TIME 1 (30 days)**	**TIME 1b (365 days)**	**TIME 2 (15 years)**
Cumulative leaching $Q^*_{leach,time}$ (mg/m²)			
ATMAC/TMAC	0.226	1.515	22.722
Propiconazole	0.334	1.914	2.255
Tebuconazole	0.382	1.967	2.333
Leaching rate FLUX (mg/(m²*d))			
ATMAC/TMAC	0.008	0.004	0.004
Propiconazole	0.011	0.005	0.0004
Tebuconazole	0.013	0.005	0.0004