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 APPLICATION

(submitted by the competent authority)

TEKNOL AQUA 1411-01

Product type 8 (Wood preservative)

Propiconazole and IPBC as included in the Union list of approved active substances

Case Number in R4BP: BC-FB042589-47

Evaluating Competent Authority: Denmark

Date: 09/02/2021

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1 CONCLUSION

1.1 Summary of decisions and restriction

TEKNOL AQUA 1411-01 is a wood preservative product which contains 0.6 % propiconazole and 0.3 % IPBC to be used in use class 2 and 3. The application for product authorisation was submitted on 14 September 2018.

It is concluded after evaluation that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product subject to the following conditions:

1.1.1 Usage area

User	Use area
Industrial	Wood preservative applied as a preventative treatment by flowcoating/aspersion, automated spraying, vacumat, brush machine, low pressure deluging and manual/automatic dipping to control wood rotting fungi and blue stain fungi. The use of top coat is required. The top coat cannot be a film- or a wood preservative. The topcoat has to be maintained. The product is intended to protect wood in use classes 2 (undercover but exposed to high humidity or occasional wetting) and 3 (above ground but exposed to frequent wetting).
Professional	Wood preservative applied as a preventative treatment by brush, roller, pad and manual dipping to control wood rotting fungi and blue stain fungi. The use of top coat is required. The top coat cannot be a film- or a wood preservative. The topcoat has to be maintained. The product is intended to protect wood in use classes 2 (undercover but exposed to high humidity or occasional wetting) and 3 (above ground but exposed to frequent wetting). The following conditions apply for Use Class 3 application: In-situ outdoor brush/roller and industrial application must be subject to risk mitigation measures, see below.

1.1.2 Conclusion for physical-chemical properties

TEKNOL AQUA 1411-01 is a yellowish coloured, homogeneous liquid, with a chemical odour. The relative density is 1.0023 g/cm^2, pH is 7.15 and the kinematic viscosity at 20°C is 1.3283 – 1.3003 cSt and at 40°C: 0.8515 - 0.8600 cSt. The product is surface active.
The long term stability study showed an acceptable degradation of the active substances IPBC and propioconazol at room temperature (20°C ± 2 °C) for 2 years.
Degradation of active substance in HDPE: IPBC -3.8 % and propioconazol -8.6% and paneling after 24 months at ambient temperature.
Degradation of active substance in metal can: IPBC -3.8 % and propioconazol -8.3% after 24 months at ambient temperature.
The product is stable in commercial packaging: shelf life is 24 months in a metal can. There is no classification for physical or chemical hazards. A shelf-lift of 2 years in HDPE is not supported.

1.1.3 Conclusion for efficacy and label claims

TEKNOL AQUA 1411-01 meets the efficacy requirements for PT8 preventive wood treatment products and protects treated softwood against wood destroying fungi (*Basidiomycetes*) at 90 g/m^2 (85 g/m^2) application, treated hardwood against wood destroying fungi (*Basidiomycetes*) at 100 g/m^2 (98 g/m^2) and treated wood against blue stain fungi (*Ascomycetes* and *Deuteronycetes* at 110 g/m^2, i.e. the application rates that are claimed on the label. Values were derived based on EN599-1:2009, section 5.2.15.

Application rates:
90 g/m2 against wood destroying fungi (Soft wood)
100 g/m2 against wood destroying fungi (hard wood)
110 g/m2 against blue stain fungi.

This is achieved by 1-2 applications.

1.1.4 Comparative assessment

TEKNOL AQUA 1411-01 is authorised for industrial and professional use, and subject to a comparative assessment due to the assigned classification of Repr. 1B (H360D) of propiconazole, even though not legally implemented in the active substance evaluation, as the classification was implemented in the 13th ATP of Reg. (EC) 1272/2008, i.e. Commission Regulation (EU) 2018/1480 of October 4th 2018. Although two other active substances are available for professional use on the Danish Market, only one other active substance is available on for industrial use against wood destroying fungi, and this active substance is also considered a candidate for substitution, and has a similar mode of action. Thus, no true alternative exists for this use.

1.1.5 Conclusion for human health risk assessment

A safe use was identified for all application types, also taking into consideration the combined exposure to propiconazole and IPBC. Specifically, a safe use was demonstrated for industrial automated and manual dipping, flowcoating/deluging, vacumat, brush machine, low pressure deluging, for professional manual dipping, and for the professional user when brushing if wearing gloves and coated coveralls. A safe use was demonstrated for professional spraying when using impermeable coveralls and gloves, though when this task was included in a combined scenario the exposure was close to being unacceptable, thus use of respiratory protection equipment during professional spraying is recommended. A safe use was only identified for automated dipping by the industrial user when completely mechanised/automatised. In order to comply with this organisational measure, the RMM "*TEKNOL AQUA 1411-01 is to be only used in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated articles are transported through the dip tank to the draining/ drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until after the treated articles are surface dry*" is required to ensure a safe use for this application method. Additionally, safe use was identified also for non-professional secondary exposure and for the general public when subject to secondary exposure.

The non-active substances 1-methoxy-propan-2-ol and monoethylene glycol were identified as substances of concern due to their EU applied OELs for eye irritation (PGME) and irritation of the mucosa (monoethylene glycol). A quantitative risk assessment for exposure

to air concentration in the relevant scenarios (where inhalation exposure is not considered negligible) was performed, and a safe level of exposure was identified for both substances.

1.1.6 Endocrine disruption assessment

TEKNOL AQUA 1411-01 should not be considered to have endocrine-disrupting properties.

TEKNOL AQUA 1411-01 contains the active substances propiconazole and IPBC, which have not yet been evaluated for endocrine-disrupting properties according to the scientific criteria set out in the Regulation (EU) 2017/2100.

During the ED assessment of the non-active substances the rMS identified three substances for which it was not possible to conclude, based on the available information, whether they should be considered to have ED properties before the expiration of the legal deadline in the BPR (Articles 30(2) and 34(4)) and therefore the process will be concluded at the post-authorisation stage. One of the non-active substances is already being evaluated under REACH and the other two non-active substances will be notified for an evaluation under REACH. Should these evaluations conclude that any of the three substances have endocrine disruption potential the authorisation holder is obliged to notify the reference Member State for TEKNOL AQUA 1411-01, as a reassessment of the endocrine disruption potential of TEKNOL AQUA 1411-01 will be performed. For details on the identification and evaluation of the endocrine disruption potential of TEKNOL AQUA 1411-01, see the confidential annex of the PAR.

1.1.7 Conclusion for environmental risk assessment

The environmental risk assessment showed unacceptable risk for several environmental compartments following the industrial applications of Teknol Aqua 1411-01. Therefore, RMMs have been included, which require freshly treated wood to be stored under shelter or on impermeable hard standing and that industrial application processes must be carried out within a contained area, situated on impermeable hard standing to prevent run-off and a recovery system. Furthermore, during in-situ treatment by brushing a risk was identified for the soil compartment and therefore a RMM is added, which require the soil to be covered.

An unacceptable risk was identified for the soil compartment for outdoor manual spraying for tier 1 and tier 2. No appropriate RMM was identified for the tier 2 scenario and therefore, the outdoor manual spraying application will not be authorised.

No unacceptable risk was identified for the groundwater.

Three substances of concern relevant for the environmental compartment were identified and assessed.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
TEKNOL AQUA 1411-01	Denmark

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Teknos A/S
	Address	Industrivej 19 DK-6580 Vamdrup Denmark
Authorisation number		
Date of the authorisation	02.02.2021	
Expiry date of the authorisation	02.02.2026	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	Teknos A/S
Address of manufacturer	Industrivej 19 DK-6580 Vamdrup Denmark
Location of manufacturing sites	Industrivej 19 DK-6580 Vamdrup Denmark
Name of manufacturer	Teknos Oy
Address of manufacturer	Takkatie 3 FI-00371 Helsinki Finland
Location of manufacturing sites	Rajamäki factory Perämatkuntie 12 FI-05201 Rajamäki Finland

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

Active substance	Propiconazole
Name of manufacturer	Janssen PMP, division of Janssen Pharmaceutica NV
Address of manufacturer	Turnhoutseweg 30

	2340 Beerse Belgium
Location of manufacturing sites	Jiangsu Sevencontinent Green Chemical Co. Ltd.; North Area of Dongsha Chem-Zone 215600 Zhangjiagang China

Active substance	Propiconazole
Name of manufacturer	LANXESS Deutschland GmbH, Material Protection Products
Address of manufacturer	Kennedyplatz 1, D-50569 Köln, Germany
Location of manufacturing sites	
1	Syngenta Crop Protection AG CH-4002 Basel, Switzerland Plant location CH-1870 Monthey, Switzerland
2	Jiangsu Yangnong Chemical Group Co., Ltd Plant location Wenfeng Road, Yangzhou, Jiangsu 225009, P.R. China
3	Jiangsu SevenContinent Green Chemical Co., Ltd Plant location North Area of Dongsha Chem-Zone, Zhanjiagang, Jiangsu, 215600, P.R. China

Active substance	3-iodo-2-propynyl butyl carbamate (IPBC)
Name of manufacturer	Troy Corporation
Address of manufacturer	8 Vreeland Road, Florham Park 07932 New Jersey USA
Location of manufacturing sites	One Avenue L 07105 New Jersey USA

Active substance	3-iodo-2-propynyl butyl carbamate (IPBC)
Name of manufacturer	Troy Chemical Europe BV
Address of manufacturer	Uiverlaan 12E, Maassluis 3145 XN Maassluis Netherlands
Location of manufacturing sites	Industriepark 23 D-56593 Horhausen Germany

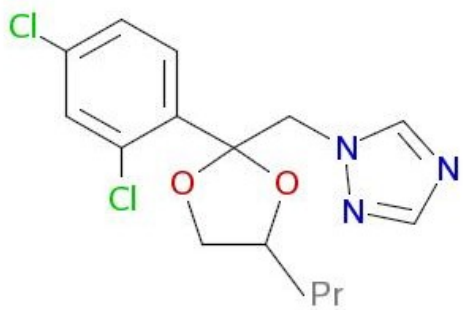
2.1.2 Product (family) composition and formulation

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

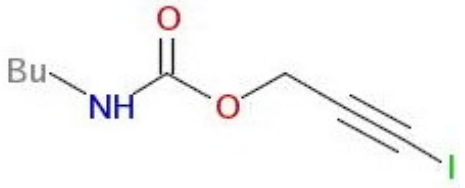
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Propiconazole
IUPAC or EC name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
EC number	262-104-4
CAS number	60207-90-1
Index number in Annex VI of CLP	613-205-00-0
Minimum purity / content	Purity: 93%
Structural formula	

Main constituent(s)	
ISO name	IPBC, 3-iodo-2-propynyl butyl carbamate
IUPAC or EC name	3-iodo-2-propynyl butyl carbamate
EC number	259-627-5
CAS number	55406-53-6

Index number in Annex VI of CLP	616-212-00-7
Minimum purity / content	Purity: 98%
Structural formula	

2.1.2.2 Candidate(s) for substitution

Propiconazole is considered a candidate for substitution. Propiconazole is classified Repr. 1B (H360D) subsequently leading to article 5(1)(c) of Reg. (EU) No. 528/2012 being fulfilled. Propiconazole is currently under evaluation for renewal as an active substance under Reg. (EU) no. 528/2012, and it has therefore not been concluded whether or not article 5(2) applies. Propiconazole therefore meets the exclusion criteria but is considered a candidate for substitution until its renewal process is finalised. Please see section 2.2.11 Comparative assessment for further information.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content Technical (%)**
Propiconazole	(2RS,4RS;2RS,4SR)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole	Active substance	60207-90-1	262-104-4	0.6
IPBC	3-iodo-2-propynyl	Active substance	55406-53-6	259-627-5	0.3

Common name	IUPAC name	Function	CAS number	EC number	Content Technical (%)
	butylcarbamate				
1-methoxypropan-2-ol	1-methoxypropan-2-ol	Non-active substance	107-98-2	203-539-1	0.225
Monoethylene glycol	1,2 ethanediol	Non-active substance	107-21-1	203-473-3	0.05
Octamethylcyclotetrasiloxane	2,2,4,4,6,6,8,8-octamethyl-1,3,5,7,2,4,6,8-tetraoxatetrasilocane	Non-active substance	556-67-2	209-136-7	0.000024
Decamethylcyclopentasiloxane	2,2,4,4,6,6,8,8,10,10-decamethyl-1,3,5,7,9,2,4,6,8,10-pentaoxapentasilecane	Non-active substance	541-02-6	208-764-9	0.000054
Dodecamethylcyclohexasiloxane	2,2,4,4,6,6,8,8,10,10,12,12-dodecamethyl-1,3,5,7,9,11-hexaoxa-2,4,6,8,10,1	Non-active substance	540-97-6	208-762-8	0.00008

Common name	IUPAC name	Function	CAS number	EC number	Content Technical (%)
	2-hexasilacyclododecane				

2.1.2.4 Information on technical equivalence

Propiconazole:
Teknos A/S is supplied with propiconazole by LANXESS Deutschland GmbH from three different manufacturing locations. The manufacturing location Syngenta Crop Protection AG, CH-4002 Basel, Switzerland , Plant location , CH-1870 Monthey, Switzerland was the reference source in the active substance approval of propiconazole in PT8. A technical equivalence assessment of the second manufacturing site Jiangsu Yangnong Chemical Group Co., Ltd, Plant location, Wenfeng Road, Yangzhou, Jiangsu 225009, P.R. China was finalized by TUKES in November 2015. A technical equivalence assessment of the third manufacturing site Jiangsu SevenContinent Green Chemical Co., Ltd, Plant location, North Area of Dongsha Chem-Zone, Zhanjiagang, Jiangsu, 215600, P.R. China was finalized by ECHA in February 2016 and can be found in R4BP-3 under case number number BC-NG020755-42.

Teknos A/S is also supplied with propiconazole by Janssen PMP, division of Janssen Pharmaceutica NV from Jiangsu Sevencontinent Green Chemical Co. Ltd.; North Area of Dongsha Chem-Zone 215600 Zhangjiagang China. Assessment of technical equivalence for this location site can be found in R4BP-3 under case number BC-KM002264-46.

IPBC:
Teknos A/S is supplied with IPBC by Troy Corporation from manufacturing site at One Avenue L, 07105 New Jersey, USA which was the reference source at active substance approval for IPBC in PT8. A letter of clarification has been distributed in the commenting period for TEKNOL AQUA 1411-01, as the manufacturing site adress was not listed in the CAR for IPBC in PT8.

Teknos A/S is also supplied with IPBC by Troy Chemical Company BV from manufacturing site Industriepark 23, D-56593 Horhausen, Germany. An assessment of technical equivalence was finalized by Germany in 2019 and is located in R4BP-3 under case number BC-ME049519-34.

2.1.2.5 Information on the substance(s) of concern

The non-active substances PGME (1-methoxypropan-2-ol CAS 107-98-2) and monoethylene glycol (CAS 107-21-1) are considered substances of concern (SoC) as defined in article 3(f) of Reg. (EU) No. 528/2012 on basis of other grounds for concern. Other grounds for concern are further elaborated in the CA note for guidance document *CA-Nov14-Doc.5.11* for human health SoCs*. PGME* has a European harmonised occupational exposure limit value of 100 ppm, and monoethylene glycol has a European harmonised occupational exposure limit value of 20 ppm, therefore meeting the criteria for being substances of concern based on subparagraph 5 of the abovementioned CA document. Please refer to the human health risk assessment for the risk assessment.

The non-active substances Octamethylcyclotetrasiloxane (D4) (CAS-no.: 556-67-2), Decamethylcyclopentasiloxane (D5) (CAS-no.: 541-02-6), and Dodecamethylcyclohexasiloxane (D6) (CAS-no.: 540-97-6) are considered substances of concern according to article 3(1)f of the BPR based on the PBT and vPvB properties. Please refer to section 2.2.8.1 for the environmental assessment of the substance.

2.1.2.6 Type of formulation

ME waterborne emulsion/micro emulsion (ready-to-use liquid)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Repr. 1B Aquatic Chronic 3
Hazard statement	H360D: May damage the unborn child. H412: Harmful to aquatic life with long lasting effects.
Labelling	
Signal words	Danger
Pictogram	GHS08
Hazard statements	H360D: May damage the unborn child. H412: Harmful to aquatic life with long lasting effects;
Precautionary statements	P201: Obtain special instructions before use. P280: Wear protective gloves/protective clothing/eye protection/face protection*. P273: Avoid release to the environment. P308 + P313: If exposed or concerned: Get medical attention P405: Store locked up P501: Dispose of contents and container in accordance with all local, regional, national and international regulations.
Additional labelling requirements	EUH208: Contains propiconazole and 3-iod-2-propynylbutylcarbamate. May produce an allergic reaction.
Note	*Manufacturer/supplier to specify the appropriate type of equipment

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Industrial –Flowcoat –Deluge –Automated spraying –Vacumat –Brushing machine

Product Type(s)	8
Where relevant, an exact description of the authorised use	Fungicide
Target organism (including development stage)	Ascomcetes and deuteromycetes – blue stain fungi - hyphae Basidiomycetes – brown rot fungi – hyphae Basidiomycets – white rot fungi - hyphae
Field of use	Outdoor Preventive treatment of wood Use Class 2 and Use Class 3. The product is for use on wood not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting
Application method(s)	Superficial application by 1-2 coats; a top coat must be applied for wood exposed to weathering): Automated spraying treatment Flow coat/aspersion Vacumat* Brush machine Low pressure deluging
Application rate(s) and frequency	Application rate: 90 g/m2 against wood destroying fungi (Soft wood) 100 g/m2 against wood destroying fungi (hard wood) 110 g/m2 against blue stain fungi. This is achieved by 1-2 applications.
Category(ies) of user(s)	Industrial, trained professional users, professional users
Pack sizes and packaging	Can/drum: 10, 20, 200, 1000 liters - metal with metal

material	lid/cap (tinplate with epoxy resin coating)

**Please find description of the vacumat application method in section 3.8 "Other"*

2.1.4.2 Use-specific instructions for use

Please refer to general instructions for use section 2.1.5.1

2.1.4.3 Use-specific risk mitigation measures

TEKNOL AQUA 1411-01 may only be loaded into industrial application equipment via a fully-automated dosing system.

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).

Wear suitable protective footwear (EN 13832) when applying the product

Also refer to general risk mitigation measures

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

Please refer to general section 2.1.5.3

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

Please refer to general section 2.1.5.4

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

Please refer to general section 2.1.5.5

Table 2. Use # 2 – Industrial –Automated dipping

Product Type(s)	8
Where relevant, an exact description of the authorised use	Fungicide
Target organism (including development stage)	Ascomcetes and deuteromycetes – blue stain fungi - hyphae Basidiomycetes – brown rot fungi – hyphae Basidiomycets – white rot fungi - hyphae
Field of use	Outdoor Preventive treatment of wood Use Class 2 and Use Class 3. The product is for use on wood not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting
Application method(s)	Superficial application by 1-2 coats; a top coat must be applied for wood exposed to weathering): Automated dipping
Application rate(s) and frequency	Application rate: 90 g/m2 against wood destroying fungi (Soft wood) 100 g/m2 against wood destroying fungi (hard wood) 110 g/m2 against blue stain fungi. This is achieved by 1-2 applications.
Category(ies) of user(s)	Industrial, trained professional users, professional users
Pack sizes and packaging material	Can/drum: 10, 20, 200, 1000 liters - metal with metal lid/cap (tinplate with epoxy resin coating)

2.1.4.7 Use-specific instructions for use

Please refer to general instructions for use section 2.1.5.1

2.1.4.8 Use-specific risk mitigation measures

Product TEKNOL AQUA 1411-01 must only be used in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place including when the treated articles are transported through the dip tank to the draining/drying and storage areas (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until after the treated articles are surface dry. Wear suitable protective footwear (EN 13832) when applying the product Also, refer to the general risk mitigation measures

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

Please refer to general section 2.1.5.3

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

Please refer to general section 2.1.5.4

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

Please refer to general section 2.1.5.5

Table 3. Use # 3 – Industrial and professional manual dipping

Product Type(s)	8
Where relevant, an exact description of the authorised use	Fungicide
Target organism (including development stage)	Ascomcetes and deuteromycetes – blue stain fungi - hyphae Basidiomycetes – brown rot fungi – hyphae Basidiomycets – white rot fungi - hyphae
Field of use	Outdoor Preventive treatment of wood Use Class 2 and Use Class 3. The product is for use on wood not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting
Application method(s)	Superficial application by 1-2 coats; a top coat must be applied for wood exposed to weathering): Manual dipping
Application rate(s) and frequency	Application rate: 90 g/m2 against wood destroying fungi (Soft wood) 100 g/m2 against wood destroying fungi (hard wood) 110 g/m2 against blue stain fungi. This is achieved by 1-2 applications.
Category(ies) of user(s)	Industrial, trained professional users, professional users
Pack sizes and packaging material	Industrial: Can/drum: 10, 20, 200, 1000 liters - metal with metal (tinplate with epoxy resin coating) Professional: Can: 10, 20 liters - metal with metal lid/cap (tinplate with epoxy resin coating)

2.1.4.12 Use-specific instructions for use

Please refer to general instructions for use section 2.1.5.1

2.1.4.13 Use-specific risk mitigation measures

TEKNOL AQUA 1411-01 may only be loaded into containers used in connection with industrial or professional application via an automated/semi-automated dosing system. Application by manual dipping cannot exceed 30 minutes per day. Application by manual dipping must be carried out within a contained area, situated on an impermeable surface. Storage of treated wood must either be under cover with a recovery system in place or on an impermeable surface). Also, refer to the general risk mitigation measures

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

Please refer to general section 2.1.5.3

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

Please refer to general section 2.1.5.4

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

Please refer to general section 2.1.5.5

Table 4. Use # 4 – Professional –Brushing, pad or roller

Product Type(s)	8
Where relevant, an exact	Fungicide

description of the authorised use	
Target organism (including development stage)	Ascomcetes and deuteromycetes – blue stain fungi - hyphae Basidiomycetes – brown rot fungi – hyphae Basidiomycets – white rot fungi - hyphae
Field of use	Outdoor Preventive treatment of wood Use Class 2 and Use Class 3. The product is for use on wood not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting
Application method(s)	Superficial application by 1-2 coats; a top coat must be applied for wood exposed to weathering): Brush/roller/pad treatment
Application rate(s) and frequency	Application rate: 90 g/m2 against wood destroying fungi (Soft wood) 100 g/m2 against wood destroying fungi (hard wood) 110 g/m2 against blue stain fungi. This is achieved by 1-2 applications.
Category(ies) of user(s)	Industrial, trained professional users, professional users
Pack sizes and packaging material	Can: 10, 20 liters - metal with metal lid/cap (tinplate with epoxy resin coating)

2.1.4.17 Use-specific instructions for use

Please refer to general instructions for use section 2.1.5.1

2.1.4.18 Use-specific risk mitigation measures

TEKNOL AQUA 1411-01 may only be loaded into containers used in connection via an automated/semi-automated dosing system. Also, refer to the general risk mitigation measures.

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

Please refer to general section 2.1.5.3

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

Please refer to general section 2.1.5.4

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

Please refer to general section 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use[1]

A top-coat must be applied to treated timber. The top coat must be a non-biocidal top coat. The topcoat has to be maintained.

The authorisation holder must assure that wood treated with TEKNOL AQUA 1411-01 always receives a non-biocidal top coat.

Wear suitable protective clothing (coveralls, gloves, footwear) when applying the product and when handling freshly treated timber. Avoid excessive contamination of coveralls.

Pre-treatment:

The wood must be clean and free from wood dust and contamination. The moisture content of the wood should be:

Windows and doors: approx. 13 % and should not exceed 15 %.

Cladding: 18 ± 2 %.

The product is delivered ready for use. Stir the product well before use.

Due to evaporation, the solid content of the liquid must be adjusted with water regularly. This adjustment is based on the measured solid of the liquid in the system.

Optimum temperature for products and surroundings is 18-22 ° C

Optimum relative air humidity: Approximately 50 %

Drying time determined at 20 °C and 50% relative humidity:

Dry to handle – 1-2 hours

Dry to recoat – 3-4 hours

The drying time can be reduced using special drying systems to force drying. The drying

times are approximate and may vary according to wood quality, temperatures, humidity and ventilation.

Equipment to be cleaned with water.

Handle product and dry freshly treated wood in areas with good ventilation.

Inform the registration holder if the treatment is ineffective.

2.1.5.2 Risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn.

Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber.

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

During application to timbers and whilst surfaces are drying, do not contaminate soil. All losses of the product have to be contained by covering the soil and disposed of in a safe way.

Any contaminated water/soil shall be collected, contained and treated as hazardous waste.

Do not use indoors, except for external window frames and external doors.

The biocidal product shall not be used for treatment of wood which is intended for contact with food, feed or livestock.

Do not use on wood which may come in direct contact with food feeding stuff and livestock animals.

Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber.

Any contaminated water/soil shall be collected, contained and treated as hazardous

waste.

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

FIRST AID: General information:

IF INHALED: Get medical attention.

IF INGESTED: Get medical attention.

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

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

Environment

Avoid discharge to lakes, streams, sewers, etc. In the event of a leakage to the surroundings, contact the local environmental authorities. Consider putting up waste collecting trays/basins to prevent leakage to the surroundings.

Methods and material for containment and cleaning up: use sand, sawdust, earth, vermiculite, diatomaceous earth to contain and collect non-combustible absorbent materials and place in container for disposal, according to local regulations. Cleaning should be done as far as possible using normal cleaning agents. Solvents should be avoided.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Avoid release to the environment. Do not empty into drains.

Do not contaminate ground, water bodies or water courses with chemical or used container.

Collect spillage.

Dispose of contents/container to an approved waste disposal plant.

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

The product must be stored at temperatures between 5°C and 20°C in well closed containers. Protect from direct sunlight. Shelf life: 24 months.

2.1.6 Other information

-

2.1.7 General directions for use

2.1.7.1 Instructions for use[2]

See section 2.1.4.

2.1.7.2 Risk mitigation measures

See section 2.1.4.

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

See section 2.1.4.

2.1.7.4 Instructions for safe disposal of the product and its packaging

See section 2.1.4.

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

See section 2.1.4.

2.1.8 Other information

-

2.1.9 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Can/drum	10, 20, 200, 1000 L	Metal with internal epoxy resin varnish.	Metal cap	Professional	Yes
Can/drum or IBC	10, 20, 200, 1000 L	Metal with internal epoxy resin varnish.	Metal cap	Industrial	Yes

2.1.10 Documentation

2.1.10.1 Data submitted in relation to product application

No new data was submitted by the applicant.

2.1.10.2 Access to documentation

Letters of Access for propiconazole and IPBC are included in the product dossier.

2.1.10.3 Similar conditions of use

Not relevant.

2.2 Assessment of the biocidal product

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

Table 5. Intended use # 1 – wood preservative

Product Type(s)	wood preservative for preventive treatment of wood UC 2 &3
Where relevant, an exact description of the authorised use	TEKNOL AQUA 1411-01 is an aqueous ready to use wood preservative for wood Use Class 2 and 3. The product protects the wood surface against wood destroying and wood discolouring fungi.
Target organism (including development stage)	Wood destroying fungi Wood discolouring fungi
Field of use	Indoor/ outdoor
Application method(s)	Superficial application (label: 90-110 g/m^2, by 1-2 coats; a top coat must be applied for wood exposed to weathering): Brush/roller/pad treatment Spray treatment Flow coat/aspersion Dipping treatment Vacumat Brush machine Low pressure deluging
Application rate(s) and frequency	The total amount to be applied is 90 – 110 g/m². Since actual absorption achieved depends on the wood species, the timber and surface quality and the application method, it may vary in practice and should be checked by appropriate means. This is achieved by 1-2 applications. Wood is treated before taken into service, or once every few

	years for in-situ application
Category(ies) of user(s)	Industrial, professional users.
Pack sizes and packaging material	Please see section 2.1.9.

2.2.2 Physical, chemical and technical properties

All tests have been performed with the biocidal product TEKNOL AQUA 1411-01 (waterborne emulsion/micro emulsion, ready-to-use liquid).

Property	**Guideline and Method**	**Purity of the test substance (% w/w)**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa	PA-U10-METDESCR		Liquid	Study N° 24264 (Cornet, 2017)
Colour at 20 °C and 101.3 kPa	PA-U10-METDESCR		Yellow, cloudy	Study N° 24264 (Cornet, 2017)
Odour at 20 °C and 101.3 kPa	PA-U10-METDESCR		chemical odour	Study N° 24264 (Cornet, 2017)
Acidity / alkalinity	CIPAC MT 75.3	Pure product tested (0.60% propiconazole, 0.30% IPBC)	pH = 7.15, no alkalinity or acidity measurement required	Study N° 24264 (Cornet, 2017)
Relative density / bulk density	CIPAC MT 3.3.2 equivalent to EU Method A.3	Pure product tested (0.60% propiconazole, 0.30% IPBC)	Relative density = 1.0023 at 20°C Density = 0.9947 at 40°C	Study N° 24264 (Cornet, 2017)

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Storage stability test – accelerated storage	CIPAC MT 46.3.1 Stored for 8 weeks at 40°C	Pure product tested (0.60% propiconazole, 0.30% IPBC)	Initial concentration: Propiconazole 0.6091 %w/w IPBC 0.2960 %w/w concentration after 8 weeks in HDPE: Propiconazole 0.6014 %w/w; -1.3% IPBC 0.2653 %w/w; 10.4% No modification of appearance. concentration after 8 weeks in metal can: Propiconazole 0.5573 %w/w; -8.5% IPBC 0.2387 %w/w; -19.4% Modification of colour, light brown.	Study N° 24264 (Cornet, 2017)
Storage stability test – long term storage at ambient temperature	- Performed for 24 months at 20°C ±2°C in commercial pack.	Pure product tested (0.60% propiconazole, 0.30% IPBC)	Initial concentration in HDPE container: Propiconazole 0.6091 %w/w IPBC 0.2960 %w/w concentration after 24	Study N° 24264 (Cornet, 2017)

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			months in HDPE container: Propiconazole 0.5862 %w/w; -3.8%. IPBC 0.2704 %w/w; -8.6%. Initial: Apperance: yellow, cloudy homogeneos liquid free from visible suspended matter and sediment with pH 7.15 After 24 months: Apperance: yellow, cloudy with pH 6.59 Initial concentration in metal can : Propiconazole 0.6091 %w/w; IPBC 0.2960 %w/w concentration after 24 months in metal can: Propiconazole 0.5860 %w/w; -3,8% IPBC 0.2713 %w/w; -8.3%. Initial: Apperance: yellow,	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			cloudy homogeneos liquid free from visible suspended matter and sediment wiht pH 7.15 After 24 months: Apperance: yellow, cloudy homogeneos liquid free from visible suspended matter and sediment with pH 6.76 Apperance of packaging is reported on the "reactivity toward container material"	
Storage stability test – low temperature stability test for liquids	CIPAC MT 39.3 7 days at 0°C ±2°C	Pure product tested (0.60% propiconazole, 0.30% IPBC)	Visually not stable at low temperature, with presence of crystals. 10mL of crystals on the top and 0.5 mL of crystals on the bottom	Study N° 24264 (Cornet, 2017)
Effects on content of the active substance and technical characteristics of the biocidal product - light			Not required: label mentions "protect from direct sunlight"; the packaging is not transparent	
Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity			Not required: Label mentions "store in a cool, dry place"	
Effects on content of the active substance	PA-U10-	Pure product	No modification of	Study N°

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
and technical characteristics of the biocidal product - reactivity towards container material	METDESCR	tested (0.60% propiconazole, 0.30% IPBC)	appearance or significant pack weight change during 8 weeks at 40°C. HDPE can after long-term stability test: Modification of appearance (panelling), no significant pack weight change, -0.1%. Metal can after long-term stability test: No modification of appearance or significant pack weight change, -0.0%.	24264 (Cornet, 2019)
Wettability			Test not required: product is a liquid	
Suspensibility, spontaneity and dispersion stability			Test not required: product is RTU	
Wet sieve analysis and dry sieve test			Test not required: product is a liquid	
Emulsifiability, re-emulsifiability and emulsion stability			Test not required: product is not an emulsion and is ready to use	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Disintegration time			Test not required: product is a liquid	
Particle size distribution, content of dust/fines, attrition, friability			Test not required: product is a liquid	
Persistent foaming			Test not required: product is a RTU liquid and does not need to be diluted	
Flowability/Pourability/Dustability	CIPAC MT 148	Pure product tested (0.60% propiconazole, 0.30% IPBC)	Meets requirements (max. 5% for pour residue and 0.25% for rinsed residue, respectively) for pourability (rinsability). Testing for flowability and dustability is not required for liquids.	Study N° 24264 (Cornet, 2017)
Burning rate — smoke generators			Test not required: product is not a smoke generator	
Burning completeness — smoke generators			Test not required: product is not a smoke generator	
Composition of smoke — smoke generators			Test not required: product is not a smoke generator	
Spraying pattern — aerosols			The product is not an aerosol and is not sold in spray packaging	
Physical compatibility			Not applicable, product not to be mixed with	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			other products	
Chemical compatibility			Not applicable, product not to be mixed with other products	
Degree of dissolution and dilution stability			Study not required: product is a RTU liquid	
Surface tension	PA-U10-METTENS Equivalent to EU Method A.5	Pure product tested (0.60% propiconazole, 0.30% IPBC)	Surface tension is 29.4 mN/m at 25°C and 23.5 mN/m at 40°C. The test item is surface active.	Study N° 24264 (Cornet, 2017)
Viscosity	ASTM method D445 based on OECD guideline 114	Pure product tested (0.60% propiconazole, 0.30% IPBC)	Kinematic viscosity at 20°C: 1.3283 – 1.3003 cSt Kinematic viscosity at 40°C: 0.8515 – 0.8600 cSt	Study N° 24264 (Cornet, 2017)

Conclusion on the physical, chemical and technical properties of the product
Yellowish coloured, homogeneous liquid. Relative density: 1.0023 Kinematic viscosity: at 20°C: 1.3003 – 1.3283 cSt, at 40°C: 0.8515 - 0.8600 cSt. The product is surface active. Surface tension: 29.4 mN/m at 25°C (surface active). The product is not stable at 40°C as the degradation of the active substance IPBC during the accelerated stability study at 40°C for 8 weeks was 10.4% in HDPE can and 19,4% in metal can. The degradation of propioconazol is acceptable. The long term stability study showed an acceptable degradation of the active substances IPBC and propioconazol, at room temperature (20°C ± 2 °C) for 2 years. HDPE: IPBC -3.8 % and propioconazol -8.6% and paneling after 24 months at ambient temperature. There is a paneling after storage. A

shelf-life of 2 years HDPE is not supported. Metal can: IPBC-3.8 % and propioconazol -8.3% after 24 months at ambient temperature. The product is stable in commercial packaging: shelf-life is 24 months in metal containers.

2.2.3 Physical hazards and respective characteristics

More detailed info is provided in IUCLID relevant sections

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	NAA14 Desk Top Assessment	0.6 % propiconazole % & 0.3 % IPBC	No evidence of possessing explosive properties Product not classified	GLP3016002649A R1V1/2017 (Younis, 2017)
Flammable gases	NA	NA	NA	
Flammable aerosols	NA	NA	NA	
Oxidising gases	NA	NA	NA	
Gases under pressure	NA	NA	NA	
Flammable liquids	EEC A.9 Flash point in a closed cup.NA	0.6% propioconazole & 0.3 % IPBC	> 93°C Product not classified	
Flammable solids	NA	NA	NA	
Self-reactive substances and mixtures	NA	NA	The mixture does not contain ingredients containing a chemical group linked to explosive or self-reactive properties. TEKNOL AQUA 1411-01 does not show any	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			evidence of possessing self-reactive properties. Based on examination of the structural formulas of the ingredients, the material is considered as not self-reactiveProduct not classified	
Pyrophoric liquids	NA	NA	The product does not ignite spontaneously in contact with air at room temperature. The mixture does not contain ingredients containing a chemical group linked to pyrophoric properties. TEKNOL AQUA 1411-01 does not show any evidence of possessing pyrophoric properties. Product not classified	
Pyrophoric solids	NA	NA	NA classified	
Self-heating substances and mixtures	NA	NA	The product is liquid. The phenomenon of self-heating applies to solids. Product not classified	
Substances and mixtures which in contact with water emit flammable gases	NA	NA	The product contains 94.5% water. Product not classified	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Oxidising liquids	A21 Desk Top Assesment	0.6 % propiconazole & 0.3 % IPBC	The product does not show any evidence of possessing oxidising properties. Oxygen and halogen are present but not chemically bonded to nitrogen or oxygen. Based on examination of the structural formulas of the ingredients, the material is considered as not oxidising. Product not classified	GLP3016002649A R1V1/2017 (Younis, 2017)
Oxidising solids	NA	NA	NA	
Organic peroxides	NA	NA	NA	
Corrosive to metals	N/A	N/A	The product is pH-neutral and contains no complexing agents. The product is being tested toward corrosive to metals and the result will be amended. Product not classified	
Auto-ignition temperatures of products (liquids and gases)	A15	0.6 % propiconazole % & 0.3 % IPBC	< 600°C Product not classified	GLP3016002649A R1V1/2017 (Younis, 2017)
Relative self-ignition temperature for solids	NA	NA	NA	
Dust explosion hazard	NA	NA	NA	

Conclusion on the physical hazards and respective characteristics of the product
The product is not flammable (flash point >93°C), not oxidizing, no auto-ignigtion < 600°C. No classification of the product for physical or chemical hazards. The product is being tested on corrosive to metal, and the result will be amended.

2.2.4 Methods for detection and identification

Method by capillary Gas Chromatography with flame ionisation detector (GC-FID)
Active substances are dissolved/extracted from the sample with acetone. The solution is filtered and an aliquot is analysed by Gas Chromatography (GC) with flame ionisation detection (FID) using internal standard calibration.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Accuracy**			**Limit of quantification (LOQ)**	**Reference**
					Range	Mean	RSD		

Propiconazole	GC-FID	Fortification range 50% - 150% Number of measurment: n=6	Correlation coefficient (r) 0.9998 Liniarity: the response is linear in the range of 80 - 651 microg/mL, r^2= 0.9996 (r=0.9998) y=0.8381x+ 2.9621	Not more than 1% deviation compared to the calibration solution. There is no interference and there is a blank sample	50% of nominal conc. (0.3228% w/w) 100% of nominal conc. (0.6464% w/w) 150% of nominal conc. (0.9744% w/w) Recovery 99.6 – 102.9 %	103.1 % 100.2% 99.8% total mean 101%	0.29% 0.14% 0.28% RSD_r: 0.63% Acceptable RSD_r: 2.89%	0.3228% w/w	Study N° 24263 Cornet, 2017
IPBC	GC-FID	Fortification range 50% - 150% Number of measurment: 6	Correlation coefficient (r) 0.9989 Linearity: the response is linear in the range of 38 - 292 microg/mL, r^2 = 0.9977 (r = 0.9989) y=0.5017x-1.45852	Not more than 1% deviation compared to the calibration solution.	50% of nominal conc. (0.1639% w/w) 100% of nominal conc. (0.3281% w/w) 150% of nominal conc. (0.4946% w/w) Recovery 98.6-108.1%	107.9% 102.9% 98.8% total mean 103.2%	0.32% 0.48% 0.20% RSD_r: 2.40 % Acceptable RSD_r: 3.21	0.1639% w/w	Study N° 24263 Cornet, 2017

Analytical methods for monitoring the product in soil, water and air are covered by the methods as described in the active substances dossiers of propiconazole and IPBC.

Analytical methods for monitoring in animal and human body fluids and tissues are not required.

Analytical methods for the determination of the active substances residues in food of plant and animal origin or feeding stuffs are only required if the biocidal product is intended to be used in a manner which may cause contact with food or feedstuffs. Since this is not the case for TEKNOL AQUA 1411-01, as exposure to food and feedstuff can be excluded when the product is applied according to the recommended uses, an analytical method for the determination in food or feeding stuffs is not required.

Conclusion on the methods for detection and identification of the product
The GC-FID analytical method used for the quantification of the active substances propiconazole and IPBC in the biocidal product TEKNOL AQUA 1411-01 is sufficiently validated. The method shows linearity, accuracy, and specificity. There is no interference in blank matrix. Other analytical methods for monitoring purposes are covered by active substance information where needed.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

TEKNOL AQUA 1411-01 is a wood preservative (product type 8) with fungicidal effect.

TEKNOL AQUA 1411-01 is intended for use in use class 2 and use class 3.
The product is intended for use by industrial and professional users:

- Industrial: flow-coating, automated spraying and dipping (automated and manual), vacumat, brush machine, low pressure deluging.
- Professional: spraying (indoor and outdoor), dipping and brushing.

The total amount to be applied is between 90 g/m^2 and 110 g/m^2. Treated parts must always be protected with a topcoat treatment before they are exposed to the influence of the weather.

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

TEKNOL AQUA 1411-01 is used as a preventative treatment against wood rotting fungi and blue stain fungi in softwood and hardwood.

Category	**Wording**	**Code**
User category	Industrial Professional	A.20 A.30
Wood category	Softwood Hardwood	B.10 B.20
Wood product	Solid wood Reconstituted wood	C.10 C.11

Application aim and field of use	Preventive treatment / blue stain in service Use class 2 Use class 3 (3.1: wood and wood based products will not remain wet for long periods. Water will not accumulate)	D.30 E.20 E.30 (E.31)
Method of application and rate	Superficial application (label: 90-110 g/m^2, by 1-2 coats; a top coat must be applied for wood exposed to weathering): Brush/roller/pad treatment Spray treatment Flow coat/aspersion Dipping treatment Vacumat Brush machine Low pressure deluging	 F.10 F.11 F.12 F.14 F.70 (1) F.70 (2) F.70 (3)
Target organisms	Wood rotting fungi: brown and white rot fungi Wood discolouring fungi: blue stain in service	G.10, G.11 G.21.2

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product prevents fungal species from attacking the treated wood. No unexpectable suffering is expected"

2.2.5.4 Mode of action, including time delay

Mode of action for the active substances:

Propiconazole is a triazole fungicide. Triazoles inhibit the C-14 demethylation step in the ergosterol biosynthesis of fungi.

IPBC is a carbamate fungicide. Carbamates disturb cell membrane permeability and fatty acids metabolism.

2.2.5.5 Efficacy data

All experimental studies on efficacy have been performed with the biocidal product TEKNOL AQUA 1411-01 in accordance with the Guidance on BPR: Volume II Parts B&C (ECHA, 2017). The product has been tested at the proposed application rates, for efficacy against relevant target organisms: white and brown rot fungi (four species), blue stain fungi (two species).

The EN113 test standard is a laboratory test to determine the toxic values of wood preservatives against wood destroying basidiomycetes cultured on agar medium. A conversion from biological reference value per cubic meter to biological reference value per square meter is performed in accordance with point 5.2.15 of EN599-1 stating that 'the biological reference value in grams per square metre shall be deemed to be

equivalent to twice the biological reference value established in kilograms per cubic metre in the EN113 test.

The test organisms that were investigated are:
Coniophora puteana (pine sapwood)
Poria placenta (pine sapwood)
Gloeophyllum trabeum (pine sapwood)
Trametes versicolor (beech)
EN73 and EN84 standards were used as pre-treatments prior to this fungal testing.
In addition, an EN152 test has been performed on pine sapwood test specimen after 4 weeks of QUV weathering against *Aureobasidium pullulans and Sydowia pithyophilia*. All tests were conducted by the Danish Technological Institute.

Experimental data on the efficacy of the biocidal product against target organism(s)					
Function & tested wood	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Preservative – Scots pine and beech	*Coniophora puteana., Poria placenta., Gloeophyllum trabeum, Trametes versicolor (3x brown rot and 1x white rot fungi)*	EN73 + EN113	40-80 kg/m^3 (brown rot), 50-90 kg/m^3 (white rot), duration 16.7 weeks, after ageing test	Softwood: b.r.v. 41,2 kg/m^3 (Pine) Hardwood: b.r.v. 48.0 kg/m^3 (Beech)	Test report no: 635690-4
Preservative – Scots pine and beech	*Coniophora puteana., Poria placenta., Gloeophyllum trabeum, Trametes versicolor (3x brown rot and 1x white rot fungi)*	EN84 + EN113	40-80 kg/m^3 (brown rot), 50-90 kg/m^3(white rot), duration 20 weeks, after ageing test	Softwood: b.r.v. 42.7 kg/m^3 (Pine) Hardwood: b.r.v. 48.8 kg/m^3 (Beech)	Test report no: 635690-1
Preservative – Scotch pine	*Sydowia pithyofilia and Aureobasidium pullulans* spp. (blue stain fungi)	EN152 with acrylic standard top coat	110 g/m^2, duration 6 weeks, after 4 weeks QUV accelerated weathering	no individual rating ≥2 of blue stain, min. stain-free zone 1.0 mm, mean 2.5 mm.	Test report no: 635704-1

Conclusion on the efficacy of the product

TEKNOL AQUA 1411-01 meets the efficacy requirements for PT8 preventive wood treatment products and protects treated softwood against wood destroying fungi (*Basidiomycetes*) (tested organisms *Coniophora puteana, Poria placenta*, *Gloeophyllum trabeum*, *Trametes versicolor*) at 90 g/m^2 (85 g/m^2) application, treated hardwood against wood destroying fungi (*Basidiomycetes*) (tested organisms *Coniophora puteana, Poria placenta*, *Gloeophyllum trabeum*, *Trametes versicolor*) at 100 g/m^2 (98 g/m^2) and treated wood against blue stain fungi (*Ascomycetes and Deuteromycetes*)(tested

organisms *Sydowia pithyofilia* and *Aureobasidium pullulans spp*.) at 110 g/m^2, i.e. the application rates that are claimed on the label. Values were derived based on EN599-1:2009, section 5.2.15

2.2.5.6 Occurrence of resistance and resistance management

Propiconazole:
According to the active substance assessment report for propiconazole no specific resistance cases have been reported. Resistance to fungicides is a normal phenomenon embodied in the natural process of the evolution of biological systems and all demethylation inhibitors (DMIs) including propiconazole have a similar resistance risk but resistance factors may be different. Propiconazole should be strictly used as all DMI's according to the Fungicide Resistance Action Committee guidelines.

IPBC:
The risk of resistance formation against carbamate fungicides is regarded to be low to medium by FRAC (Fungicide Resistance Action Committee). This applies to the use of carbamate fungicides in agriculture, where yearly applications to the same fields are possible.
Based on the unspecific mode of action of IPBC, the risk of resistance formation during wood preservation is regarded to be low.

2.2.5.7 Known limitations

No known limitations.

2.2.5.8 Evaluation of the label claims

The label claims supported by the efficacy data for TEKNOL AQUA 1411-01 when used according to use class 2 and 3 are:

Wood rotting fungi (*Basidiomycetes*) on softwood at 90 g product/m^2
Wood rotting fungi (*Basidiomycete*) on hardwood at 100 g product/m^2
Wood discolouring fungi (*Ascomycetes and Deuteromycetes*) at 110 g product/m^2

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

The product is not to be used together with other biocidal products.

2.2.6 Risk assessment for human health

No toxicological studies are available on the biocidal product, TEKNOL AQUA 1411-01. The requirement for such studies can be waived, with reference to the Guidance on the Biocidal Products Regulation: Volume III Human Health, Part A (Information Requirements), on the basis that there is sufficient toxicological data on the active substances and non-active substances to allow classification of TEKNOL AQUA 1411-01 according to Regulation (EC) No. 1272/2008 (CLP), and no synergistic effects between any of the components are expected.

The toxicology of the active substances propiconazole and IPBC was examined according to the standard requirements under the Biocidal Products Directive (BPD) 98/8/EC. The toxicological properties of the active substances are summarized in their respective Competent Authority Report (CAR) for product type 8:

- Propiconazole –rMS Finland (2007)
- IPBC –rMS Denmark (2008)

FI CA submitted in November 2015 a reclassification proposal for propiconazole to ECHA Risk Assessment Committee (RAC) for the purpose of a harmonised classification. RAC adopted an opinion on 9 December 2016 by consensus for a harmonised classification of propiconazole of the following: Repr. 1B, H360D, Acute Tox. 4, H302, Skin Sens 1, H317, Aquatic Acute, H400 (M=1) and Aquatic Chronic H410 (M=1). The harmonised classification was entered in Annex VI to the CLP legislation through the *Adaptation to Technical Progress* (ATP) no. 13 update (enforced May 2020).

DK CA submitted in June 2011 a classification proposal for IPBC to RAC for the purpose of a harmonised classification. RAC adopted its opinion 28 November 2012 by consensus for a harmonised classification of the following: Acute Tox. 3, H331; Acute Tox. 4, H302; Eye Dam. 1, H318; Skin Sens. 1, H317; STOT RE 1, H372 (larynx), Aquatic Acute 1, H400, M=10; Aquatic Chronic 1, H410, M= 1. The harmonised classification was entered in Annex VI to the CLP legislation through the ATP no. 6 update (enforced June 2014).

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	TEKNOL AQUA 1411-01 does not cause skin irritation.
Justification for the value/conclusion	None of the active substances or non-active substances in the mixture allow for classification for skin irritation of TEKNOL AQUA 1411-01 as they are either not classified themselves for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.1 "Skin corrosion or skin irritation"

Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	TEKNOL AQUA 1411-01 does not cause eye irritation.
Justification for the value/conclusion	None of the active substances or non-active substances in the mixture allow for classification for eye irritation of TEKNOL AQUA 1411-01 as they are either not classified themselves for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.2 "Eye irritation"
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	TEKNOL AQUA 1411-01 does not cause respiratory tract irritation.
Justification for the conclusion	None of the active substances or non-active substances in the mixture allow for classification for respiratory tract irritation of TEKNOL AQUA 1411-01 as they are either not classified themselves for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Not a core data requirement.
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules

	laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	TEKNOL AQUA 1411-01 is assigned labelling with EUH208.
Justification for the value/conclusion	IPBC and propiconazole are classified as Skin Sens. 1. Their concentrations in TEKNOL AQUA 1411-01 are below the generic cut off value of 1% for classification of the product with Skin Sens 1, H317, but above the limit value of 0.1% for labelling with EUH208. None of the non-active substances in the mixture trigger classification for skin sensitisation or labelling with EUH208 of TEKNOL AQUA 1411-01 as they are either not classified themselves for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP and DSD	Labelling with EUH208: Contains propiconazole and 3-iodo-2-propynyl butylcarbamate (IPBC). May produce an allergic reaction.

Data waiving	
Information requirement	Annex III of BPR, point 8.3 "Skin sensitization"
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	TEKNOL AQUA 1411-01 does not cause respiratory sensitisation.
Justification for the value/conclusion	None of the active substances or non-active substances in the mixture allow for classification for respiratory sensitisation of TEKNOL AQUA 1411-01 as they are either not classified themselves for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.4 "Respiratory sensitization" (ADS)
Justification	Currently no testing methods or test guidelines are available. Classification is therefore based on apparent evidence of potential respiratory sensitization attained from other sources submitted in the dossier.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	TEKNOL AQUA 1411-01 is not acutely toxic via the oral route – ATE_{mix} > 2000 mg/kg bw.
Justification for the selected value	According to the calculation rules laid down in Reg. (EC) no. 1272/2008, the ATE_{mix} for TEKNOL AQUA 1411-01 is > 2000 mg/kg bw.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.1 "Acute toxicity by oral route".
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	TEKNOL AQUA 1411-01 is not acutely toxic via inhalation -ATE_{mix} > 20 mg/L
Justification for the selected value	According to the calculation rules laid down in Reg. (EC) no. 1272/2008, the ATE_{mix} for TEKNOL AQUA 1411-01 vapour is >5 mg/L.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.2 "Acute toxicity by inhalation"
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	TEKNOL AQUA 1411-01 is not acutely toxic via the dermal route.
Justification for	None of the non-active substances in the mixture trigger classification

the selected value	for acute dermal toxicity of TEKNOL AQUA 1411-01 as they are either not classified themselves for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.3 "Acute toxicity by dermal route"
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

Information on dermal absorption

The document CA-July13-Doc6.2.b presents the approach for assessment of dermal absorption in biocidal products to be authorised. If no dermal absorption studies exist with the specific formulation of the biocidal product, next step is to either apply a default value from the *EFSA (2017) Guidance on dermal absorption*[3] for a first worst-case exposure estimate or perform read across with data from the CAR of the active substance or other product formulations similar to the biocidal product to be authorised provided that 2 conditions are met:

1. It is justified that the formulations presented in dermal absorption studies submitted for the active substance approval (or the other product formulation) have a similar composition as compared to the biocidal product to be authorised when using the criteria laid down in the before mentioned *EFSA (2017) Guidance on dermal absorption*, and
2. The applicant holds a Letter of access from the data owner of the dermal absorption study which is relevant for the biocidal product to be authorised.

If no safe use can be demonstrated, further refinements should be applied in the external exposure calculation. If the unacceptable risk remains, dermal absorption test studies for the specific formulation should be performed before the introduction of risk mitigation measures.

There are no dermal absorption studies available with the specific formulation of TEKNOL AQUA 1411-01. In the Assessment Report for propiconazole in PT8 it is explained that product specific studies should be submitted for product authorisation if a read across is not justified. The representative product for the inclusion of propiconazole in Annex I of the BPD was solvent-based and therefore does not readily meet the criteria for read across regarding dermal absorption. An absorption value of 50 % for water-based formulations should therefore be applied as a default according to *EFSA (2017) Guidance*

[3] EFSA (European Food Safety Authority), Buist H, Craig P, Dewhurst I, Hougaard Bennekou S, Kneuer C, Machera K, Pieper C, Court Marques D, Guillot G, Ruffo F and Chiusolo A, 2017. Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp

on dermal absorption. The Applicant has however submitted a justification for use of a dermal absorption value of 9% based on read across to similar products with propiconazole which is located in IUCLID. The rMS has further conducted a specific read across to the representative product formulation in the CAR of propiconazole in PT8 (FI CA, 2007). This read across is placed in the Confidential Annex restricted to authorities. The rMS has accepted the use of the dermal absorption value of 9% from the representative product formulation applied to TEKNOL AQUA 1411-01, but as this dermal absorption was derived using the *EFSA (2012) Guidance on dermal absorption*, the rMS has evaluated the representative product according to *EFSA (2017) Guidance on dermal absorption* leading to a dermal absorption value of 14 %.

The representative product for the inclusion of IPBC in Annex I of the BPD was solvent-based and therefore does not meet the criteria for read across. The default value for water-based formulation was therefore applied by the applicant. The rMS did not find is necessary to refine the dermal absorption value for IPBC.

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Propiconazole	IPBC
Value(s) according to the CAR	9%	30%
Values used for current risk assessment	14%	50%
Justification for the selected value(s)	Read across to representative product formulation in the CAR for propiconazole in PT8 (FI CA, 2007). Justification is given in the Confidential Annex restricted to authorities.	Default value for water-based formulation according to *EFSA Guidance on dermal absorption* (2017).

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

In addition to the active substances, the product may contain non-active substances (co-formulants) that are substances of concern (SoC). In order to identify relevant SoC, the Guidance on BPR Volume III Human Health, Annex A (2017) has been consulted. Based on the categories presented, methoxypropan-2-ol (PGME) and monoethylene glycol are considered substances of concern, as they have been assigned an OEL (criterion 5). No other non-active substance is considered a substance of concern for human health in TEKNOL AQUA 1411-01. Please refer to the Confidential Annex for the details of the evaluation.

According to the SCOEL recommendation on PGME, the 8-hour TWA OEL is set at 100 ppm or 375 mg/m^3, and the STEL (15 min.) OEL is set at 568 mg/m^3. PGME has a low vapour pressure and will not be readily available for exposure via inhalation, however calculations for inhalation exposure have been performed in the relevant exposure scenarios for a worst case assumption. Although a skin notation is also assigned to the substance, a dermal quantitative risk assessment to evaluate systemic effects is not considered relevant, as the assigned OEL is based on eye irritation. A skin notation was

assigned by SCOEL as PGME has a low vapour pressure and therefore exposure will be mainly by the dermal route. When retrieving data for systemic effects by PGME from dermal exposure, the closest to a potential NOAEL for systemic effects was a dermal NOAEL of 1860 mg/kg bw/day derived from a 90-day dermal study conducted on rabbits and based on the end-point narcosis. In the same dermal study, and in 21-day dermal study, local effects (mild skin irritation) were observed at 1000 mg/kg bw/day, and no systemic effects were observed in the 21-day dermal study. Applying a safety factor of 100 to the systemic NOAEL, it is not likely that dermal exposure will lead to an exceedance of 18.60 mg/kg bw/day for systemic effects of PGME as industrial and professional users will also wear coveralls and gloves, and considering that local effects are present before systemic effects, a systemic uptake is not relevant.

Risk assessment for PGME				
Scenario	1.2.2 Flowcoating and 1.2.2 Autospraying	2.2.1 Manual dipping	2.2.2 Professional brushing	2.2.3 Professional manual spraying
Max exposure mg/m³	0.0022	0.0022	0.1672	0.00035
8h TWA	0.00028	0.00014	0.0279	0.00018
EU STEL	568	568	568	568
% PGME of STEL	0.00039	0.00039	0.02944	0.00006
8h TWA	375	375	375	375
% PGME of 8h TWA	0.00007	0.00004	0.00743	0.00005

When assessing inhalation exposure to PGME during the primary exposure scenarios relative to the 8-hour TWA of 375 mg/m^3 no risk was found. When assessing the inhalation exposure to PGME during the primary exposure scenarios relative to the STEL of 568 mg/m^3 no risk was found.

According to the SCOEL recommendation on monoethylene glycol, the 8-hour TWA OEL is set at 20 ppm or 52 mg/m^3, and the STEL (15 min.) OEL is set at 104 mg/m^3. The OEL was set on basis of irritation of the mucosae in human volunteers. Although a skin notation is also assigned to the substance, a dermal quantitative risk assessment to evaluate systemic effects is not considered relevant, as the assigned OEL is based on the local risk of irritation of mucosal membranes. The skin notation was assigned, as exposure to monoethylene glycol via the dermal route could contribute substantially to the total body burden. The SCOEL recommendation also reviewed a study in which the substance in liquid form was concluded to have eye irritation potential but not sufficiently to be assigned a hazard statement. Considering that it is required to wear coveralls and gloves when applying TEKNOL AQUA 1411-01, and that irritation of mucosal membranes are the primary local effect combined with the fact that no hazard statements for skin irritation or eye irritation has been assigned to monoethylene glycol, a dermal quantitative assessment is not considered relevant.

Risk assessment for Monoethylene glycol				
Scenario	1.2.2 Flowcoating and 1.2.2 Autospraying	2.2.1 Manual dipping	2.2.2 Professional brushing	2.2.3 Professional manual spraying
Max exposure mg/m³	0.0005	0.0005	0.038	0.00008
8h TWA	0.00006	0.00003	0.00633	0.00004
EU STEL	104	104	104	104

% PGME of STEL	0.00048	0.00048	0.03654	0.00008
8h TWA	52	52	52	52
% PGME of 8h TWA	0.00012	0.00006	0.01218	0.00008

Based on existing knowledge and the available scientific information from the submitted SDSs for the non-active substances there are no indications of endocrine disruption properties for all of the non-active substances except one. A RMOA has been established under REACH legislation for grounds of concern for ED properties for one non-active substance. No suggestion is yet available for the further evaluation. Should it be concluded in the future that this non-active substance has endocrine disruptive properties, legal consequences will apply for TEKNOL AQUA 1411-01. Please refer to the Confidential Annex for the detailed evaluation of the endocrine disrupting properties of the non-active substances.

Propiconazole and IPBC are currently not considered to have endocrine disrupting properties under Regulation (EU) 528/2012 and have not been assessed according to the new ED criteria[4]. With reference to current guidance for application of these criteria[5] the evaluating body should not evaluate endocrine disrupting properties nor request additional data in the context of product authorisation procedures. It is therefore concluded that the active substances do not possess endocrine disruptive properties which should be taken into account for the authorization of TEKNOL AQUA 1411-01.

Available toxicological data relating to a mixture

There is no toxicological data available for the mixture in which PGME is contained.

Other

Propiconazole is classified Repr. 1B (H360D) and is present in TEKNOL AQUA 1411-01 at a concentration of 0.6%. The GCL for assignment of Rep.1B in mixtures according to Reg. (EC) no. 1272/2008 is 0.3%. TEKNOL AQUA 1411-01 should therefore be classified with Repro 1B, H360D: *May damage the unborn child*.

2.2.6.2 Exposure assessment

TEKNOL AQUA 1411-01 is a ready-to-use aqueous wood preservative (Product Type 8) for wood designated. The product protects the wood surface against wood destroying fungi and blue stain fungi (Use Classes 2 and 3, preventive wood protection).

The product is intended for use in **industrial** application techniques and by **professionals** as follows:

- Industrial: flow-coating, automated spraying, deluging, brush machine treatment, vacumat treatment, and dipping (automated and manual).
- Professional: spraying and brushing (indoor and outdoor), manual dipping.

4 Commission Delegated Regulation (EU) 2017/2100.

5 CA_March18_Doc.7.3b-final, paragraph 19.

The total amount of product to be applied is 90-100 g/m^2 against wood destroying fungi, respectively for softwood or hardwood, and 110 g/m^2 against blue stain fungi. Treated wood must always be protected with a topcoat treatment before exposed to the influence of the weather. The product contains 0.6% w/w propiconazole and 0.3% w/w IPBC. A maximum application rate of 110 g/m^2 equates to a maximum rate of 0.66g propiconazole/m^2 and 0.33g IPBC/m^2 (considering a product density of 1.0023 g/ml at 20°C).

During application of TEKNOL AQUA 1411-01, exposure could occur by inhalation and dermal routes. Additionally, post-application exposure can occur while handling treated wood, and cleaning the brush/dipping tank. Primary oral exposure is not considered to be relevant for adult users. Secondary exposure is possible for professional users and non-professional users, when sanding treated wood, and for non-professional users when handling treated wood[6]. Secondary exposure is possible for l the general public due to indoor inhalation of volatilised residues from treated wood and, for adults, due to laundering of work clothes. Acute (incidental) secondary exposure is via dermal and oral routes is considered for children.

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

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Prof. use**	**Non-prof. use**	**Industrial use**	**Prof. use**	**Non-prof. + general public**	**Via food**
Inhalation	Yes	Yes	n.a.	N.a.	Yes	Yes	N.a.
Dermal	Yes	Yes	n.a.	N.a.	Yes	Yes	N.a.
Oral	No	No	n.a.	N.a.	No	Yes	N.a.

List of scenarios

6 According to the Technical Agreements for Biocides (TAB) – TOX v.2.0 (of 09.11.2018), Point 'TOX 36' for PT8, "*secondary exposure of professionals handling treated dried wood does not need to be assessed as it is covered by the exposure during the handling of wet wood after the application of the biocidal product".*

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
Industrial			
1.1	Mixing and loading	Chronic primary exposure. Fully-automated transfer/pumping of product in industrial settings.	Industrial users
1.2.1	Application Flow coating (deluge)	Chronic primary exposure. Flow coating.	Industrial users
1.2.2	Application Automated spraying/ deluge/brush machine treatment/ vacumat treatment	Chronic primary exposure. Automated enclosed spraying/deluging/brush machine treatment/vacumat treatment.	Industrial users
1.2.3	Application Automated dipping	Chronic primary exposure. Automated dipping.	Industrial users
1.2.4	Application Manual dipping	Chronic primary exposure. Manual dipping.	Industrial users
1.3	Post-application Cleaning of dipping tank	Acute primary exposure. Cleaning of dipping tank.	Industrial users
Professional			
2.1	Mixing and loading	Chronic primary exposure. Semi-automatic transfer of product from pack sizes > 20 litres to dipping vessel	Professionals
2.2.1	Application Manual dipping	Chronic primary exposure. Manual dipping.	Professionals
2.2.2	Application Spray application	Chronic primary exposure. Loading and stirring the RTU product and applying it to wood using spray equipment.	Professionals
2.2.3	Application Brushing and rolling	Chronic primary exposure. Stirring RTU product and applying it to wood using a brush.	Professionals
2.3.1	Post-application emptying and refilling of the dipping vessel	Acute intermediary primary exposure Semi-automatic emptying dipping vessel.	Professionals

2.3.2	Post-application Cleaning of spray equipment	Chronic primary exposure. Cleaning spray equipment after use.	Professionals
2.3.3	Post-application Washing out of a brush	Chronic primary exposure. Cleaning brush after application	Professionals
2.3.4	Post-application Sawing and sanding wood	Chronic secondary exposure. Sawing and sanding surface treated wood	Professionals
Non-professional			
3.1	Sawing and sanding wood	Acute secondary exposure. Sawing and sanding surface of treated wood	Non-professionals
3.2	Handling treated wood once dry	Acute secondary exposure. Non-professional (adult) handling treated wood after application of the product.	Non-professionals
General public			
4.1	Laundering professional work clothes	Acute intermediary secondary exposure. Contaminated work clothing is handled prior to mechanical laundering.	Professionals, non-professionals, General public
4.2	Touching freshly treated wood	Acute secondary exposure, incidental. Toddler touching freshly treated wood with subsequent mouthing of fingers.	General public (toddler)
4.3	Chewing off-cut of treated wood	Acute secondary exposure. Infant chews wood cut-off, which has been treated with wood preservative	General public (infant)
4.4	Playing on playground structure outdoors and mouthing	Chronic secondary exposure. Infant playing and mouthing weathered structure outdoors. Child playing on treated playground structure outdoors.	General public (infant, toddler, child)
4.5	Inhalation volatilised residues	Chronic secondary exposure. Inhalation of volatilised residues from treated wood indoors (restricted to windows, exterior doors and roof structures)	Industrial users, Professionals, non-professionals,, General public (infant, child, adult)

Industrial exposure

Scenario 1.1. Fully-automated transfer/pumping of product in industrial settings

Description of Scenario 1.1.
TEKNOL AQUA 1411-01 is a ready-to-use (RTU) product and does not require mixing. HEEG Opinion no. 1 *On the use of available data and models for the assessment of the exposure of* operators during the loading of products into vessels or systems in industrial scale provides models for assessing exposure related to loading of the product into industrial systems. Loading of TEKNOL AQUA 1411 in industrial settings is expected to by fully-automated transfer/pumping. Exposure during fully-automated transfer/pumping is expected to be associated with negligible or only accidental exposure (see HEEG Opinion no. 1, under Comments, p. 8). Consequently, exposure during this task is not considered.

Scenario 1.2.1. Flow coating

Description of Scenario 1.2.1		
During flow coating, timber is passed through an enclosed tunnel in which the wood preservative is applied. Due to its contained nature, operator exposure is expected to be low, and mainly constitutes handling freshly treated wood. Although there is no generic model available for automated flow coating, the professional Dipping Model 1 is considered as a good approximation in assessing exposure from the deluge process according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. The Dipping Model 1 covers exposure of industrial users and includes dipping wooden articles, mixing/loading, handling wet articles and loading/unloading. Deluge process are operated on a batch basis, assuming as a worst case one batch per day, with a duration of 60 minutes per event. According to HEEG Opinion 9 (TM I, 2010), it is assumed that operators wear coated coveralls when handling wet wood preservatives. The indicative value for hand exposure is an 'inside glove' value.		
	Parameters	Value
Tier 1	IPBC	0.3 % w/w
	Propiconazole	0.6 % w/w
	Indicative values for hands inside gloves[1]	25.7 mg/min.
	Indicative values for body[1]	178 mg/min.
	Inhalation (non-volatile a.s.)[1]	< 1 mg/m^3
	Inhalation fraction	1
	Inhalation rate[3]	1.25 m^3/h
	Body weight[3]	60 kg
	Event exposure duration[1]	60 min.
	Number of events[1]	1/day
	Dermal absorption, IPBC	50 %
	Dermal absorption, propiconazole	9 %
	Coated coveralls[2]	90 % protection

[1] HEAdhoc Recommendation no. 6 - Methods and models to assess exposure to biocidal products in different product types p. 22 (version 3, 2017).

[2] HEEG opinion 9 - Default protection factors for protective clothing and gloves (TM I, 2010).

[3] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017).

Scenario 1.2.2. Automated spraying deluge/brush machine treatment/ vacumat treatment

Description of Scenario 1.2.2
Like flow coating, automated spraying, deluging, brush machine treatment, vacumat treatment are assumed to be fully enclosed processes, whereby operator exposure occurs mainly by handling treated wet wood. These are treatments using closed circuits and/or conveyor belts, similar exposure is assumed for such closed systems. The Dipping model 1 is used to assess industrial exposure and includes mixing/loading, handling wet articles. Loading/ unloading will be similar for all closed system treatments as it is for dipping. Exposure during the closed system treatments are covered by calculations described in scenario 1.2.1.

Scenario 1.2.3. Fully automated dipping

Description of Scenario 1.2.3		
Automated dipping includes the following operations: an operator using a fork-lift truck or similar equipment lowers the wood into the dipping tank or transfers the wood to a bathing tray. The wood stays in the wood preservative for a few minutes or for a few hours before being lifted out of the tank by the fork-lift truck (or similar). The wood is then transferred by the fork-lift truck (or similar) to a storage area where it is placed to dry. The operator exposure arises from handling of the treated wood. Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure and HEEG Opinion no. 8 (TM III, 2009) considers 4 cycles of each 60 minutes duration to represent realistic circumstances for automated dipping and the water-based Handling Model 1 to represent the model best suited for estimation of exposure. According to HEEG Opinion no. 9 (TM I, 2010), it is assumed that operators wear coated coveralls when handling wet wood preservatives. The indicative value for hand exposure is an 'inside glove' value. Dermal exposure is considered the only relevant exposure pathway, as HEEG Opinion 8 (TM 2013) considers exposure from inhalation negligible. According to HEEG opinion no. 18 when all steps are automated and no manual handling occurs, dermal exposure is assumed to decrease by a factor 4. This will act as the tier 2 approach.		
	Parameters	Value
Tier 1	IPBC	0.3 % w/w
	Propiconazole	0.6 % w/w
	Indicative values for hands inside gloves[1]	1080 mg/cycle
	Indicative values for body[1]	8570 mg/cycle
	Inhalation[1, 5]	Negligible for non-volatile a.s.
	Body weight[4]	60 kg

	Number of cycles[1, 5]	4/day
	Dermal absorption, IPBC	50 %
	Dermal absorption, propiconazole	9 %
	Coated coveralls[2]	90% protection
Tier 2	Reduction factor for fully automated process[3]	4

[1] HEAdhoc Recommendation no. 6 - Methods and models to assess exposure to biocidal products in different product types p. 19 (version 3, 2017). The option to consider 'new gloves' (defined as gloves that are replaced in each cycle was) in the scenario, permitting hand exposure (inside gloves) to be reduced by a factor of 0.6 (TNsG 2002, Part 2, p. 192) on the condition that use of new gloves with each cycle is listed as a RMM, was not taken as application of the reduction factor of 4 for the fully automated process resulted in acceptable exposure to both active substances alone and combined (i.e. in the 'Risk characterisation from combined exposure'.

[2] HEEG opinion 9 - Default protection factors for protective clothing and gloves (TM I, 2010).

[3] HEEG opinion 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping (TM III, 2013) - all steps are mechanized and no manual handling: dermal exposure is assumed to decrease by a factor of 4.

[4] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017).

[5] HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8).

Scenario 1.2.4. Manual dipping

Description of Scenario 1.1.
The manual dipping exposure scenario has been assessed under scenario 2.2.1 for the professional user and is considered to cover that of the industrial user as they are subject to the same exposure following this application.

Scenario 1.3. Cleaning the dipping tank

Description of Scenario 1.3		
A post-application task potentially leading to contamination is cleaning of the inner surface of the industrial dipping tank. Cleaning operations can be assumed to be undertaken infrequently. According to HEEG opinion no. 8 (TM III, 2009), a survey of 24 companies informed of the number of times dip tanks were cleaned. The answers ranged from 2 times per year to every 5th year with only one company performing the cleaning 2 times per year. In the 19 companies the cleaning were performed by in house workers and the scenario is therefore considered relevant. There is no generic model for cleaning of dipping tanks, but this scenario can be approached by the exposure values from the Handling Model 1, covering intermittent handling of water-wet wood and associated equipment according to HEAdhoc Recommendation no. 6, p. 19. According to HEEG Opinion no. 8 for water-based formulations no inhalation exposure is expected to occur. It is assumed that industrial and professional users wear gloves and a coverall when cleaning out a dipping tank, and according to HEEG Opinion 9 (TM I, 2010), it is assumed that these coveralls are coated and provides a 90 % protection from contamination from wet wood preservatives.		
	Parameters	Value

Tier 1	IPBC	0.3 % w/w
	Propiconazole	0.6 % w/w
	Indicative values for hands inside gloves[1]	1080 mg/cycle
	Indicative values for body[1]	8570 mg/cycle
	Body weight[4]	60 kg
	Inhalation[1]	negligible
	Number of treatments[2]	1/ year
	Dermal absorption, IPBC	50 %
	Dermal absorption, propiconazole	9 %
	Coated coveralls[3]	90 % protection

[1] HEAdhoc Recommendation no. 6 - Methods and models to assess exposure to biocidal products in different product types (version 3, 2017)

[2] HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8) (TM III, 2009)

[3] HEEG opinion 9 - Default protection factors for protective clothing and gloves (TM I, 2010)

[4] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)

Calculations for Scenario 1.1, 1.2.1, 1.2.2, 1.2.3, 1.2.4, and 1.3

Summary table: estimated systemic exposure from industrial uses					
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 systemic uptake** (mg/kg bw/d)
IPBC					
1.1 Automated transfer	1*	Negligible	Negligible	Not relevant	Negligible
1.2.1 Flow coating	1*	0.00375	3.9150	Not relevant	0.06531
1.2.2 Automated spraying	1*	0.00375	3.9150	Not relevant	0.06531
1.2.3 Automated dipping	1*	Negligible	11.6220	Not relevant	0.19370
	2*/Reduction factor	Negligible	2.9055	Not relevant	0.04843
1.2.4 Manual dipping	1/Gloves	0.002	9.1665	Not relevant	0.0550
	2/Gloves, coated coveralls	0.002	1.9575	Not relevant	0.01175
1.3 Cleaning of dipping tank	1*	Negligible	2.9055	Not relevant	0.04843

Propiconazole					
1.1 Fully automated transfer	1*	Negligible	Negligible	Not relevant	Negligible
1.2.1 Flow coating	1*	0.00750	2.1924	Not relevant	0.03667
1.2.2 Automated spraying	1*	0.00750	2.1924	Not relevant	0.03667
1.2.3 Automated dipping	1*	Negligible	6.5083	Not relevant	0.10847
	2*/Reduction factor	Negligible	1.6271	Not relevant	0.02712
1.2.4 Manual dipping	1/Gloves	0.004	5.1332	Not relevant	0.08555
	2/Gloves, coated coveralls	0.004	1.0962	Not relevant	0.01827
1.3 Cleaning of dipping tank	1*	Negligible	1.627	Not relevant	0.02712

* Recommended model used with standard assumptions: for industrial treatments, wearing of suitable protective gloves, a coated coverall and footwear is assumed.

Combined scenarios

A combined scenario industrial exposure is not considered warranted as: a) chronic exposure from 2 or more sources is not expected to occur (it is assumed that only 1 application task will be performed daily and that fully automated transfer of TEKNOL AQUA 1411-01 from its packaging to treatment equipment results in negligible exposure), and b) only a single acute exposure has been identified. The automated dipping procedure and cleaning of the tank can take place on the same day, though clearing of the dipping tank is considered to be an acute exposure. In this regard, Point 'TOX 37' for PT8 of the Technical Agreements for Biocides (TAB) – TOX v.2.0 (of 09.11.2018) states: "*exposure during the application and post-application tasks should be assessed but not combined in those cases where the post-application scenario is not a long-term scenario"*. However, to evaluate such a combined exposure as an acute risk, the 2 tasks were included in a combined scenario for acute exposure. As a considerable risk was found in tier 1 of the automated dipping process, the combined exposure scenario only considers the tier 2 exposure value for automated dipping.

Summary table: combined systemic exposure from industrial uses						
Scenarios combined	**Tier**	**Estimated inhalation uptake (mg)**	**Estimated dermal uptake (mg)**	**Estimated oral uptake (mg)**	**Estimated total uptake (mg)**	**Estimated total dose (mg/kg bw)**
Propiconazole						
Automated dipping and cleaning of the dipping tank 1.2.3+1.3	2+1	Negligible	3.25416	Not relevant	3.25416	0.05424
IPBC						

Automated dipping and cleaning of the dipping tank 1.2.3+1.3	2+1	Negligible	5.811	Not relevant	5.811	0.0969

Professional exposure

Scenario 2.1 Loading of product into manual dipping tank or painting pot

Description of Scenario 2.1		
TEKNOL AQUA 1411-01 is a ready-to-use product and does not require mixing, however as pack sizes of 20 liters and greater are intended to be available to professionals, exposure during transfer of the product from a large container to a painting pot and/or a dipping tank should be considered. HEEG Opinion no. 1 (TM I, 2008) provide models for assessing such exposure. Loading of TEKNOL AQUA 1411-01 in relation to professional use may be performed via automated- or semi-automated transfer/pumping and is expected to be a relatively brief activity. Exposure during automated transfer/pumping is expected to be associated with very low or only accidental exposure according to HEEG Opinion no. 1, under *Comments*, p. 8), and semi-automated transfer/pumping is considered more relevant for professional users of the product, thus a model for the latter is considered most relevant. The RISKOFDERM *Potential Dermal Exposure Model* calculator was used to estimate exposure to the product (process for assessment: Filling, mixing or loading; level of automation: Automated or semi-automated task), and assuming negligible inhalation exposure. The model does not estimate body exposure. Assuming a daily exposure duration of 10 minutes and a product transfer rate of 10 L/min as a worst-case (giving a daily transfer of 100 L product), a hand exposure of 13 mg/min was calculated. It is considered unrealistic that the professional user does not wear gloves when performing this task, and tier 2 therefore includes wearing of these.		
	Parameter	**Value**
Tier 1	Dermal exposure, hands (90% percentiles)[1]	13 mg/min
	Indicative dermal exposure, body[1]	No exposure foreseen
	Indicative inhalation exposure[1]	Negligible; normal or good ventilation
	Exposure duration[1]	10 min
	Transfer rate of product[1]	10 L/min (as a worst case)
	Body weight, adult[2]	60 kg
	Dermal absorption, IPBC	50 %
	Dermal absorption, propiconazole	9 %
Tier 2	Gloves[3]	90% protection

[1] RISKOFDERM Dermal Model Loading liquid, automated or semi-automated.

[2] HEEG Opinion no. 17 - Default human factor values for use in exposure assessment for biocidal products.

[3] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessment for biocidal products.

Scenario 2.2.1 Manual dipping

Description of Scenario 2.2.1		
In manual dipping operations, the operator lifts and places – by hand – the wooden article into the dipping tank. The operator then pushes, using a post, the wooden article under the wood preservative in the dipping tank and/or uses a broom to brush the wood preservative onto the wooden article (the article is still in the dipping tank as the preservative is brushed on the wood). The operator then lifts by his/her gloved hand the wooden article from the dipping tank and stacks the article to dry. The operator gets relatively highly contaminated by the wood preservative. To assess worker exposure during manual dipping, the Dipping Model 1 is used according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure p. 20 (version 3, 2017). This is also advised in the HEEG Opinion 8 (TM III, 2009). The model covers professional users carrying out a range of dipping activities, including mixing/loading, handling wet articles, machine minding and loading/ unloading, involving a variety of articles. It is assumed that operators spend 30 minutes dipping, once a day. According to HEEG Opinion 9 (TM I, 2010), it is assumed that operators wear coated coveralls when handling wet wood preservatives, and tier 2 therefore includes this. The model includes gloves.		
	Parameters	Value
Tier 1	IPBC	0.3 % w/w
	Propiconazole	0.6 % w/w
	Indicative values for hands inside gloves[1]	25.7 mg/min
	Indicative values for body[1]	178 mg/min
	Body weight[4]	60 kg
	Inhalation[1]	< 1 mg/m^3
	Inhalation fraction	1
	Inhalation rate[4]	1.25 m^3/h
	Event exposure duration[3]	30 min
	Number of treatments[3]	1/day
	Dermal absorption, IPBC	50 %
	Dermal absorption, propiconazole	9 %
	Gloves	In model
Tier 2	Coated coveralls[2]	90 % protection

[1] HEAdhoc Recommendation no. 6 - Methods and models to assess exposure to biocidal products in different product types (version 3, 2017).

[2] HEEG opinion 9 - Default protection factors for protective clothing and gloves (TM I, 2010).

[3] HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8) (TM III, 2009).

[4] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017).

Scenario 2.2.2. Stirring the RTU product and applying it to wood using spray equipment

Description of Scenario 2.2.2		
An operator may spray on wood preservative to wood outdoors. To assess exposure arising from manual spray applications, Spraying model 2 relating to professional spray applications (medium pressure) indoors and outdoors in an overhead and downward direction is considered most appropriate according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure (version 3, 2017). The model relates to the application of remedial biocides to structural wood applications in industrial, recreational and residential settings. Mixing, loading and application are included in this scenario. The average exposure duration is set to 80 minutes (2 times 40 minutes of application) according to previously mentioned Recommendation no. 6, p. 21. Although it is considered that a professional user will wear both coveralls and gloves, the tier 1 approach is without the inclusion of such with regards to whether or not wearing this should act as a risk mitigation measure or recommendation.		
	Parameters	Value
Tier 1	IPBC	0.3 % w/w
	Propiconazole	0.6 % w/w
	Indicative values dermal exposure, hands[1]	273 mg/min
	Indicative values for body[1]	222 mg/min
	Body weight[3]	60 kg
	Inhalation[1]	76 mg/m^3
	Inhalation fraction	1
	Inhalation rate[3]	1.25 m$^{3/h}$
	Duration[1]	2x 40 min/day
	Dermal absorption, IPBC	50 %
	Dermal absorption, propiconazole	9 %
Tier 2	Coated coveralls[2]	90 % protection
	Indicative values for hands inside gloves[1]	7.8 mg/min
Tier 3	Impermeable coveralls[2]	95 % protection
Tier 4	Half-filtering respiratory protection mask reduction factor[4]	10

[1] HEAdhoc Recommendation no. 6 - Methods and models to assess exposure to biocidal products in different product types (version 3, 2017).

[2] HEEG opinion 9 - Default protection factors for protective clothing and gloves (TM I, 2010).

[3] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017).

[4] Biocides Human Health Exposure Methodology (2015), p. 154.

Scenario 2.2.3. Stirring RTU product and applying it to wood using a brush

Description of Scenario 2.2.3		
The professional user stirs and applies wood preservative to wood using a brush indoors or outdoors. The model "Professional brush treatment" based on Summary Report - Human Exposure to Wood Preservatives, Lingk, W.; Reifenstein, H.; Westphal, D.; Plattner, E., BfR Wissenshaft, 2006 is used for estimation of dermal and inhalatory exposure as recommended in Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure (version 3, 2017). Input values is further noted in the recommendation as application area 31.6 m^2 according to TNsG 2002 "Consumer product painting Model 3" with an exposure duration of 240 min. and a median work (application) rate at 7.6 min./m^3. The indicative values are normalized to 1 % active substances and refers to the exposure when brushing an area of 1 m^2 according to the abovementioned Summary Report. It is unrealistic that a professional user does not wear gloves and coated coveralls, and tier 2 is considered to represent the true circumstances for this task.		
	Parameters	Value
Tier 1	IPBC	0.3 % w/w
	Propiconazole	0.6 % w/w
	Indicative values dermal exposure, hands[1]	0.5417 mg/m^2
	Indicative values dermal exposure, body[1]	0.2382 mg/m^2
	Body weight[3]	60 kg
	Inhalation[1]	0.0016 mg/m^2
	Treated surface[1]	31.6m^2
	Event exposure duration[1]	240 min
	Dermal absorption, IPBC	50 %
	Dermal absorption, propiconazole	9 %
Tier 2	Gloves[2]	90 % protection
	Coated coveralls[2]	90 % protection

[1] HEAdhoc Recommendation no. 6 - Methods and models to assess exposure to biocidal products in different product types (version 3, 2017).

[2] HEEG opinion 9 - Default protection factors for protective clothing and gloves (TM I, 2010).

[3] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017).

Scenario 2.3.1. Semi-automated emptying and refilling dipping tank

Description of Scenario 2.3.1

Refilling and or emptying of the product from dipping vessels occurs intermediately as product will be applied to the wooden materials during application, and refilling the tank is necessary for optimal application of wood preservative. Emptying of the tank is likewise possible and occurs infrequently. Exposure arising from these tasks is considered equivalent to or less than that of scenario 2.1. and loading of TEKNOL AQUA 1411-01 into dipping vessels covers the exposure following emptying and/or refilling the dipping vessels. The tasks are not considered to be performed at the same day, further confirming that the exposure should not be accumulated.

Scenario 2.3.2. Cleaning spray equipment

Description of Scenario 2.3.2		
Post-application exposure after application of wood preservative with spray equipment can occur while cleaning the spray equipment. For water-based formulations, the spray equipment is cleaned with water. Cleaning is carried out in many different ways depending on the equipment and personal preferences. The most appropriate available input values for this task is considered to be those referred to in Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure from the Delgado et al., 2004 study[7]. The cleaning process is performed at the end of each working day and a maximum duration is expected to be 20 min. and is therefore considered to be relevant for long term exposure. Exposure from inhalation is not considered relevant.		
	Parameters	Value
Tier 1	IPBC	0.3 % w/w
	Propiconazole	0.6 % w/w
	Body weight[2]	60 kg
	Product density	1.0023 g/mL
	Indicative dermal exposure, hands (90% percentiles)[1]	35.87 µL/min.
	Indicative dermal exposure, body[1]	19.28 µL/min.
	Potential inhalation exposure	Negligible
	Number of cleanings[1]	1/day
	Event exposure duration[1]	20 min.
	Dermal absorption, IPBC	50 %
	Dermal absorption, propiconazole	9 %

[1] HEAdhoc Recommendation no. 4 -Cleaning of spray equipment in antifouling use (PT21)

[2] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)

Scenario 2.3.3. Cleaning brush after application

[7] Delgado P., Porcel J., Abril I., Torres N., Teran A., Zugasti A. (2004) Potential Dermal Exposure during the painting Process in Car Body Repair Shops. Annals of Occupational Hygiene (2004) 48 (3): 229-236

Description of Scenario 2.3.3
A post-application task which may lead to some degree of exposure is cleaning the brush used to apply the product. Brush cleaning by professionals can be expected to last for no more than 15 minutes and might result in some exposure to hands. A water-based formulation might be removed by washing the brush under a water stream, a process that would result in negligible dermal exposure. Thus, as discussed at WGIII2017, inclusion of a brush washing scenario may not be warranted for water-based products. However, in order to assess the contribution of an eventual brush-washing phase to exposure, exposure of professionals to the product is assessed using the *General Exposure Calculator for Washing out Of Brushes* of the annex to HEEG Opinion 11. It is considered a worst-case scenario as it is normally intended for non-water-based paints and does not involve cleaning under a stream of water. Cleaning a brush used for water-based formulations may be done by repeated dipping and swaying it in a vessel containing clean water. In HEEG Opinion 11 (TM III, 2010), a large size brush with the dimensions 10 cm x 10 cm x 2 cm (200 mL) is used for calculation. The brush is assumed to be cleaned (dipped and swayed) three times, using fresh water on each occasion (step). The volume of water should be large enough to allow a sufficient dilution of the residues in the brush. For a brush having a volume of 200 mL, the required water volume would be at least 400 mL per step. Each washing step is assumed to result in an approximately 10-fold dilution of the residues in the brush. After each step the brush is assumed to be squeezed by hand to remove as much liquid as possible. It is assumed that with each step 50% of the solution in the brush is released and may potentially contaminate the hand. It is further assumed that the squeezing is not done by the bare hand but rather by wrapping it first with a cleaning rag, which may absorb ~ 90% of the released liquid. Washing and squeezing may each be done a maximum of three times. During brush cleaning, professionals may retain gloves worn during brush application of the product (Tier 2 assessment). No exposure of areas of the body other than the hands is assumed to occur; and exposure via inhalation is considered negligible.

	Parameters	Value
Tier 1	IPBC	0.3 % w/w
	Propiconazole	0.6 % w/w
	Body weight[2]	60 kg
	Brush size	200 mL
	Volume of residual solution in brush	1/8 of brush volume = 25 mL
	Volume of each washing solution[1]	400 mL
	Remaining residues in brush after each washing step[1]	10%
	Remaining residues in brush after each squeezing[1]	50%
	Penetration through cleaning cloth during squeezing[1]	10%
	Dermal absorption, IPBC	50 %

	Dermal absorption, propiconazole	9 %
Tier 2	Gloves Coated coveralls[2]	90% protection 90% protection
Tier 3	Gloves Impermeable coveralls[2]	90% protection 95% protection

[1] HEEG opinion 11 - Exposure model Primary exposure scenario – washing out of a brush which has been used to apply a paint (TM III 2010)

[2] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)

Scenario 2.3.4 Sawing and sanding surface treated wood by a professional user

Description of Scenario 2.3.4

Cutting and sanding treated wood by professionals is considered a chronic exposure scenario as this is a daily activity. The highest end retention is the application rate of 110 g product/m^2 (the effective volume for prevention of wood discolouring fungal effects). Exposure data used in this scenario is derived from exposure studies conducted with amateurs without the use of gloves and presented in TNsG 2002 User Guidance - Version 1. Professionals are very likely to wear gloves, and the exposure is therefore considered an overestimation. The sanding scenario values from the abovementioned studies is further extrapolated from acute settings of one-hour duration to chronic settings for the professional user by assuming that exposure time is six hours.

The active substances are fixed in the outer 1cm layer of a treated wooden post (4 x 4 x 250 cm). The concentration of the active substances (AS) in the wood is calculated as follows:

Application rate product (g/m^2) x AS in product (%) x retention in wood (%) x layer thickness (cm)

And the amount of active substances present in the treated wood will then be:

Volume wooden post (cm^3) x conc. AS in wood (mg/cm^3) / treated volume wooden post (cm^3)

Conc. A.s. in wood

110 g/m^2 x 0.6% propiconazole x 100 % x 1 cm=0.66 g/m^2 equal to 0.066 mg/cm^3

110 g/m^2 x 0.3% IPBC x 100 % x 1 cm =0.33 g/m^2 equal to 0.033 mg/cm^3

Con. A.s. in treated outer 1 cm

4000 cm^3 x 0.066 mg propiconazole/cm^3 / 3008 cm^3 = 0.088 mg/cm^3

4000 cm^3 x 0.033 mg IPBC/cm^3 / 3008 cm^3 = 0.044 mg/cm^3

Dermal exposure is based on the surface area exposed (both hand palms), the percentage of this area that is affected by contamination and a transfer coefficient for painted wood using the following formula:

Conc. AS x exposed surface area (cm^2) x contaminated surface (%) x transfer efficiency (%)

To assess exposure by inhalation it is assumed that the concentration of wood dust would not exceed the occupational exposure limits for dust at the workplace. The Operator Exposure Limit (OEL) of the EU for respirable hardwood dust is used as worst-case. professional uses the task duration is six hours and a wood density of 0.40 g/cm^3 is assumed.

	Parameters	Value
Tier 1	Concentration of a.s. on the surface[1]	Propiconazole: 0.066 mg/cm^2
		IPBC: 0.033 mg/cm^2
	Application rate product	110 g/m^2 (11.0 mg/cm^2)
	Volume wooden post[1]	4000 cm^3
	Surface area of treated wood[1]	4032 cm^2
	Exposed surface area (palms of two hands)[2]	410 cm^2
	Body weight[2]	60 kg

	Percent dislodgeable dried paint[4]	3%
	Wood dust in the air (OEL)[3]	5 mg/m^3
	Event exposure duration[3]	6 hours
	Density of wood dust[5]	0.4 g/cm^3
	Dermal absorption, IPBC	50%
	Dermal absorption, propiconazole[7]	9 %

[1] TNsG Part 3 (2002), p. 50.

[2] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017).

[3] TNsG User Guidance, Part 2, version 1 (2002) -General dust/m^3 of sanded treated wood (8-hour TWA).

[4] TNsG User Guidance version 1 General dust/m^3 of sanded treated wood (8 hour TWA) (2002).

[4] Biocides Human Health Exposure Methodology 2015, p. 171.

[5] Technical Agreements for Biocides (TAB) -TOX v.2.0 (November 2018).

Calculations for Scenario 2.1, 2.2.1, 2.2.2, 2.2.3, 2.3.1, 2.3.2, 2.3.3, and 2.3.4

Summary table: estimated systemic exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg)	**Estimated dermal uptake** (mg)	**Estimated oral uptake** (mg)	**Estimated total systemic uptake** (mg/kg bw/d)
Propiconazole					
2.1 Semi-automated transfer	1	Negligible	0.1134	Not relevant	0.00189
	2/Gloves	Negligible	0.01134	Not relevant	0.000189
2.2.1 Manual dipping	1/Gloves	0.004	5.1332	Not relevant	0.08555
	2/Gloves, coated coveralls	0.004	1.0962	Not relevant	0.01827
2.2.2 Spray application	1	0.760	33.2640	Not relevant	0.56707
	2/Gloves, coated coveralls	0.760	2.0160	Not relevant	0.04627
	3/Gloves, impermeable coveralls	0.760	1.2701	Not relevant	0.003383
	4/Gloves, impermeable coveralls, RPE	0.076	1.2701	Not relevant	0.02243

2.2.3 Brush application	1	0.03	2.191	Not relevant	0.03705
	2/Gloves, coated coveralls	0.03	0.219	Not relevant	0.00419
2.3.1 Cleaning dipping tank	1/See 2.1, 1	Negligible	0.1134	Not relevant	0.00189
	2/See 2.1, 2	Negligible	0.01134	Not relevant	0.000189
2.3.2 Cleaning spray equipment	1	Negligible	0.92865	Not relevant	0.01548
	2/Gloves, coated coveralls	Negligible	0.09287	Not relevant	0.00155
	3/Gloves, impermeable coveralls	Negligible	0.07663	Not relevant	0.001277
2.3.3 Cleaning brush	1	Negligible	0.1088	Not relevant	0.0018
	2/Gloves	Negligible	0.0109	Not relevant	0.0002
2.3.4 Cutting and sanding wood	1	0.0083	0.11365	Not relevant	0.00203
IPBC					
2.1 Semi-automated transfer	1	Negligible	0.2025	Not relevant	0.003375
	2/Gloves	Negligible	0.02025	Not relevant	0.0003375
2.2.1 Manual dipping	1/Gloves	0.002	9.1665	Not relevant	0.15278
	2/Gloves, coveralls	0.002	1.9575	Not relevant	0.03263
2.2.2 Spray application	1	0.380	59.4	Not relevant	0.99633
	2/Gloves, coated coveralls	0.380	3.6	Not relevant	0.06633
	3/Gloves, impermeable coveralls	0.380	2.268	Not relevant	0.04413
	4/Gloves, impermeable coveralls, RPE	0.038	2.268	Not relevant	0.0384
2.2.3 Brush application	1	0.02	3.77	Not relevant	0.06186
	2/Gloves, coated coveralls	0.02	0.37	Not relevant	0.00641
2.3.1 Cleaning dipping tank	1/See 2.1, 1	Negligible	0.2025	Not relevant	0.003375
	2/See 2.1, 2	Negligible	0.02025	Not relevant	0.0003375

2.3.2 Cleaning spray equipment	1	Negligible	1.6583	Not relevant	0.027638
	2/Gloves, coated coveralls	Negligible	0.1658	Not relevant	0.002764
	3/Gloves, impermeable coveralls	Negligible	0.13686	Not relevant	0.002281
2.3.3 Cleaning brush	1	Negligible	0.1978	Not relevant	0.0033
	2/Gloves	Negligible	0.0198	Not relevant	0.0003
2.3.4 Cutting and sanding wood	1	0.0041	0.203	Not relevant	0.0035

Combined scenarios

A professional may be exposed to several of the scenarios listed above for long-term exposure. Combined exposure can be expected to occur via loading of product for use in manual dipping or loading the painting pot for brush treatment, the application task, and cleaning of brush. Spray application combined with cleaning of spray equipment is also considered relevant for long-term exposure. Combined exposure of loading and refilling/emptying dipping vessels is not expected as both exercises are performed infrequently. In addition, cutting and sanding of wood is likewise relevant following all application methods. Professionals may launder their work clothes,; please refer to scenario 4.1 in the section 'General public' for description and calculations. This exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term. Point 'TOX 37' for PT8 of the Technical Agreements for Biocides (TAB) – TOX v.2.0 (of 09.11.2018) states: "*exposure during the application and post-application tasks should be assessed but not combined in those cases where the post-application scenario is not a long-term scenario"*. Consequently, Although the task may be a longer-term activity, the fact that it is not performed on a daily basis means that this scenario is not included in the combined exposure scenarios for comparison with the $AEL_{long\text{-}term}$, however the additional exposure for a professional laundering their work clothes is considered in relation to acute exposure in the Risk Characterisation. Chronic exposure of professionals via inhalation of volatilised residues at home has not been included in the combined scenarios for professionals due to the limited extent of the exposure (0.69% of the $AEL_{long\text{-}term}$ for IPBC and 0.05% of the $AEL_{long\text{-}term}$ for propiconazole); please refer to scenario 4.5.

The combinations of scenarios have been divided to only include tier 1 or tier 2 protective measures (when feasible). Note, that scenario 2.2.1 Manual dipping and scenario 2.2.2 Spray application have not been combined for tier 1, as there were considerable risks in tier 1 for both scenarios and they were not further assessed, please refer to the risk characterisation for details. For spray application, tier 2, tier 3 and tier 4 have been combined with tier 2, and tier 3 for cleaning of spray equipment. A tier 4 for cleaning of spray equipment is not considered relevant, as the tier 4 for spray application is the addition of RPE, and exposure via inhalation is negligible when cleaning equipment.

Summary table: combined systemic exposure from professional uses

Scenarios combined (tier)	Tier	Estimated inhalation uptake (mg)	Estimated dermal uptake (mg)	Estimated oral uptake (mg)	Estimated total uptake (mg)	Estimated total dose (mg/kg bw)
Propiconazole						
Semi automated transfer + manual dipping + sanding 2.1+2.2.1+2.3.4	2/Gloves*	0.01204	1.22119	Not relevant	1.233324	0.02055
Semi-automated transfer + brushing + cleaning the brush + sanding 2.1+2.2.3+2.3.3+2.3.4	1/No PPE	0.0404	2.52677	Not relevant	2.56717	0.04279
	2/Gloves**	0.0404	0.4.37391	Not relevant	0.39536	0.00659
Spray application + cleaning spray equip. + sanding 2.2.2+2.3.2+2.3.4	2/Gloves***, coated coveralls	0.7683	2.2225	Not relevant	2.9908	0.04985
	3/Gloves***, impermeable coveralls	0.7683	1.46036	Not relevant	2.22867	0.03714
	4/Gloves***, impermeable coveralls, RPE	0.0843	1.46036	Not relevant	1.54466	0.02574
IPBC						
Semi-automated transfer + manual dipping + sanding 2.1+2.2.1+2.3.4	2/Gloves*	0.0060	2.1807	Not relevant	2.18672	0.03645
Semi-automated transfer + brushing + cleaning the brush + sanding 2.1+2.2.3+2.3.3+2.3.4	1/No PPE	0.0193	4.3000	Not relevant	4.3193	0.07199
	2/Gloves**	0.01931	0.61265	Not relevant	0.63197	0.01053
Spray application + cleaning spray equip. + sanding 2.2.2+2.3.2+2.3.4	2/Gloves***, coated coveralls	0.38415	3.9688	Not relevant	4.3529	0.07255
	3/Gloves***, impermeable coveralls	0.38415	2.6078	Not relevant	2.9919	0.04987
	4/Gloves***, impermeable coveralls, RPE	0.04215	2.60779	Not relevant	2.64994	0.04417

* Gloves worn when loading the product and dipping wooden items; no gloves worn during sanding.

** Gloves worn when loading product, brushing and washing the brush; no gloves are worn when sanding.

*** Gloves worn during spray application (including loading) and cleaning the spray equipment; no gloves are worn when sanding.

Non-professional exposure

TEKNOL AQUA 1411-01 is not for use by non-professional users, but they are subject to secondary exposure.

Scenario 3.1. Sawing and sanding surface-treated wood by the non-professional user

Description of Scenario 3.1		
Cutting and sanding treated wood by the non-professional user (from the general public) is considered an acute exposure scenario as non-professionals are not likely to perform this task frequently. The highest end retention is the application rate of 110 g product/m^2 (the effective volume for prevention of wood discolouring fungal effects). This value is considered worst case for this scenario. Exposure data used in this scenario is derived from exposure studies conducted with amateurs without the use of gloves and presented in TNsG 2002 User Guidance -Version 1. Exposure duration is one hour. The active substances are fixed in the outer 1cm layer of a treated wooden post (4 x 4 x 250 cm). The concentration of the active substances (AS) in the wood is calculated as follows: *Application rate product (g/m^2) x AS in product (%) x retention in wood (%) x layer thickness (cm)* And the amount of active substances present in the treated wood will then be: *Volume wooden post (cm^3) x conc. AS in wood (mg/cm^3) / treated volume wooden post (cm^3)* Dermal exposure is based on the surface area exposed (both hand palms), the percentage of this area that is affected by contamination and a transfer coefficient for rough-sawn wood, using the following formula: *Conc. AS x exposed surface area (cm^2) x contaminated surface (%) x transfer efficiency (%)* To assess exposure by inhalation it is assumed that the concentration of wood dust would not exceed the occupational exposure limits for dust at the workplace. The Operator Exposure Limit (OEL) of the EU for respirable hardwood dust is used as worst-case. For non-professional uses the task duration is one hour and a wood density of 0.40 g/cm^3 is assumed.		
	Parameters	Value
Tier 1	Concentration of a.s. on the surface[1]	Propiconazole: 0.066 mg/cm^2
		IPBC: 0.033 mg/cm^2
	Application rate product	110 g/m^2 (11.0 mg/cm^2)
	Layer thickness (product in wood)[1]	1 cm
	Volume wooden post	4000 cm^3
	Surface volume of treated wood	4032 cm^3

	Exposed surface area (palms of two hands)[2]	410 cm^2
	Surface area of hand contaminated[3]	20% - 82 cm^2
	Body weight[2]	60 kg
	Percent dislodgeable dried paint[4]	3%
	Wood dust in the air (OEL)[3]	5 mg/m^3
	Event exposure duration[3]	One hour
	Density of wood dust[5]	0.4 g/cm^3
	Dermal absorption, IPBC	50 %
	Dermal absorption, propiconazole	9 %

[1] Calculated for Scenario 2.3.4.
[2] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)
[3] TNsG User Guidance version 1 Genereal dust/m^3 of sanded treated wood (8 hour TWA) (2002)
[4] Biocides Human Health Exposure Methodology 2015, p. 171.
[5] Technical Agreements for Biocides (TAB) -TOX v.2.0 (November 2018)

Scenario 3.2. Handling of treated wood by the non-professional user

Description of Scenario 3.2		
Although the product is not intended for use by non-professionals it is possible that a non-professional may handle treated wood if purchasing treated wood items such as windows, doors etc. The wood-preservative is assumed to be completely dry at the time of handling/contact. The number of exposure (handling) cycles has been set to 3. Exposure via inhalation is considered negligible.		
	Parameters	Value
Tier 1	Concentration of a.s. on the surface[1]	Propiconazole: 0.066 mg/cm^2
		IPBC: 0.033 mg/cm^2
	Application rate product	110 g/m^2 (11.0 mg/cm^2)
	Layer thickness (product in wood)[1]	1 cm
	Exposed surface area (palms of two hands)[2]	410 cm^2
	Surface area of hand contaminated[3]	20% - 82 cm^2
	Body weight[2]	60 kg
	Percent dislodgeable dried paint[4]	3%
	Dermal absorption, IPBC	50 %
	Dermal absorption, propiconazole	9 %

[1] Calculated for Scenario 2.3.4.
[2] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017).
3 TNsG User Guidance version 1 Genereal dust/m3 of sanded treated wood (8 hour TWA) (2002).

[4] Biocides Human Health Exposure Methodology 2015, p. 171.

Calculations for Scenario 3.1, 3.2

Summary table: estimated exposure from non-professional uses						
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg)**	**Estimated dermal uptake (mg)**	**Estimated oral uptake (mg)**	**Estimated total uptake (mg)**	**Estimated total dose (mg/kg bw)**
Propiconazole						
3.1 Cutting and sanding wood	1	0.0014	0.1137	Not relevant	0.1137	0.00203
3.2 Handling treated wood	1	Negligible	0.11	Not relevant	0.11	0.00189
IPBC						
3.1 Cutting and sanding wood	1	0.0041	0.2028	Not relevant	0.02038	0.0034
3.2 Handling treated wood	1	Negligible	0.2	Not relevant	0.2	0.0034

Combined scenarios

Non-professional users may be exposed from both cutting, sanding and additionally handling treated dried wood. Chronic exposure of non-professionals via inhalation of volatilised residues at home has not been included in the combined scenario for non-professionals due to the limited extent of the exposure (0.69% of the $AEL_{long\text{-}term}$ for IPBC and 0.05% of the $AEL_{long\text{-}term}$ for propiconazole); please refer to scenario 4.5.

Summary table: combined systemic exposure from non-professional uses						
Scenarios combined (tier)	**Tier**	**Estimated inhalation uptake (mg)**	**Estimated dermal uptake (mg)**	**Estimated oral uptake (mg)**	**Estimated total uptake (mg)**	**Estimated total dose (mg/kg bw)**
Propiconazole						
Sanding and handling 3.1+3.2	1	0.00138	0.2273	Not relevant	0.22869	0.00381
IPBC						
Sanding and handling 3.1+3.2	1	0.0069	0.4059	Not relevant	0.4066	0.0068

Exposure of the general public

Scenario 4.1. Laundering of work clothes

Description of Scenario 4.1

Exposure to TEKNOL AQUA 1411-01 may occur when laundering contaminated work clothing. Persons at risk are adults (professionals and the general public). The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term. Laundering is assumed to occur mechanically. The only likely exposure is during handling of the contaminated clothing while preparing it for laundry. Exposure is restricted to the hands and is dependent on the area and concentration of dislodgeable residues on the surface of the clothing and the transfer coefficient to skin. It is assumed that the clothing to be washed is a coverall worn by a professional, that the coverall is washed after one working week (corresponding to five working days), and that the total residue accumulated during this time is equivalent to 5-times the daily contamination associated with application by either dipping, brushing or spray application following the exposure scenarios 2.2.1, 2.2.2 and 2.2.3. The contamination of the coveralls is based on the type from which the tiers in the aforementioned scenarios show safe use (tier 1 for dipping, tier 1 for brush application and tier 2 for spray application). The mixing and loading step contamination of clothes is considered negligible and is not included for manual dipping and brushing. The sum transfer area is determined by estimating how many times the coverall is touched by the hands while preparing it for laundering. As a first tier, it is assumed that this happens three times, twice with the palms of both hands and once with the total hands surface, the sum transfer area is 1640 cm^2. As a worst-case assumption, 50% of the residues in the touched area is transferred to the skin (transfer coefficient). The scenario is modelled after the CAR for Propiconazole in PT8 (FI CA, 2007).

	Parameter	**Value**
Tier 1	Clothing contamination from manual dipping[1]	Propiconazole: 28.83 mg/day
		IPBC: 14.418 mg/day
	Clothing contamination from brushing[1]	Propiconazole: 4.050 mg/day
		IPBC: 2.070 mg/day
	Clothing contamination from spray application[1]	Propiconazole: 95.9 mg/day
		IPBC: 47.95 mg/day
	Clothing contamination from cleaning spray equipment[1]	Propiconazole: 3.88 mg/day
		IPBC: 1.94 mg/day
	Days before washing	5 days
	Percentage dislodgeable (transfer coefficient)	50%
	Surface of medium coated coverall[2]	22700 cm^2
	Sum transfer area[3]	1640 cm^2

1 Clothing contamination equals the highest potential body exposure (2.2.1, 2.2.2, 2.2.3) minus the amount that penetrates through the clothing (10 % tier 1, 5 % tier 2), and is expressed as mg a.s./day.

2 See the CAR for Propiconazole (FI CA, 2007). Body exposure from scenarios 2.2.1, 2.2.2, and 2.2.3 is assumed to be equally distributed over this area.

3 Based on a surface area of both palms of 410 cm2 and total surface of both hands of 820 cm2; see HEAdhoc Recommendation no. 14 Default human factors values for use in exposure assessment for biocidal products.

Scenario 4.2. Toddler touching freshly treated wood

Description of Scenario 4.2		
Although it is expected that organizational measures are in place when professionals apply wood preservatives, it is possible that a toddler or child may come into contact with wood preservative being applied by professionals, e.g. when applying wood preservatives to public fences etc. Contact with freshly-treated surfaces is assumed to be of short duration, as parents/guardians will remove the product from the toddler's or child's hands as soon as the incident is observed. This scenario is therefore only included in exposure evaluation for consideration of worst-case scenario. Harmonised input values are given in HEAdhoc Recommendation no. 5. It is assumed that 100% of the palms of both hands is exposed. The transfer coefficient (from freshly treated wood to hands) is set to 50%. All of the material on the palms of both hands is considered available for mouthing; the amount ingested is set to 10%, constituting the area of two fingers. The toddler is used as a risk envelope for all relevant child groups; the scenario is not considered relevant for infants.		
	Parameter	**Value**
Tier 1	Concentration of a.s. on the surface[1]	Propiconazole: 0.066 mg/cm^2
		IPBC: 0.033 mg/cm^2
	Toddler hand surface (palm)[2]	115.2 cm^2
	Hand area contaminated[3]	100 %
	Transfer coefficient[3]	50 %
	Transferable fraction to mouth[3]	10 %
	Toddler body weight[2]	10 kg
	Dermal absorption	IPBC: 50%
		Propiconazole: 9%
	Oral absorption[4]	Propiconazole: 100 %
		IPBC: 100 %

[1] Calculated for Scenario 2.3.4.
[2] HEAdhoc Recommendation no. 14- Default human factors values for use in exposure assessment for biocidal products.
[3] HEAdhoc Recommendation no. 5 - Non-professional use of antifouling paints: exposure assessment for a toddler.
[4] CARs for propiconazole (PT7, FI CA, 2015) and IPBC, (PT13 DK CA, 2015).). The CAR for propiconazole states 86% oral absorption within 48 h, however the 'Guidance on the BPR: Volume III Parts B+C' (Version 4.0, December 2017) notes (p. 66) that "…*when the oral absorption rate exceeds 80%, the default value of 100% should be applied for the derivation of AELs and internal exposure levels*."

Scenario 4.3. Infant chewing off-cut of treated wood

Description of Scenario 4.3

Secondary exposure can occur if an infant chews a piece of treated wood. This scenario is considered an acute scenario. In accordance with scenario 2.3.4 and 3.1 for sanding of treated wood, it is assumed that the active substances are bound to the outer 1 cm of the wood and that this part is accessible for infants chewing. It is assumed that an infant chews a 4x4x1cm piece of wood chip and in doing so releases 10% of the active substances according to TNsG User guidance, version 1, 2002. The TnsG further regards the scenario unrealistic for children as opposed to infants, as they are unlikely to chew treated wood. Dermal exposure is not considered.		
	Parameters	Value
Tier 1	Concentration of a.s. substances in treated wood	Propiconazole: 0.088 mg/cm^3
		IPBC: 0.044 mg/cm^3
	Infant body weight [3]	8 kg
	Application rate product	110 g/m^2 (11.0 mg/cm^2)
	Volume off-cut from treated wood [1,2]	16 cm^3
	Oral uptake of a.s. from wood by chewing [1,2]	10%
	Oral absorption[4]	Propiconazole: 100 %
		IPBC: 100 %

[1] TNsG, Part 3 (2002).

[2] TNsG User Guidance version 1 (2002).

[3] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017).

[4] CARs for propiconazole (PT7, FI CA, 2015) and IPBC, (PT13, DK CA, 2015). The CAR for propiconazole states 86% oral absorption within 48 h, however the 'Guidance on the BPR: Volume III Parts B+C' (Version 4.0, December 2017) notes (p. 66) that "…*when the oral absorption rate exceeds 80%, the default value of 100% should be applied for the derivation of AELs and internal exposure levels*."

Scenario 4.4. Playing on playground structure and mouthing

Description of Scenario 4.4
Chronic exposure to infants, toddlers can occur from playing on and mouthing weathered playing structures. Likewise, chronic exposure can occur for children playing on weathered structures. The exposure settings are based on TNsG 2002 User guidance – Version 1 and TNsG 2002, part III and implements that during play on timber structures, infants, toddlers, and children are exposed dermally and orally (via hand-to-mouth transfer route). Dermal exposure is based on the hand surface area exposed, the percentage of this area that is affected by contamination and a transfer coefficient for painted wood, using the following formula: *Conc. AS x exposed surface area (cm^2) x contaminated surface (%) x transfer efficiency (%)* For oral exposure 50% hand-to-mouth transfer is assumed (external dermal exposure = external oral exposure). Only infant exposure has been calculated and is considered to act as a risk envelope for the other age populations.

	Parameters	Value
Tier 1	Concentration of a.s. on treated surface[5]	Propiconazole: 0.066 mg/cm^2
		IPBC: 0.033 mg/cm^2
	Application rate product	110 g/m^2 (11.0 mg/cm^2)
	Body weight, infant[3]	8 kg
	Area of hands- both palms and backs of both hands, infant[3]	196.8 cm^2
	Contamination of hands[1]	20% Infant 39.4 cm^2 Child 85.6 cm^2
	Dislodgeable fraction[2]	3%
	Dermal absorption[4]	IPBC: 50%
		Propiconazole: 9%
	Oral uptake after licking of hands[5]	50 % (of potential dermal exposure)

[1] TNsG User Guidance version 1 (2002)

[2] Biocides Human Health Exposure Methodology 2015, p. 171.

[3] HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)

[4] Biocides Human Health Exposure Methodology 2015, p. 171.

[5] HEAdhoc Recommendation no. 5, Non-professional use of antifouling paints: exposure assessment for a toddler.

Scenario 4.5. Inhalation of volatilised residues

Description of Scenario 4.5
Chronic exposure to wood preservatives may arise from the interior surfaces of exterior window frames and and exterior doors (including their frames) treated with a wood preservative. As a worst case, inhalation exposure was taken as 100% of the saturated vapour pressure/concentration (SVC) according to HEEG opinion 13[1]. SVC = (vp (Pa) x mw (g/mol)) / (8.31 (gas constant, J/mol.K) x T (K)) The calculation is highly conservative and is designed as a screening tool for identifying a risk. Preserved window frames or joists are required to be coated and hence the wood preservative is sealed and cannot evaporate. Furthermore the vapour pressures of IPBC and propiconazole are in general considered to be low (<0.5 kPa). In TNsG 2002[2], a similar exposure model was presented using 1% of SVC for a room of moderate ventilation and considering the arguments above, this is regarded a more realistic scenario for TEKNOL AQUA 1411-01. For details on the exposure calculations please refer to Appendix 3.2.

	Parameters		Value
Tier 1	Vapour pressure	IPBC	4.5 x 10^{-3} Pa (at 20°C)
		Propiconazole	5.6 x 10^{-5} Pa (at 25°C)
	Molecular weight	IPBC	281 g/mol
		Propiconazole	342.2 g/mol
	Adult	Body weight	60 kg
		Inhalation rate	16 m^3/day
	Child	Body weight	23.9 kg
		Inhalation rate	12 m^3/day
	Toddler	Body weight	10 kg
		Inhalation rate	8 m^3/day
	Infant	Body weight	8 kg
		Inhalation rate	5.4 m^3/day

[1]HEEG opinion 13 - Assessment of inhalation exposure of volatilised biocide active substance
[2] TNsG 2002, part 3 p.50

Calculations for Scenario 4.1, 4.2, 4.3, 4.4, 4.5

Summary table: estimated systemic exposure for general public					
Exposure scenario	**Population**	**Estimated inhalation uptake** (mg/kg bw/d)	**Estimated dermal uptake** (mg/kg bw/d)	**Estimated oral uptake** (mg/kg bw/d)	**Estimated total systemic uptake** (mg/kg bw/d)

Propiconazole					
4.1 Laundry Manual dipping	Adult/Coated coveralls	Negligible	0.7292	Not relevant	0.0122
4.1 Laundry Manual spraying	Adult/Impermeable coveralls	Negligible	2.3969	Not relevant	0.0399
4.1 Laundry Brushing	Adult/Coated coveralls	Negligible	0.1024	Not relevant	0.0017
4.2 Toddler touching and mouthing freshly treated wood	Toddler	Negligible	0.532	0.380	0.091
4.3 Infant chewing on wood cut off	Infant	Negligible	Negligible	0.106	0.013
4.4 Infant playing and mouthing on weathered play structures	Infant	Negligible	0.013	0.046	0.0073
4.5 Inhalation of volatilised residues	Adult	0.0012	Not relevant	Not relevant	0.00002
	Child	0.0010	Not relevant	Not relevant	0.00004
	Toddler	0.0006	Not relevant	Not relevant	0.00006
	Infant	0.0004	Not relevant	Not relevant	0.00005
IPBC					
4.1 Laundry Manual dipping	Adult/Coated coveralls	Negligible	1.3021	Not relevant	0.0217
4.1 Laundry Manual spraying	Adult/Impermeable coveralls	Negligible	4.2802	Not relevant	0.0713
4.1 Laundry Brushing	Adult/Coated coveralls	Negligible	0.1869	Not relevant	0.0031
4.2 Toddler touching and mouthing freshly treated wood	Infant	Negligible	0.950	0.190	0.114
4.3 Infant chewing on wood cut off	Infant	Negligible	Negligible	0.0053	0.0066
4.4 Infant playing and mouthing on weathered play structures	Infant	Negligible	0.023	0.023	0.006
4.5 Inhalation of	Adult	0.0828	Not relevant	Not relevant	0.00138

volatilised residues	Child	0.0624	Not relevant	Not relevant	0.00261
	Toddler	0.0415	Not relevant	Not relevant	0.00415
	Infant	0.0281	Not relevant	Not relevant	0.00351

Combined scenarios

The two chronic scenarios, infant playing on a playground structure and inhalation of volatilised residues are relevant for combined exposure and are considered to act as a risk envelope for the other human age groups. The other general public scenarios are incidental; laundering of work clothes may occur on a long-term basis, but as it is not a daily activity (assumed to occur once e week) it has not been combined with inhalation of volatised residues, the only other chronic exposure for adults of the general public.

Summary table: combined systemic exposure for general public					
Scenarios combined	**Estimated inhalation uptake** (mg)	**Estimated dermal uptake** (mg)	**Estimated oral uptake** (mg)	**Estimated total uptake** (mg)	**Estimated total uptake** (mg/kg bw/d)
Propiconazole					
Infant playing and mouthing + inhalation long-term 4.4+4.5	0.00043	0.01277	0.04562	0.05426	0.00735
IPBC					
Infant playing and mouthing + inhalation long-term 4.4+4.5	0.02804	0.02281	0.02281	0.07366	0.00921

Monitoring data

No further information on surveys or studies with the actual biocidal product or with a surrogate were submitted.

Dietary exposure

Exposure to food, drinking water or livestock can be excluded when the product is applied according to the recommended uses. Additionally, the RMM "*Do not apply the product to wood or place treated wood in areas where food/feed, food utensils or food processing surfaces may come into contact with, or be contaminated by the product or treated wood.*" is applied to exclude contact with food and feedstuff.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s)**

Propiconazole			
1.	Plant protection products	MRL range of different crops and products of animal origin Not approved under Plant Protection Products Regulation. Withdrawn 19 June 2019.	0.01 – 9 mg/kg [1]
IPBC			
1.	Cosmetics	Preservative	Daily recommended dose in Europe 150 µg/d (with an upper short term limit of 1000 µg/d) [2]

[1] Commision Regulation EU 2016/452 Amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for captan, propiconazole and spiroxamine in or on certain products (29 March 2016)
[2] SCCNFP/0826/04 Opinion on Iodopropynyl Butylcarbamate (1 July 2004)

Estimating Livestock Exposure to Active Substances used in Biocidal Products
Impregnated wood must not come in contact with food or feedstuffs. The RMM "Do not use on wood that will come in direct contact with food or animal feed" and "Treated wood should not be intended for uses involving contact with food, feed or livestock" should be applied .

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)
Impregnated wood must not come in contact with food or feedstuffs. The RMM "Do not use on wood that will come in direct contact with food or animal feed" and "Treated wood should not be intended for uses involving contact with food, feed or livestock" should be applied .

Estimating transfer of biocidal active substances into foods as a result of non-professional use
TEKNOL AQUA 1411-01 is not intended for non-professional use. The RMM "Do not use on wood that will come in direct contact with food or animal feed" and "Treated wood should not be intended for uses involving contact with food, feed or livestock" should ensure that treated wood is not for use for direct contact to food.

Exposure associated with production, formulation and disposal of the biocidal product
Exposure during the production of the biocidal product should be addressed under other EU legislation (e.g. REACH) and not repeated under Regulation (EU) 528/2012. The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance was not required, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for propiconazole and IPBC which are existing biocidal active substances within the EU.

Aggregated exposure

Summary of exposure assessment

Scenarios and values to be used in risk assessment	

Scenario number	Exposed group (e.g. professionals, non-professionals, bystanders)	Tier/PPE	Estimated total uptake propiconazole (mg/kg bw)	Estimated total uptake IPBC (mg/kg bw)
1.1 Automated transfer	Industrial	1*	Negligible	Negligible
1.2.1 Flow coating	Industrial	1*	0.03667	0.06531
1.2.2 Automated spraying	Industrial	1*	0.03667	0.06531
1.2.3 Automated dipping	Industrial	1*	0.10847	0.19370
	Industrial	2*/Reduction factor	0.02712	0.04843
1.2.4 Manual dipping	Industrial	1/Gloves	0.08555	0.15278
		2/Gloves, coated coveralls	0.01827	0.03263
1.3 Cleaning of dipping tank	Industrial	1*	0.02712	0.04843
2.1 Semi-automated transfer	Professional	1	0.00189	0.003375
	Professional	2/Gloves	0.000189	0.0003375
2.2.1 Manual dipping	Professional	1/Gloves	0.08555	0.15278
	Professional	2/Gloves, coveralls	0.01827	0.03263
2.2.2 Spray application	Professional	1	0.56707	0.99633
	Professional	2/Gloves, coated coveralls	0.04627	0.06633
	Professional	3/Gloves, impermeable coveralls	0.003383	0.04413
	Professional	4/Gloves, impermeable coveralls, RPE	0.02243	0.03843
2.2.3 Brush application	Professional	1	0.03705	0.06186
	Professional	2/Gloves, coated coveralls	0.00419	0.00641
2.3.1 Cleaning dipping tank	Professional	1/See 2.1, 1	0.00189	0.003375
	Professional	2/See 2.1, 2	0.000189	0.0003375
2.3.2 Cleaning spray equipment	Professional	1	0.01548	0.027638
	Professional	2	0.00155	0.002764

	Professional	3	0.001277	0.002281
2.3.3 Cleaning brush	Professional	1	0.0018	0.0033
	Professional	2/Gloves	0.0002	0.0003
2.3.4 Cutting and sanding wood	Professional	1	0.00203	0.0035
3.1 Cutting and sanding wood	Non-professional	1	0.00203	0.0034
3.2 Handling treated wood	Non-professional	1	0.00189	0.0034
4.1 Laundry Manual dipping	General public, adult	1	0.0122	0.0217
4.1 Laundry Manual spraying	General public, adult	2	0.0399	0.0713
4.1 Laundry Manual spraying	General public, adult	3	0.0399	0.0713
4.1 Laundry Brushing	General public, adult	1	0.0017	0.0031
4.2 Touching and mouthing freshly treated wood	General public, toddler	1	0.091	0.114
4.3 Chewing on wood cut off	General public, infant	1	0.013	0.0066
4.4 Playing and mouthing on weathered play structures	General public, infant	1	0.0073	0.0057
4.5 Inhalation of volatilised residues	General public, Adult	1	0.00002	0.00138
	General public, child	1	0.00004	0.00261
	General public, toddler	1	0.00006	0.00415
	General public, infant	1	0.00005	0.00351

Combined scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake propiconazole (mg/kg bw/d)**	**Estimated total uptake IPBC (mg/kg bw/d)**

Automated dipping and cleaning of the dipping tank 1.2.3+1.3	Industrial	2	0.05424	0.097
Semi-automated transfer + manual dipping + sanding 2.1+2.2.1+2.3.4	Professional	2/Gloves, coated coveralls	0.02055	0.03645
Semi-automated transfer + brushing + cleaning the brush + sanding2.1+2.2.3+2.3.3	Professional	1	0.02644	0.07199
	Professional	2/Gloves, coated coveralls	0.00432	0.01053
Spray application + cleaning spray equip. + sanding2.2.2+2.3.2+2.3.4	Professional	2	0.04985	0.07255
	Professional	3	0.03714	0.04987
	Professional	4	0.02574	0.04417
Sanding and handling 3.1+3.2	Non-professional	1	0.00381	0.00678
Infant playing and mouthing + inhalation long-term 4.4+4.5	General public, infant	1	0.00735	0.00921

2.2.6.3 Risk Characterisation for human health

Reference values to be used in Risk Characterisation for IPBC

The data provided in the following table are according to the AR on IPBC (PT13 2015 - DK).

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	90-day gavage rat study	35 mg/kg bw/d	100	No[2]	0.35 mg/kg bw/d
AELmedium-term	2-year rat study	20 mg/kg bw/d	100	No[2]	0.2 mg/kg bw/d
AELlong-term	2-year rat study	20 mg/kg bw/d	100	No[2]	0.2 mg/kg bw/d

[1] Default value of 100 that accounts for inter-species variation (x10) and intra-species variation (x10).

[2] Not required, as the AR states 100% oral absorption.

Reference values to be used in Risk Characterisation for propiconazole

The data provided in the following table are according to the AR on propiconazole (PT7 2015 -FI).

Reference	Study	NOAEL (LOAEL) (mg B/kg bw/day)	AF	Correction for oral absorption	Value (mg B/kg bw/day)
$AEL_{short-term}$	Developmental study rat	30	100	No[2]	0.3
$AEL_{medium-term}$	2-gen rat study	8	100	No[2]	0.08
$AEL_{long-term}$	2 year rat study	3.6	100	No[2]	0.04

[1] Default value of 100 that accounts for inter-species variation (x10) and intra-species variation (x10)

[2] Not required. The CAR for propiconazole (PT7, FA CA, 2015) states 86% oral absorption within 48 h, however the 'Guidance on the BPR: Volume III Parts B+C' (Version 4.0, December 2017) notes (p. 66) that "…*when the oral absorption rate exceeds 80%, the default value of 100% should be applied for the derivation of AELs and internal exposure levels*."

Risk for industrial users

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)
1.1 Fully-automated transfer	1	3.6	0.04	Negligible	-	Yes
1.2.1 Flow coating	1	3.6	0.04	0.03667	91.7	Yes
1.2.2 Automated spraying	1	3.6	0.04	0.03667	91.7	Yes
1.2.3 Automated dipping	1	3.6	0.04	0.10847	271.2	**No**
	2	3.6	0.04	0.02712	67.8	Yes
1.2.4 Manual dipping	1	3.6	0.04	0.08555	213.9	**No**
	2	3.6	0.04	0.01827	45.7	Yes
1.3 Cleaning of dipping tank	1	30	0.3	0.02712	9.0	Yes

Systemic effects IPBC

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)
1.1 Fully	1	20	0.2	Negligible	-	Yes

automated transfer						
1.2.1 Flow coating	1	20	0.2	0.06531	59.0	Yes
1.2.2 Automated spraying	1	20	0.2	0.06531	59.0	Yes
1.2.3 Automated dipping	1	20	0.2	0.19370	96.9	Yes
	2	20	0.2	0.04843	24.2	Yes
1.2.4 Manual dipping	1	20	0.2	0.15278	76.4	Yes
	2	20	0.2	0.03263	16.3	Yes
1.3 Cleaning of dipping tank	1	35	0.35	0.04843	13.8	Yes

Combined scenarios* propiconazole

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Automated dipping and cleaning of the dipping tank 1.2.3+1.3	2	30	0.3	0.05424	18.1	Yes

* This scenario compares the combined exposure from the 2 tasks is performed on the same day to the $AEL_{short\text{-}term}$.

Combined scenarios* IPBC

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Automated dipping and cleaning of the dipping tank 1.2.3+1.3	1	35	0.35	0.097	27.7	Yes

* This scenario compares the combined exposure from the 2 tasks is performed on the same day to the $AEL_{short\text{-}term}$.

Local effects

TEKNOL AQUA 1411-01 is not classified for local effects and a local risk assessment has therefore not been performed.

Conclusion for industrial users

Safe use was identified for all application types when wearing gloves and coated coveralls. A safe use was however only identified for the automated dipping process when completely mechanised. In order to comply with this organisational measure, the RMM "*TEKNOL AQUA 1411-01 is to be only used in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated articles are transported through the dip tank to the draining/ drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured*

(e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until after the treated articles are surface dry" is required for TEKNOL AQUA 1411-01 in order for the user to know the specifications for a safe use. Considering that the industrial scenarios include gloves in tier 1, these will also be required in order to secure a safe use of the product. The RMM "*Application by manual dipping can be performed for a maximum of 30 minutes per day*" is required for manual dipping.

Risk for professional users

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)
2.1 Semi-automated transfer	1	3.6	0.04	0.00189	4.7	Yes
	2	3.6	0.04	0.000189	0.47	Yes
2.2.1 Manual dipping	1	3.6	0.04	0.08555	213.9	**No**
	2	3.6	0.04	0.01827	45.7	Yes
2.2.2 Spray application	1	3.6	0.04	0.56707	1417.7	**No**
	2	3.6	0.04	0.04627	115.7	**No**
	3	3.6	0.04	0.003383	84.6	Yes
	4	3.6	0.04	0.02243	56.1	Yes
2.2.3 Brush application	1	3.6	0.04	0.03705	92.63	Yes
	2	3.6	0.04	0.00419	10.47	Yes
2.3.1 Cleaning dipping tank	1/See 2.1, 1	3.6	0.04	0.00189	4.7	Yes
	2/See 2.1, 2	3.6	0.04	0.000189	0.47	Yes
2.3.2 Cleaning spray equipment	1	3.6	0.04	0.01548	38.7	Yes
	2	3.6	0.04	0.00155	3.9	Yes
	3	3.6	0.04	0.001277	3.2	Yes
2.3.3 Cleaning brush	1	3.6	0.04	0.0018	4.5	Yes
	2	3.6	0.04	0.0002	0.45	Yes
2.3.4 Cutting and sanding wood	1	3.6	0.04	0.00203	5.1	Yes

Systemic effects IPBC

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)
2.1 Semi-automated transfer	1	20	0.2	0.003375	1.7	Yes
	2	20	0.2	0.0003375	0.2	Yes
2.2.1 Manual	1	20	0.2	0.15278	76.39	Yes

dipping	2	20	0.2	0.03263	16.3	Yes
2.2.2 Spray application	1	20	0.2	0.99633	498.2	**No**
	2	20	0.2	0.06633	33.2	Yes
	3	20	0.2	0.04413	22.1	Yes
	4	20	0.2	0.03843	19.2	Yes
2.2.3 Brush application	1	20	0.2	0.06186	30.9	Yes
	2	20	0.2	0.00641	3.2	Yes
2.3.1 Cleaning dipping tank	1/See 2.1, 1	20	0.2	0.003375	1.7	Yes
	2/See 2.1, 2	20	0.2	0.0003375	0.2	Yes
2.3.2 Cleaning spray equipment	1	20	0.2	0.027638	69.1	Yes
	2	20	0.2	0.002764	1.4	Yes
	3	20	0.2	0.002281	1.1	Yes
2.3.3 Cleaning brush	1	20	0.2	0.0033	1.7	Yes
	2	20	0.2	0.0003	0.2	Yes
2.3.4 Cutting and sanding wood	1	20	0.2	0.0035	1.7	Yes

Combined scenarios propiconazole

Scenarios combined	Tier*	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Semi-automated transfer + manual dipping + sanding 2.1+2.2.1+2.3.4	2	3.6	0.04	0.02055	51.4	Yes
Semi-automated transfer + brushing + cleaning the brush + sanding 2.1+2.2.3+2.3.3+ 2.3.4	1	3.6	0.04	0.04279	107	**No**
	2	3.6	0.04	0.00659	16.5	Yes
Spray application + cleaning spray equip. + sanding 2.2.2+2.3.2+2.3.4	2	3.6	0.04	0.04985	124.6	**No**
	3	3.6	0.04	0.03714	92.9	Yes
	4	3.6	0.04	0.02574	64.4	Yes

* Tier is referring to the tier used in the application scenario.

Combined scenarios IPBC

Scenarios combined	Tier*	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Semi-automated transfer + manual dipping + sanding 2.1+2.2.1+2.3.4	2	20	0.2	0.03645	18.2	Yes

Semi-automated transfer + brushing + cleaning the brush + sanding 2.1+2.2.3+2.3.3+ 2.3.4	1	20	0.2	0.07199	36.6	Yes
	2	20	0.2	0.01053	5.3	Yes
Spray application + cleaning spray equip. + sanding 2.2.2+2.3.2+2.3.4	2	20	0.2	0.07255	36.3	Yes
	3	20	0.2	0.04987	24.9	Yes
	4	20	0.2	0.04417	22.1	Yes

As noted in Section 2.2.6.2 Exposure assessment, professionals may launder their work clothes. The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term. The scenario is not included in the combined exposure scenarios for comparison with the $AEL_{long\text{-}term}$, however to evaluate the additional exposure to a professional of laundering work clothes on a work-day, the contribution of the activity has been added to the combined scenario* and the sum value compared to the $AEL_{short\text{-}term}$ (* excluding tiers at which a coverall was not included).

Combined scenarios + laundry propiconazole

Scenarios combined	**Tier***	**Systemic NOAEL mg/kg bw/d**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Semi-automated transfer + manual dipping + sanding+ laundry 2.1+2.2.1+2.3.4+4.1	2	30	0.3	0.02055 + 0.0122 (laundry) = 0.03275	10.9	Yes
Semi-automated transfer + brushing + cleaning the brush + sanding + laundry 2.1+2.2.3+2.3.3+2.3.4+4.1	2	30	0.3	0.00659 + 0.0017 (laundry) = 0.00829	2.8	Yes
Spray application + cleaning spray equip. + sanding+ laundry 2.2.2+2.3.2+2.3.4+4.1	2	30	0.3	0.04985 + 0.0378 (laundry) = 0.08765	29.2	Yes
	3	30	0.3	0.03714 + 0.0399 (laundry) = 0.07704	25.7	Yes
	4	30	0.3	0.02574 + 0.0399 (laundry) = 0.06564	21.9	Yes

*'Tier' refers to the tier used in the application scenario, and the coverall type (and thus degree of contamination) for the tier in question has been considered.

Combined scenarios + laundry IPBC

Scenarios combined	Tier*	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Semi-automated transfer + manual dipping + sanding+ laundry 2.1+2.2.1+2.3.4+4.1	2	35	0.35	0.03645 + 0.0217 (laundry) = 0.05815	16.6	Yes
Semi-automated transfer + brushing + cleaning the brush + sanding + laundry 2.1+2.2.3+2.3.3+2.3.4+4.1	2	35	0.35	0.01053 + 0.0031 (laundry) = 0.01363	3.9	Yes
Spray application + cleaning spray equip. + sanding+ laundry 2.2.2+2.3.2+2.3.4+4.1	2	35	0.35	0.07255 + 0.0676 (laundry) = 0.1402	40.0	Yes
	3	35	0.35	0.04987 + 0.0713 (laundry) = 0.1212	34.6	Yes
	4	35	0.35	0.04417 + 0.0713 (laundry) = 0.1155	33.0	Yes

*'Tier' refers to the tier used in the application scenario, and the coverall type (and thus degree of contamination) for the tier in question has been considered.

Local effects

TEKNOL AQUA 1411-01 is not classified for local effects and a local risk assessment has not been performed.

Conclusion for professional users

Safe use for professional users was identified for all exposure scenarios individually and in combination. For spray application, specific risk mitigation measures are impermeable coveralls and gloves to assure a wide safety margin for propiconazole; RPE is not required for a safe use when looking at exposure to active substances in isolation. When performing manual dipping and brush application, gloves and coated coveralls are required to ensure a safe use.

Risk for non-professional users

Systemic effects propiconazole

Task/ Scenario	Tier	Systemic NOAEL	AEL mg/kg	Estimated uptake	Estimated uptake/	Acceptable (yes/no)

		mg/kg bw/d	bw/d	mg/kg bw/d	AEL (%)	
3.1 Cutting and sanding wood	1	30	0.3	0.00192	0.6	Yes
3.2 Handling treated wood	1	30	0.3	0.00189	0.6	Yes

Systemic effects IPBC

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)
3.1 Cutting and sanding wood	1	35	0.35	0.0034	1	Yes
3.2 Handling treated wood	1	35	0.35	0.0034	1	Yes

Combined scenarios propiconazole

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Sanding and handling 3.1+3.2	1	30	0.3	0.00381	1.3	Yes

Combined scenarios IPBC

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Sanding and handling 3.1+3.2	1	35	0.35	0.00678	1.9	Yes

Local effects

TEKNOL AQUA 1411-01 is not classified for local effects and a local risk assessment has therefore not been performed.

Conclusion for non-professional users

Safe use was identified for the non-professional user, when considering the secondary exposure scenarios in individually and in combination. There is no primary exposure of non-professionals to TEKNOL AQUA 1411-01.

Risk for the general public

Systemic effects propiconazole

Task/ Scenario	Tier	Systemic NOAEL mg/kg	AEL mg/kg bw/d	Estimated uptake mg/kg	Estimated uptake/ AEL	Acceptable (yes/no)

		bw/d		bw/d	(%)	
4.1 Laundry Manual dipping	2	30	0.3	0.0122	4.1	Yes
4.1 Laundry Manual spraying	2	30	0.3	0.0399	13.3	Yes
	3	30	0.3	0.0399	13.3	Yes
4.1 Laundry Brushing	2	30	0.3	0.0017	0.6	Yes
4.2 Toddler touching and mouthing freshly treated wood	1	30	0.3	0.091	30.4	Yes
4.3 Infant chewing on wood cut off	1	30	0.3	0.013	4.4	Yes
4.4 Infant playing and mouthing on weathered play structures	1	3.6	0.04	0.0073	18.2	Yes
4.5 Inhalation of volatilised residues	1	3.6	0.04	0.00002	0.1	Yes
	1	3.6	0.04	0.00004	0.1	Yes
	1	3.6	0.04	0.00006	0.2	Yes
	1	3.6	0.04	0.00005	0.1	Yes

Systemic effects IPBC

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)
4.1 Laundry Manual dipping	2	35	0.35	0.0217	6.2	Yes
4.1 Laundry Manual spraying	2	35	0.35	0.0676	19.3	Yes
	3	35	0.35	0.0713	20.4	Yes
4.1 Laundry Brushing	2	35	0.35	0.0031	0.89	Yes
4.2 Toddler touching and mouthing freshly treated wood	1	35	0.35	0.143	33.0	Yes
4.3 Infant chewing on wood cut off	1	35	0.35	0.0053	1.5	Yes
4.4 Infant playing and mouthing on weathered play structures	1	20	0.2	0.0057	2.9	Yes
4.5 Inhalation of volatilised residues	1	20	0.2	0.00138	0.7	Yes
	1	20	0.2	0.00261	1.3	Yes
	1	20	0.2	0.00415	2.1	Yes
	1	20	0.2	0.00351	1.8	Yes

Combined scenarios propiconazole

Scenarios combined	Tier	Systemic NOAEL mg/kg	AEL mg/kg bw/d	Estimated uptake mg/kg	Estimated uptake/ AEL (%)	Acceptable (yes/no)

		bw/d		**bw/d**		
Infant playing and mouthing + inhalation long-term 4.4+4.5	1	3.6	0.04	0.00735	18.4	Yes

Combined scenarios IPBC

Scenarios combined	**Tier**	**Systemic NOAEL mg/kg bw/d**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Infant playing and mouthing + inhalation long-term 4.4+4.5	1	20	0.2	0.00921	4.6	Yes

Local effects
TEKNOL AQUA 1411-01 is not classified for local effects and a local risk assessment has therefore not been performed.

Conclusion for the general public
Safe use was identified for all populations of the general public considering the exposure scenarios in individually and in combination.

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

The Guidance on Human health risk assessment (ECHA Guidance on BPR: Volume III Part B, Risk Assessment – October 2015) describes a tiered approach for the risk assessment for products containing multiple active substances and/or substances of concern. Although PGME and monoethylene glycol are SoC in TEKNOL AQUA 1411-01, exposure was assessed for the local effect eye irritation for PGME and mucosal irritation for monoethylene glycol and should therefore not be combined with the systemic exposure from the active substances.

In Tier I the risk assessment is performed for each active substance separately, as currently described in above sections.
In this Tier I assessment the HQ is determined: HQ = internal exposure/ AEL, and if HQ<1 the risk is considered acceptable.

Tier II implements the worst-case scenario in combining the exposures for all the active substances in the product. The approach uses assessment of combined exposure to mixture by concentration or dose-addition.

In Tier II the HQ of the individual active substances will be added up resulting in the HI for the mixture/product.

$HI = \sum HQ_{a.s.}$
If HI ≤ 1 the risk related to use of the mixture will be considered acceptable;
If HI > 1 the risk related to use of the mixture will be considered unacceptable and refinement is needed.

When HI > 1, both risk refinement, considering RMM and Tier III could be performed in parallel.

Please refer to the output tables for the individual scenarios. All exposure scenarios except scenario 1.2.1 flow coating have an HI ≤ 1 when considered individually. For the combined exposure, please refer to the table below. For a tier III assessment of scenario 1.2.1, please see below.

TIER II

Hazard index for combined exposure to propiconazole and IPBC						
Scenario number	**Exposed group**	**Tier**	**HQ propiconazole**	**HQ IPBC**	**HI**	**Acceptable**
Fully-automated dipping and cleaning of the dipping tank 1.2.3+ 1.3	Industrial	2	0.181	0.277	0.46	Yes
Semi-automated transfer + manual dipping + sanding 2.1+2.2.1+2.3.4	Professional	2/Gloves, coated coveralls	0.514	0.182	0.7	Yes
Semi-automated transfer + brushing + cleaning the brush + sanding 2.1+2.2.3+2.3.3+2.3.4	Professional	2	0.165	0.053	0.22	Yes
Spray application + cleaning spray equip. + sanding 2.2.2+2.3.2+2.3.4	Professional	3/ Gloves, impermeable coveralls	0.929	0.249	1.18	**No**
	Professional	4/Gloves, impermeable coveralls, RPE	0.644	0.221	0.86	Yes
Sanding and handling 3.1+3.2	Non-professional	1	0.013	0.019	0.03	Yes
Infant playing and mouthing + inhalation long-term 4.4+4.5	General public, infant	1	0.184	0.046	0.23	Yes

As can be seen from above, safe use can be demonstrated for industrial automated dipping, for professional manual dipping, and for professional brushing when wearing gloves and coated coveralls, and for professional spraying when using impermeable coveralls and gloves and the use of respiratory protection equipment (e.g. a half-filtering respiratory protection mask). Additionally, safe use was identified for the non-professional user, and for the general public, when subject to secondary exposure.

TIER III
A HI of 1.24 was identified for the industrial flow coating scenario in tier II (please refer to the excel output tables scenario 1.2.1), and a tier III mixture toxicity assessment is therefore required.

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

If there is no target organ or mode of action in common, the concentration (dose) addition is not confirmed thus, the effects are considered dissimilar. Consequently, independent action is the rule and the risks are, in this case, covered by Tier I of this approach: assessment made substance by substance.

For TEKNOL AQUA 1411-01 the AEL determinations could not be confirmed by the same target organ and or the same mode of action. In the following section an overview of these data is given, which summarizes the effects as described in the respective competent authority reports on the active substances.

IPBC
Efficacy/mode of action: disturb cell membrane permeability and fatty acids metabolism.
The IPBC toxicity profile does not indicate a clear primary target organ. Irritancy effects were seen at the local sites of treatment, in the lungs when inhaled, dermally affected skin or affected stomach in case of diet or gavage studies.
At doses equal to or greater than 30 to 40 mg/kg bw/day, increased absolute and relative liver weights were observed in rats sometimes accompanied by hepatocellular changes (Hepatocyte enlargement):
In a two-year feeding study with rats, an increased incidence in foamy macrophages aggregates was noted in the lungs in males at 40 and 80 mg/kg bw/day.

Propiconazole
Efficacy/ mode of action: propiconazole inhibits the C-14 demethylation step in the ergosterol biosynthesis of fungi.
The liver is the main target organ of propiconazole toxicity. Increased liver weights and slight histopathological changes in the liver were seen already in short term studies.
Propiconazole is a strong inducer of xenobiotic metabolism and a tumour promoter in rodents which probably explains the induction of tumours in male mice. It may be presumed that rodents are more susceptible than humans to the hepatotoxicity of propiconazole.

Target organ/ Mode of Action	**IPBC** NOAEL (AEL)	**Propiconazole** NOAEL (AEL)
Liver (chronic)	35 mg/kg bw/d (0.35 mg/kg bw/d)	10 mg/kg bw/d (0.1 mg/kg bw/d)
Kidney (chronic)	35 mg/kg bw/d (0.35 mg/kg bw/d)	N.A.
Stomach (chronic)	20 mg/kg bw/d (0.2 mg/kg bw/d)	N.A.
Salvery glands (chronic)	20 mg/kg bw/d (0.2 mg/kg bw/d)	N.A.
Adreal glands (chronic)	N.A.	3.6 mg/kg bw/d

		(0.04 mg/kg bw/d)
Iron concentration ↓ (acute)	35 mg/kg bw/d (0.35 mg/kg bw/d)	N.A.
Malformations (acute)	N.A	30 mg/kg bw/d (0.3 mg/kg bw/d)

The derived AEL chronic and or AEL acute are based on different target organs for each active substance, however there are overlaps for liver effects which makes it reasonable to combine the risk values for this target organ.

Target organ/ Mode of Action	**IPBC**	**Propiconazole**	**HI**
Scenario 1.2.1 Flow coating			
Systemic uptake a.s.	0.06531	0.03667	-
HQ Liver (chronic)	0.1866	0.3667	0.553

As can be seen, the combined risk of the mixture toxicity for the common target organ is acceptable.

2.2.7 Risk assessment for animal health

Methodology for exposure to companion animals is lacking. Safe use for human exposure was demonstrated and is considered to cover exposure from treated articles to companion animals.

The product TEKNOL AQUA 1411-01 should be labelled with the RMM "Do not use on wood which may come in direct contact with food, feeding stuff and livestock animals".

2.2.8 Risk assessment for the environment

The biocidal product Teknol Aqua 1411-01 is a water-based wood preservative with 0.6 % propiconazole and 0.3 % IPBC. The product is intended to be used by professionals/industrial by brushing/rolling, spraying, dipping, flow-coating, by vacumat and deluging for wood in use class 2 and 3.
Teknol Aqua 1411-01 should be used with an application rate of 90 – 110 g/m^2 and the use of a top coat is required.

2.2.8.1 Effects assessment on the environment

No additional studies on fate and/or effects of the active substances or the products were provided for the product authorisation. Therefore, the product has been assessed according to the information provided in the CARs for the two active substances. For propiconazole (and 1,2,4-triazole), updated PNEC values are available in the CAR for PT7 and PT9. These will be used, as they represent the newest data. For IPBC, PNEC-values from PT8 has been used (these are confirmed in CARs for other PTs).

PNEC-values for IPBC and propiconazole		
Compartment	**IPBC**	**Propiconazole**
Surface water (ug/L)	0.5	6.8
Soil (mg/kg wwt)	0.005	0.1

STP (mg/L)	0.44	100
Sediment (mg/kg wwt)	Covered by surface water	0.054

In the CAR for propiconazole in PT 7 and 9, two relevant metabolites are determined in the soil. One metabolite is considered to degrade faster than the parent compound, but for the other metabolite, 1,2,4-triazole, it is necessary to conduct an environmental risk assessment.

Two metabolites from IPBC is considered in the environmental risk assessment, i.e. PBC and iodine. For iodine, the background level has to be taken into consideration as the substance is not xenophobic, but is present in the environment as an essential trace element. These values are found in the CAR for iodine.

PNEC-values for relevant metabolites			
Compartment	**1,2,4-triazole**	**PBC**	**Iodine/iodate/iodide**
Surface water (ug/L)	Not relevant*	41.3	0.59 / 58.5 / 0.83
Soil (mg/kg wwt)	0.01	0.169	0.0118 / 0.304 / 0.0043
STP (mg/L)	Not relevant*	IPBC in considered worst case	2.9
Sediment (mg/kg wwt)	Not relevant*	Covered by surface water	Covered by surface water

*1,2,4-triazole is a soil metabolite, and it is thus not relevant to consider risk to any other compartment.

Background levels of iodine	
Compartment	Background level (as iodine)
Soil	Typically 0.5 - 20 mg/kg dw but with extremes up to 98 mg/kg Global mean value of 5 mg/kg
Groundwater	Mean concentration: 1 µg/l Range: < 1-70 µg/l with extremes up to 400 µg/l
Freshwater	0.5 - 20 µg/l

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

Both active substances are classified according to CLP regulation for the environment as follows.
IPBC: Aquatic Acute 1 (M-factor = 10) and Aquatic Chronic 1 (M-factor = 1).
Propiconazole: Aquatic Acute 1 (M-factor = 1) and Aquatic Chronic 1 (M-factor = 1).

With a concentration of 0.6 % propiconazole and 0.3 % IPBC and the classification of co-formulants, the biocidal product is classified according to CLP regulation as Aquatic Chronic 3 (H412).

None of the co-formulants trigger classification of the product for the environment.

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

Emission to the environment can occur from industrial application and storage. According to the ESD for PT8 it can be assumed that most storage places for treated wood are sealed to prevent any release to the soil. Furthermore, release of wood preservatives from the treatment plants to the STP is not permitted anymore. These exposure scenarios are however listed in the ESD and will thus be assessed in the PAR.

Exposure to the environment can also occur from application of the biocidal product in-situ. Furthermore, leaching from the treated wood in use class 3 should be assessed for all environmental compartments. For brushing and rolling, the service life of the treated wood is 5 years and for spraying, flow-coating and dipping the service life is 15 years. Use of the product by a vacumat-treatment has also been applied for. The applicant has explained that this treatment is a surface treatment and not a penetrative treatment as vacuum pressure or double vacuum pressure treatments. Therefore, the service life of wood treated by vacumat is more comparable to that of other industrial surface treatments such as dipping or flow-coating, i.e. 15 years.

Leaching behaviour

Leaching tests were used to derive leaching values for propiconazole and IPBC. Three semi-field leaching studies and two laboratory immersion studies were submitted. Due to information on the product composition, the derivation of leaching rates for Teknol Aqua 1411-01 can be found in the confidential annex to the PAR.

Leaching rate for Teknol Aqua 1411-01			
	30 days (mg/m²/d)	**5 years (mg/m²/d)**	**15 years (mg/m²/d)**
IPBC/PBC	3.6999	0.1808	0.0603
Propiconazole	1.3522	0.1331	0.0543

A comparison of leaching from treated wood with and without the use of a top coat can be found in Annex 3.9 to the PAR.

Assessment of substance(s) of concern

According to the BPR, a substance that meet the criteria for being PBT or vPvB can be considered a substance of concern cf. article 3(1)f.

The substance octamethylcyclotetrasiloxane (D4) (CAS-no.: 556-67-2) is present in a mixture in Teknol Aqua 1411-01 and constitutes 0.000024 % of the biocidal product.

A similar substance, decamethylcyclopentasiloxane (D5) (CAS-no.: 541-02-6) is present in the same mixture in Teknol Aqua 1411-01 and constitutes 0.000054 % of the biocidal product.

Lastly, the substance dodecamethylcyclohexasiloxane (D6) (CAS-no.: 540-97-6) is present in the same mixture in Teknol Aqua 1411-01 and constitutes 0.00008 % of the biocidal product.

The substances are considered SVHCs and are on the candidate list as they meet the criteria for being PBT and vPvB. Therefore, these substances are a SoC in Teknol Aqua 1411-01 relevant for the environment.

According to Annex VI of the BPR an environmental risk assessment should be conducted for substance(s) of concern in the relevant environmental compartment. Furthermore, if a quantitative risk assessment is not possible a semi-quantitative or qualitative assessment can be conducted.

The current guidance (Guidance on BPR, Vol IV, Part B+C) refers to a quantitative risk assessment, i.e. a PEC/PNEC assessment for a substance of concern. However there is no guidance on how to do the risk assessment for a substance with PBT or vPvB properties. rMS DK does not consider that a quantitative risk assessment using the PEC/PNEC quotient is appropriate for an assessment of a substance with PBT or vPvB properties as there is currently no lower threshold for these properties. Therefore, in such a risk assessment the vPvB properties would not be properly addressed and a qualitative risk assessment is more appropriate.

The combined content of D4, D5 and D6 in the biocidal product is 0.000158 %. The density of the product is 1 g/mL and the application rate is 110 g/m^2 resulting in an application rate for D4+D5+D6 of 0.0001738 g/m^2. rMS DK has been in contact with the applicant regarding substitution of these substances out of the biocidal product. They have informed the rMS DK that the content of D4, D5 and D6 is a result of the production process of the silicone emulsion added as defoamer, such that D4, D5 and D6 are residual monomers. The applicant has tested many defoamers and has presently not found an alternative that works well in this product. The applicant continue to focus on the phasing out of SVHC substances and work to substitute whenever possible.
The rMS DK consider that D4, D5 and D6 are substances of concern in TEKNOL AQUA 1411-01, but from the qualitative assessment of the substances, it is determined that since the substances are a result of the production process of the mixture in the biocidal product and due to the low concentration of the substances, it does not results in an unacceptable risk from the use of TEKNOL AQUA 1411-01.

IPBC is considered to be toxic (T) but not persistent (P) or bioaccumulative (B). Due to the classification of propiconazole as Repr. 1B, the substance is considered to meet the T-criterion. Propiconazole furthermore meets the P-criterion and is therefore considered as a candidate for substitution. Please see the comparative assessment in section 2.2.11.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 8
Assessed scenarios	Product application: Scenario 1: industrial process: dipping and storage of wood Scenario 2: industrial process: automated spraying and storage of wood Scenario 3a: in-situ treatment: brushing bridge over pond Scenario 3b: in-situ treatment: brushing house Scenario 4: in-situ treatment: spraying house Life cycle stage: Scenario 5: treated wood in service: house Scenario 6: treated wood in service: bridge over pond

	Scenario 7: treated wood in service: noise barrier
ESD(s) used	Emission Scenario Document for Product Type 8: Revised Emission Scenario Document for Wood Preservatives ENV/JM/MONO(2013)21
Approach	Average consumption
Distribution in the environment	Calculated based on BPR Guidance Volume VI part B+C
Groundwater simulation	Groundwater assessment of 1,2,4-triazole using FOCUS PEARL and a tier 1 assessment of iodine is included. Due to the rapid degradation of IPBC and PBC in the soil, these substances are not expected to be found in the groundwater, cf. CAR for IPBC.
Confidential Annexes	Leaching calculations
Life cycle steps assessed	Production: No Formulation No Use: Yes (scenarios 1-4) Service life: Yes (scenarios 5-7)
Remarks	

Emission estimation

The product is to be used for wood UC2 and UC3. As described in the ESD for PT8, the emission to the environment from wood UC2 is considered negligible, or at least compared to exposure from UC3. The scenarios presented below are applicable for wood UC3.
All PEC calculations are based on the maximum recommended application rates. Given the max. retention rate of 110 g of product/m^2 and concentrations of a.s. in the product formulation, the active substance max. retention rates are 0.66 g a.i. /m^2 for propicanozole and 0.33 g a.i. /m^2 for IPBC.

The application rate of the biocidal product is similar for all application methods.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario:			
Application rate of biocidal product	0.110*	l/m²	Max. retention
Concentration of active substance in the product			
Propiconazole	0.66	g/m²	
IPBC	0.33	g/m²	

*Density of the product is 1 kg/l / 1.0023 g/ml

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway							
		Surface water	Freshwater sediment	STP	Air	Soil	Ground water
Scenario 1	Dipping + storage	Yes	No	Yes	N.R	Yes	N.R.
Scenario 2	Spraying +storage	Yes	No	Yes	NR.	Yes	N.R.
Scenario 3a	Brushing: bridge over pond	Yes	No	No	N.R.	No	No
Scenario 3b	Brushing: House	No	No	No	N.R.	Yes	No
Scenario 4	Spraying: House	No	No	No	N.R.	Yes	No
Scenario 5	In service: House	No	No	No	N.R.	Yes	Yes
Scenario 6	In service: Bridge over pond	Yes	Yes	No	N.R.	No	No
Scenario 7	In service: Noise barrier	(Yes)	(Yes)	Yes	N.R.	(Yes)	(Yes)

N.R.: not relevant
(Yes): covered by another scenario, which is worst case

Input parameters (only set values) for calculating the fate and distribution in the environment for propiconazole			
Input	Unit	Propiconazole	IPBC
Molecular weight	g/mol	342.2	281.1
Vapour pressure (at XC)	Pa (@25°C)	$5.6*10^{-5}$	$2.36\text{-}4.5*10^{-3}$
Water solubility (at X°C)	mg/l (@20°C)	100	168
Log Octanol/water partition coefficient	Log 10 (@25°C)	3.72	2.81
Organic carbon/water partition coefficient (Koc)	L/kg	944	113.25 198.1*
Henry's Law Constant (at 25°C)	Pa/m3/mol	$9.2 *10^{-5}$	$3.38\text{-}6.45*10^{-3}$ @25°C
Biodegradability		Not readily biodegradable	Not readily biodegradable
DT50 in soil	d (@12°C)	82 115.5*	0.196 9.5*
DT50 for biodegradation in surface water(at 12ºC)	d	6.4 (for calculation of PEC_{sw}) 1206 (for calculation of PEC_{sed})	0.129 31.2*
DT50 for hydrolysis in surface water (at 12ºC)	d	Stable	Not relevant under environmental conditions
DT50 for photolysis in surface water	d	Stable	Stable
Distribution in STP		90 % water 10 % sludge	IPBC is completely degraded into PBC in the STP. PBC**: 0.935 % air 96.7 % water 2.41 % sludge

*Value for degradation product (PBC/1,2,4-triazole)
**From DOC IIB of the CAR for IPBC in PT6 (July 2013).

Relevant degradation products
The decomposition of propiconazole in aerobic soil results in the formation of CGA 118245 and 1,2,4-triazole (both occurring in amounts > 10 %). CGA 118245 is degraded in soil faster than propiconazole itself and according to the CAR (PT7) PECs of this compound are not assumed to exceed PECs of propiconazole in soil. Therefore, PEC values of propiconazole in soil is used as the worst case assumption in the risk assessment of CGA 118245.

For the assessment of propiconazole in PT7, the bi-phasic behaviour of 1,2,4-triazole in soils (fast and slow degradation phases), the DT_{50} of 1.68 d for the fast fraction (48.9 %) and 60.5 d for the slow fraction (51.1 %) was discussed. It was decided by the BPC Environmental Working Group that instead of the previous value of 12 d, the DT_{50} of 60.5 d from the slow fraction should be used in PEC soil calculations as a worst-case. For groundwater assessment, a bi-phasic approach including the fast phase as well as the slow phase degradation should be employed according to FOCUS guidance.

The primary degradation of IPBC results in the two metabolites PBC (propargyl butyl carbamate) and iodine. PEC values have been calculated for relevant environmental

compartments. The emissions from iodine has been calculated by applying a molecular weight conversion for relevant environmental compartments. These values are compared to the background levels of iodine. The environmental risk assessment of iodine is found in Annex 3.3.

Calculated PEC values

The predicted environmental concentration (PEC) are calculated using the available guidance documents (Revised Emission Scenario Document for Wood Preservatives (OECD, 2013); Guidance on the BPR: Volume IV Environment, Part B Risk Assessment (active substances) (2017)) and relevant entries in the TAB (Technical Agreements for Biocides).

Scenario 1 - Industrial process: dipping and storage of wood

Scenario 1 includes emission to the STP and subsequent surface water from the industrial application by dipping. From the storage of treated wood, emission can occur to soil and surface water during rainfall events. PEC values from storage of treated wood have been calculated for Time 1 and Time 2, but only the worst-case value is presented below.

Summary table on calculated PEC values – Scenario 1				
		PEC_{STP}	**PEC_{water}**	**PEC_{soil}**
		[ug/L]	[ug/L]	[mg/kg wwt]
Scenario 1 – Dipping application	Propiconazole	17.1	1.77	-
	IPBC	19.8	1.06 (*)	-
Scenario 1 – Storage	Propiconazole	-	0.1 (#)	1.02 (#)
	IPBC	-	$8.34*10^{-2}$ (#)	$6.7*10^{-3}$ (#)

(*)PBC is worst-case compared to IPBC.

(#) including degradation

Scenario 2 – Industrial process: automated spraying and storage of wood

Scenario 2 includes emission to the STP and subsequent surface water from the industrial application by automated spraying. PEC-values have been calculated from small and big plants, but only the worst case is presented. From the storage of treated wood, emission can occur to soil and surface water during rainfall events. PEC values from storage of treated wood have been calculated for Time 1 and Time 2, but only the worst-case value is presented below.

Summary table on calculated PEC values – Scenario 2				
		PEC_{STP}	**PEC_{water}**	**PEC_{soil}**
		[ug/L]	[ug/L]	[mg/kg wwt]
Scenario 1 – Spraying application	Propiconazole	88.6	8.85	-
	IPBC	99.0	5.28 (*)	-

Scenario 1 – Storage	Propiconazole	-	0.113 (#)	1.02 (#)
	IPBC	-	$9.41*10^{-2}$ (#)	$6.7*10^{-3}$ (#)

(#) including degradation

Scenario 3a – 4: in-situ treatments

The bridge scenario represents a worst case emissions to adjacent water from in situ brushing (according to ESD for PT8).

For wood treated in-situ the bridge over pond scenario is calculated to assess the risk to surface water during the application phase. Furthermore, the house scenario is calculated for in-situ brushing as well as spraying. The house scenario is considered worst-case compared to the fence scenario for determining risks to the soil compartment. For in-situ spraying, a tier 1 and tier 2 is calculated as according to the ESD for PT 8. Emission originates either from run-off to soil or by drift. Spray drift depends on height of application, wind speed and droplet size. At tier 1, it is assumed that application is performed at low wind speed. At tier 2, a higher wind speed is taken into account which can lead to drift beyond a zone of 1 m from the house wall.

Summary table on calculated PEC values – Scenarios 3-4			
		PEC_{water}	**PEC_{soil}**
		[ug/L]	[mg/kg wwt]
Scenario 3a – in situ brushing, bridge over pond	Propiconazole	0.198	-
	IPBC	$9.9*10^{-2}$	-
Scenario 3b – in-situ brushing, house	Propiconazole	-	0.112
	IPBC	-	$5.6*10^{-2}$
Scenario 4 - In-situ spraying – house, tier 1	Propiconazole	-	1.12
	IPBC	-	0.56
Scenario 4 - In-situ spraying – house, tier 2	Propiconazole	-	0.123
	IPBC	-	$5.6*10^{-7}$

Scenario 5: in service – house scenario

The risks from treated wood during service life is assessed for the soil compartment by the house scenario. Risks are assessed for time 1 (30 days) and time 2 (5 years and 15 years). According to the ESD for PT8, wood treated by brushing have a service life of 5 years and the remaining application methods intended to be relevant for Teknol Aqua 1411-01 have a service life of 15 years. All application methods are relevant for the house scenario. For refinement of time 1 and 2, the equations 3.11 and 3.12 in the ESD for PT8 has been used.

The risk from treated wood at the "New Time 2", i.e. 365 days should be calculated if there is a risk at time 1 (30 days), cf. agreement at the Environmental Working Group under the BPC. This assessment should not be used for any decision-making.

Summary table on calculated PEC values – Scenario 5		
		PEC_{soil}
		[mg/kg wwt]
Scenario 5 – House, 30 days	Propiconazole	0.203
	IPBC	$5.91*10^{-3}$
Scenario 5 – House, 365 days	Propiconazole	9.97*10-4
	IPBC	0.262
Scenario 5 – House, 5 years	Propiconazole	$8.76*10^{-2}$
	IPBC	$2.84*10^{-4}$
Scenario 5 – House, 15 years	Propiconazole	$3.61*10^{-2}$
	IPBC	$9.58*10^{-5}$

In the soil compartment, the metabolite 1,2,4-triazole from propiconazole needs to be assessed, as described in the CAR for propiconazole in PT7. However, as the substance has a low $logK_{ow}$ and high water solubility, the soil is not expected to be the most sensitive compartment. The worst case scenario for the soil compartment is the house scenario, with 100 % of the propiconazole leached at each time degrading to 1,2,4,-triazole. The calculations take the ratio of molecular weights between 1,2,4-triazole and propiconazole into consideration, i.e. 69.07 g/mol divided by 342.2 g/mol = 0.2 as is the approach in the CAR for propiconazole in PT7. The worst case degradation of 1,2,4-triazole is taken into consideration, i.e. the slow phase as was done in the CAR for propiconazole in PT7. This is a very worst case calculation, as it assumes an instant transformation of propiconazole to 1,2,4-triazole after release to the soil (corrected by molecular weight) and the DT50 of propiconazole in soil is 82 days. For the tier 1 assessment, 100 % transformation is assumed. In the CAR for PT7 a $F_{peak,occurrence}$ of 43.2% is found after 120 days; therefore for refinement in the tier 2 assessment a 43.2% transformation is used.

	Summary table on calculated PEC values – Scenario 5 – 1,2,4-triazole	
	PEC_{soil} – tier 1	**PEC_{soil} – tier 2**
	[mg/kg wwt]	[mg/kg wwt]
Scenario 5 – House, 30 days	$4.20*10^{-2}$	$1.81*10^{-2}$
Scenario 5 – House, 365 days	$7.49*10^{-2}$	$3.24*10^{-2}$
Scenario 5 – House, 5 years	$2.51*10^{-2}$	$1.08*10^{-2}$

Scenario 5 – House, 15 years	$1.02*10^{-2}$	$4.41*10^{-3}$

Scenario 6: in service – bridge over pond scenario

The risks from treated wood during service life is assessed for the surface water compartment by the bridge over pond scenario. Risks are assessed for time 1 (30 days) and time 2 (5 years and 15 years). According to the ESD for PT8, wood treated by brushing have a service life of 5 years and the remaining application methods intended to be relevant for Teknol Aqua 1411-01 have a service life of 15 years. All application methods are relevant for the bridge over pond scenario.

The receiving compartment is surface water and therefore additional and indirect the sediment compartment. However, as stated in the CAR for IPBC and mentioned above, the risk to sediment from IPBC is covered by the surface water. For refinement of time 1 and 2, the equations 3.16 and 3.16 in the ESD for PT8 or EPM has been used.

Summary table on calculated PEC values – Scenario 6			
		PEC_{water}	**$PEC_{sediment}$**
		[ug/L]	[mg/kg wwt]
Scenario 6 – Bridge over pond, 30 days	Propiconazole	$8.79*10^{-2}$	$4.30*10^{-3}$
	IPBC	$6.85*10^{-3}$	Covered by surface water
Scenario 6 – Bridge over pond, 5 years	Propiconazole	$1.20*10^{-2}$	$1.85*10^{-2}$
	IPBC	$4.38*10^{-2}$ (*)	Covered by surface water
Scenario 6 – Bridge over pond, 15 years	Propiconazole	$4.98*10^{-3}$	$1.39*10^{-2}$
	IPBC	$1.49*10^{-2}$ (*)	Covered by surface water

(*)PBC is worst-case compared to IPBC.

The risk assessment for groundwater is found in section 2.2.8.3 below.

Scenario 7: in service – noise barrier scenario

As described in the ESD for PT8 for the noise barrier scenario, only application by dipping or spraying treatment is considered. Therefore, the service life for noise barrier is set at 15 years. As described in the ESD, it is assumed that 70% of the leached substances enters the STP and 30% seeps into adjacent soil. The emissions to STP can lead to exposure to surface water and sediments by discharge of STP effluent to the water compartment. Additionally, application of sewage sludge to agricultural or grassland soil can lead to exposure to soil compartment. Risks to these environmental compartments are however, covered by the worst-case scenario calculated in scenario 5 and 6.

Summary table on calculated PEC values – Scenario 7		
		PEC_{STP}
		[ug/L]
Scenario 7 – Noise barrier, 30 days	Propiconazole	1.27
	IPBC	3.88
Scenario 7 – Noise barrier, 15 years	Propiconazole	$5.10*10^{-2}$
	IPBC	$6.33*10^{-2}$

Primary and secondary poisoning

Primary poisoning

The product is a ready-to-use wood preservative for brushing, spraying and industrial treatments. The risk of primary poisoning is not likely.

Secondary poisoning

According to the Guidance on the BPR, vol IV Part B+C there are several different factors of a substance, which can indicate whether the substance has a potential to bioaccumulate. This includes if a substance has a LogKow ≥ 3.

As described in the CAR of IPBC, the log Kow for this compound is less than 3, therefore secondary poisoning potential is considered to be low.

According to the CAR of propiconazole, the substance has a slight potential for bioaccumulation, i.e. a LogKow of 3.72, but despite this it is stated that an assessment of secondary poisoning is not necessary for propiconazole as a wood preservative.

2.2.8.3 Risk characterisation

Atmosphere

Emissions to air during the application and service life of the treated wood are negligible, as the volitality of both active substances is low and both compounds are not persistent in atmosphere. Concentrations in the air are considered to be negligible.

Conclusion: no risk identified for the air compartment.

Sewage treatment plant (STP)

The risk to the STP is calculated from the industrial application of the product by dipping and straying (scenario 1 and 2). Furthermore, the noise barrier scenario leads to emission to STP during the service life. Given the leaching behaviour in time, the emission per day will be largest at the initial assessment period (time 1).

Summary table on calculated PEC/PNEC values – Scenario 1 and 2			
		$PEC/PNEC_{STP}$	**Combined PEC/PNEC**
Scenario 1 – Dipping application	Propiconazole	$1.77*10^{-4}$	$4.52*10^{-2}$
	IPBC	$4.5*10^{-2}$	
Scenario 2 – Spraying application	Propiconazole	$8.86*10^{-4}$	0.226
	IPBC	0.225	

Summary table on calculated PEC/PNEC values – Scenario 7			
		$PEC/PNEC_{STP}$	**Combined PEC/PNEC**
		[ug/L]	
Scenario 7 – Noise barrier, 30 days	Propiconazole	$1.27*10^{-5}$	$8.84*10^{-3}$
	IPBC	$8.83*10^{-3}$	
Scenario 7 – Noise barrier, 15 years	Propiconazole	$5.10*10^{-7}$	$1.45*10^{-4}$
	IPBC	$1.44*10^{-4}$	

Conclusion: No unacceptable risk for micro-organisms in STP at any scenario.

Aquatic compartment

Emissions of Teknol Aqua to the aquatic compartment can occur during the industrial treatment of wood and during the storage of the treated wood when exposed to rainfall, i.e. scenario 1 and 2.

Summary table on calculated PEC/PNEC values – Scenarios 1 + 2			
		$PEC/PNEC_{water}$	**Combined PEC/PNEC**
Scenario 1 – Dipping application	Propiconazole	0.260	0.286
	IPBC	$2.56*10^{-2}$ (*)	
Scenario 1 – Storage	Propiconazole	$1.48*10^{-2}$ (#)	0.182
	IPBC	0.167 (#)	
Scenario 2 – Spraying application	Propiconazole	**1.30**	**1.428**
	IPBC	0.128 (*)	

Scenario 2 – Storage	Propiconazole	$1.67*10^{-2}$ (#)	0.205
	IPBC	0.188 (#)	

(*)PBC is worst-case compared to IPBC.

(#) including degradation

Conclusion: Unacceptable risk to the environmental was identified for the surface water from industrial use. As stated earlier, release to the STP from treating facilities is not permitted in the EU. Thus, the calculations are done for completeness of the risk assessment and the following RMMs will be added:

- 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

Emissions to the aquatic compartment can furthermore occur during the in-situ brushing, which is assessed by the bridge over pond scenario (3a). Leaching from treated wood in service also lead to emission to the water and sediment compartment. Scenario 6, i.e. bridge over pond represents the worst case.

Summary table on calculated PEC/PNEC values						
	$PEC/PNEC_{water}$			**$PEC/PNEC_{sed}$**		
	IPBC/PBC	**Propiconazole**	**Combined PEC/PNEC**	**IPBC/PBC**	**Propiconazole**	**Combined PEC/PNEC**
Scenario 3a – In-situ, bridge over pond	0.198	$2.91*10^{-2}$	0.227	Covered by surface water	-	-
Scenario 6, time 1 – 30 days	$1.37*10^{-2}$	$1.29*10^{-2}$	$2.66*10^{-2}$	Covered by surface water	$7.96*10^{-2}$	$9.33*10^{-2}$
Scenario 6, time 2 – 5 years	$1.06*10^{-3}$	$1.77*10^{-3}$	$2.81*10^{-3}$	Covered by surface water	0.342	0.343
Scenario 6, time 2 – 15 years	$3.60*10^{-4}$	$7.32*10^{-4}$	$1.09*10^{-3}$	Covered by surface water	0.258	0.258

Conclusion: There are no unacceptable risks to the aquatic environment from the in-situ brushing with Teknol Aqua 1411-01 by professionals. Furthermore, there are no unacceptable risks to the aquatic compartment form wood in service treated with Teknol Aqua.

Terrestrial compartment

Emission to the terrestrial compartment can occur from the storage of industrially treated wood, which are subject to rainfall, i.e. scenario 1 and 2.

Summary table on calculated PEC/PNEC values – Scenario 1 and 2			
		PEC/PNEC$_{soil}$	**Combined PEC/PNEC**
Scenario 1 – Dipping - storage	Propiconazole	**10.2**	**11.76**
	IPBC	**1.56**	
Scenario 2 – Spraying - storage	Propiconazole	**10.2**	**11.76**
	IPBC	**1.56**	

Conclusion: Unacceptable risk to the environmental was identified for the surface water from industrial use. As stated earlier, most plants store treated wood to avoid release to the environment. Thus, the calculations are done for completeness of the risk assessment and the following RMMs will be added:

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

Emission to the terrestrial compartment can also occur from the in-situ brushing (scenario 3b) and in-situ spraying (scenario 4) by professionals. During the service life of the treated wood, emission can occur to the terrestrial compartment (scenario 5).

Calculated PEC/PNEC values			
	PEC/PNEC$_{soil}$		
	IPBC/PBC	**Propiconazole**	**Combined PEC/PNEC**
Scenario 3b*	12.9	1.12	**14.02**
Scenario 4, tier 1	129	11.2	**140.2**
Scenario 4, tier 2	$12.9*10^{-4}$	1.23	**1.23**
Scenario 5, time 1 – 30 days	1.36	2.03	**3.39**
Scenario 5, time 2 – 365 days	0.23	2.62	**2.85**
Scenario 5, time 2 – 5 years	$6.55*10^{-2}$	0.876	0.942
Scenario 5, time 3 – 15 years	$2.21*10^{-2}$	0.361	0.383

For the soil compartment, it is necessary to assess the risk from the metabolite 1,2,4-triazole, which was done for tier 1 and tier 2 (100 % transformation and 43.2 % transformation, respectively).

	Summary table on calculated PEC/PNEC values –

	Scenario 5 – 1,2,4-triazole	
	PEC/PNEC – tier 1	**PEC/PNEC – tier 2**
Scenario 5 – House, 30 days	**4.2**	**1.81**
Scenario 5 – House, 365 days	**7.49**	**3.24**
Scenario 5 – House, 5 years	**2.51**	**1.08**
Scenario 5 – House, 15 years	**1.02**	0.441

Conclusion: An unacceptable risk was identified for the in-situ treatment of wood by brushing and spraying by professionals. Therefore, the following RMM will be added:

- During application to timbers and whilst surfaces are drying, do not contaminate soil. All losses of the product have to be contained by covering the soil and disposed of in a safe way.

For outdoor spraying, an unacceptable risk to the soil compartment was identified for tier 2. This means that despite the ground being covered on the first meter from the house, there is a risk to the soil compartment in the soil 1-1.5 meters from the soil. The applicant suggested that the product should not be used in conditions of high wind speed. The rMS DK does not consider this RMM do be realistic as such conditions are not defined and are to be interpreted by the user. Therefore, outdoor spraying with Teknol Aqua 1411-01 will not be authorised.

During the service life of wood treated with Teknol Aqua 1411-01 an unacceptable risk to the environment was identified at time 1. This risk is however reduced to an acceptable level at time 2 for both active substances.

For the metabolite, 1,2,4-triazole an unacceptable risk to the soil compartment was identified for time 1 (30 days) and time 2 (5 years). According to the CAR for propiconazole in PT7 the metabolite 1,2,4-triazole is very mobile in soil and therefore the calculation can be considered conservative. Especially the unacceptable risk for time 2 is expected to be overestimated as the substance would not stay in the soil for 5 years.

Furthermore, the intended use of Teknol Aqua 1411-01 requires a top coat to be applied to the treated wood, and this top coat needs to be maintained throughout the service life of the wood. The calculations of risks to soil does not take into consideration the top coat, and the impact from that on leaching from the treated wood during the service life. For further comparison of risks from the service life of treated wood with and without a top coat, please refer to the annex 3.9 of the PAR. Therefore, the risk to the soil compartment can be expected to be lower due to the use of a top coat and therefore, due to the following instructions for use, the risks can be accepted:

- A non-biocidal topcoat must be applied to treated wood.
- The top coat must be maintained.

Groundwater

In the CAR for propiconazole in PT8, the groundwater concentrations of propiconazole were calculated using FOCUS-PEARL 3.3.3 simulation in nine different FOCUS scenarios with the worst-case assumption of 35 houses of treated wood per hectare. The assessment was done with a propiconazole release of 1000 mg/m2 treated wood over a period of 5 years. None of these concentrations exceeded the maximum permissible concentration of 0.1 µg/l given for groundwater in the 80th percentile for 1 meter soil depth. The maximum estimated concentration of propiconazole leached over 5 years from Teknol Aqua 1411-01 was 275.47 mg/m^2 and for 15 years the maximum amount leached was 336.83 mg/m^2. Therefore, the groundwater assessment conducted in the CAR for propiconazole in PT8 covers the use of Teknol Aqua 1411-01, and concentrations of propiconazole in the groundwater is expected to be below 0.1 ug/L.

In the CAR for propiconazole in PT7, a groundwater assessment for the main degradation product in soil (1,2,4-triazole) was conducted. The input values used are however not comparable to that of Teknol Aqua. As a results, a risk assessment for the groundwater has been made using the worst case leaching over 5 years, i.e. 243 mg/m^2 and a leaching rate of 0.1331 mg/m^2/d.

The following assumptions were made for all nine FOCUS scenarios:

1. The housing density is 16 houses per hectare with each house having treated area of 125 m², which results in the total area of 2000 m² treated wood per hectare
2. Compounds enter the soil compartment in 10 equally spaced events per year to simulate the leaching, application scheme is taken as proposed by appendix 4 of the ESD PT8 (2013).

It should be noted that for 1,2,4-triazole two DT50 values for soil are taken into account. In the trilateral discussions on CA report of propiconazole in PT7 it was raised that a PPPD review on propiconazole in January 2014 indicates DT50 of relevant metabolite in soil (1,2,4-triazole) should be 60.5 days at 20 °C.
Due to the metabolite's bi-phasic behaviour in soils (fast and slow degradation phases) the DT50 is 1.68 d for the fast fraction (48.9%) and 60.5 days for the slow fraction (51.1%). The Environmental Working Group under the BPC decided that instead of the previous value of 12 days, DT50 of 60.5 days from the slow fraction should be used in PEC soil calculations as worst case. 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. Both degradations were considered for calculations, and the worst-case is presented in the table below, i.e. a DT50 of 60.5 days.

Ground water risk assessment of 1,2,4-triazole from FOCUS	
Scenario	**1,2,4-triazole (µg/L)**
Chateaudun	0.003826
Hamburg	0.009761
Jokionen	0.00231
Kremsmuenster	0.004981
Okehampton	0.008954
Piacenza	0.010814
Porto	0.006343
Sevilla	0.00101
Thiva	0.002494

All scenarios result in a groundwater concentration of 1,2,4-triazole below the drinking

water limit of 0.1 µg/L. Therefore, no unacceptable risk to the groundwater has been identified following the use of Teknol Aqua 1411-01.

Primary and secondary poisoning

Primary poisoning

Not relevant

Secondary poisoning

Not relevant

Conclusion: No unacceptable risk for secondary poisoning based on the properties of active substances.

Mixture toxicity

The overall risk was determined by combining risk levels of both active substances. The combined PEC/PNECs have been calculated for each environmental compartment, see above.

Aggregated exposure (combined for relevant emission sources)

No overlap in time and space of this product is expected and therefore, no additional aggregated exposure is calculated.

2.2.9 Measures to protect man, animals and the environment

See conclusions made in 3.2.8.3 and section 11 of IUCLID dossier

2.2.10 Assessment of a combination of biocidal products

No combined use foreseen

2.2.11 Comparative assessment

Comparative assessment of TEKNOL AQUA 1411-01 on the Danish Market
According to the most recent scientific information available, the active substance in the biocidal product TEKNOL AQUA 1411-01, propiconazole, is considered a candidate for exclusion according to the criteria in Article 10(1) of EU Regulation 528/2012 due to its classification of Repro 1B. Propiconazole has not yet been evaluated as an active substance with this assigned classification and is therefore considered a candidate for substitution, until the renewal process of propiconazole is finalized and the legal consequences here apply.
Under Article 23(1) of Regulation 528/2012, Member States evaluating biocidal products containing an active substance that is a candidate for substitution in accordance with article 10(1) or article 5(1) are required to perform a comparative assessment.

The DK CA has used the approach in the most recent EU guidance[8] on the comparative assessment of TEKNOL AQUA 1411-01.

Intended use of the biocidal product and properties of active substances
Article 23(3) and the *CA Technical Guidance Note on Comparative Assessment of Biocidal Products* notes that the comparative assessment should address the uses specified in the application of the biocidal product, as the requirement for a comparative assessment is product specific.

Intended use of the biocidal product

Table 6. Use # 1 – Industrial and professional application of wood preservative	
Product Type	PT8 – Wood preservative
Where relevant, an exact description of the authorised use	TEKNOL AQUA 1411-01 is an aqueous ready to use wood preservative for wood Use Class 2 and 3. The product protects the wood surface against wood destroying fungi and wood discolouring fungi.
Target organism (including development stage)	Wood destroying fungi Wood discolouring fungi
Field of use	Outdoor
Application method(s)	Industrial: Flowcoating/deluging, automated spraying, manual/automated dipping, vacumat, brush machine, low pressure deluging Professional: Manual dipping, brush/roller/pad treatment
Application rate(s) and frequency	90 g/m2 against wood destroying fungi (Soft wood) 100 g/m2 against wood destroying fungi (hard wood) 110 g/m2 against wood discolouring fungi.
Category(ies) of users	Industrial, professional
Pack sizes and packaging material	Can/drum or IBC up to 1000 L for industrial use. Can/drum for up to 25 L for professional use.

Mapping of existing alternatives to the relevant BP

According to the information available to the DK CA, there are 16 biocidal products authorized under product type 8 (wood preservatives) of the Biocidal Products Directive and the Biocidal Products Regulations (including Mutual Recognitions and same product authorizations) in Denmark (2020-05-15) for preventative treatment of wood destroying fungi in use class 2 and 3.

1. Screening phase

1.1 Description of the assessment of the adequate chemical diversity in authorized BPs to minimize the occurrence of resistance and conclusion

Article 23 (3) (b) BPR refers to the adequate chemical diversity of the available active substances within a given product type/use/target organism combination as one of the two sine qua non conditions to be met in order to allow a restriction or prohibition of a biocidal product subject to comparative assessment. During the screening phase it shall

[8] Notes for guidance: Comparative assessment of biocidal products - CA May15-Doc.4.3.a - Final

be checked whether the diversity of the active substance, product type and mode of action combination in authorized biocidal products is adequate to minimize the occurrence of resistance in the target organisms. The screening phase shall allow through a simple assessment to judge whether it is required or not to perform a comprehensive comparative assessment. As a general rule, at least three different and independent active substance/mode of action - combinations should be available through authorized products.
Based on the 16 biocidal products authorized in product type 8 for preventative treatment of wood destroying fungi, the label claims refer to three active substances for which efficacy has been demonstrated against wood destroying fungi (full efficacy claim). These three are propiconazole, tebuconazole and IPBC. Of the 16 biocidal products, one is only authorized for use as pressure impregnation and therefore not readily comparable to the uses applied for TEKNOL AQUA 1411-01. Of the remaining 15 biocidal products authorized for use as preventative treatment for wood destroying fungi, 12 of these contain propiconazole. Of the remaining three, two contain IPBC, and one contain tebuconazole for the preventative treatment of wood destroying fungi. Of the two products containing IPBC, these are only authorized for professional use, and not industrial. Even when not taken into account that the Mode of Action of tebuconazole and propiconazole being similar, only three available active substances are available for preventative treatment of wood destroying fungi, when including propiconazole.

DK CA conclusion on the screening phase of the comparative assessment
DK CA's comparative assessment revealed that several biocidal products for use as wood preservatives containing propiconazole is on the Danish Market. Furthermore, by excluding products containing propiconazole used against wood destroying fungi only two other active substances will be available for this claim on the Danish Market, where one of those have a similar Mode of Action to propiconazole (tebuconazole). Additionally, the other active substance (IPBC) is only authorized in products for professional or private use, and not industrial. Therefore, the conclusion to the screening phase is that adequate chemical diversity to minimise resistance development was not found for both industrial and professional use against wood destroying fungi in use class 2 and 3. Propiconazole is considered to fulfil the exclusion criteria, and the comparative assessment therefore still needs to include a Tier I-B and Tier II according to the CA *Technical Guidance Note on Comparative Assessment of Biocidal Products.*

Tier I-B: Detailed comparison
As, the comparison will only consider tebuconazole and propiconazole.
The classification of Repr. 1B of propiconazole was implemented in the 13th ATP of the CLP (May 2020). The comparison should focus on this area of concern. Tebuconazole has been assigned the classification of Repr. 2 with the same area of concern (offspring), and therefore also fulfils the substitution criteria. IPBC is not considered a candidate for substitution (for any of the criteria). IPBC could therefore based on this simple comparison be considered a safer alternative, but is only authorized for professional and non-professional use, and by excluding the use of products containing propiconazole, only products containing an active substance with a similar Mode of Action and already fulfilling the substitution criteria will be available.
When considering alternatives, also comparison of product containing the same active substance should be taken into consideration. Firstly, the wood preservatives already authorized on the Danish Market have not been assessed including the classification of Repr. 1 for propiconazole. It would be a disadvantage to the applicant of TEKNOL AQUA 1411-01 to not authorize TEKNOL AQUA 1411-01, when several other wood preservatives with the same level of hazard are already authorized. Secondly, amongst those, several have a higher content of propiconazole than that of TEKNOL AQUA 1411-

01. Thirdly, when following the instructions for use and risk mitigation measures outlined in the SPC of TEKNOL AQUA 1411-01, no true risk to human health is evident. The classification of Repr. 1B is directed at effects on offspring when exposed as pregnant. The use of TEKNOL AQUA 1411-01 is only authorized for use industrially and professionally, and only with personal protective equipment assuring a safe level of exposure.

Tier II: Comparison to non-chemical alternatives
The Danich Competent Authority is not aware of any available non-chemical alternatives. Such information may become available through a public consultation, which will be carried out by ECHA regarding the renewal of propiconazole as an active substance for product type 8, according to Article 10(3) in Regulation (EU) No 528/2012.

Overall conclusion
When taking into consideration the use of TEKNOL AQUA 1411-01 is for industrial and professional use, no true better alternatives exist for use in industrial fields of use, and TEKNOL AQUA 1411-01 should therefore not be rejected based on the comparative assessment.

3 Annexes[9]

3.1 List of studies for the biocidal product

3.2 Output tables from exposure assessment tools

Human health exposure

TEKNOL AQUA
1411-01 HHRA Outp

3.3 Environmental risk assessment of iodine

The degradation of IPBC yields the primary degradation product PBC as well as iodine. In the assessment report for IPBC in PT8 the risk assessment of iodine was left out, as iodine was evaluated by SE as an active substance for disinfection. At the TM II, 2012 it was agreed to include iodine in the future evaluations in PT8 and base the calculations on the CAR for iodine.

Background concentrations of iodine

Iodine is not a xenophobic substance but is an essential dietary trace nutrient that is present ubiquitously in the environment. Therefore, background levels of iodine have to be taken into consideration.

Iodine has a natural cycle in the environment. It can be present in different forms; the form of iodine is largely dependent on redox potential and pH. Iodide and iodate are the dominant iodine species in soil and surface water. The background values (as iodine) are presented the table below.

Environmental background levels of iodine	
Environmental compartment	**Background level as iodine**
Soil	Typically 0.5 - 20 mg/kg dwt but with extremes up to 98 mg/kg Global mean value of 5 mg/kg
Groundwater	Mean concentration: 1 µg/l Range: < 1-70 µg/l with extremes up to 400 µg/l
Freshwater (rivers and lakes)	0.5 - 20 µg/l
Marine water	45 - 60 µg/L
Rainwater	0.1-15 µg/l
Freshwater sediment	Typically: 6 mg/kg
Marine sediment	Typically: 3-400 mg/kg
Air	Atmosphere: 10-20 ng/m3 Atmospheric concentration: over land 2-14 ng/m3; over

[9] When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

	ocean 17-52 ng/m3 Marine air contains: 100 µg/l (may refer to local inhalable air)

The PNEC values used for the environmental risk characterisation are from the CAR for iodine.

PNEC values for iodine species			
	Iodine (I_2)	**Iodide (I^-)**	**Iodate (IO_3^-)**
Soil (mg iodine/kg wwt)	0.0118	0.0043	0.304
STP (µg iodine/L)	2900	-	-
Water (µg iodine/L)	0.59	0.83	58.5
Sediment (mg/kg wwt)	Covered by surface water		

PEC calculations

The PEC calculations follow the available guidance documents (Revised Emission Scenario Document for Wood Preservatives (OECD, 2013); Vol IV, Part B). For the iodine risk assessment only the worst case scenarios (highest IPBC output values) for each relevant compartment has been taken into consideration.

In the assessment of iodine released from IPBC, a 100 % formation of iodide and iodate should be considered, which is worst case as the formation of iodine species is expected to be lower. However, for calculating the concentration in soil it is assumed that the total iodine concentration in soil is transformed into 14 % iodide and 100 % iodate (CAR for IPBC, PT6 (2013) and agreed to use for PT8 products at TM II 2012).

If 100 % transformation of IPBC is assumed the molar fraction of PBC produced is 0.552 and for iodine (I2) it is 0.451 (2 moles of IPBC to form one mole of I2). Further, it is assumed that all iodine is transformed either to iodide or iodate. As one mole of iodine (I2) form two moles of iodide (I-) the molar fraction between iodine and iodide is 1, whereas for iodate (IO3-) the molar fraction is 1.38.

Risk assessment for sewage treatment plant

In the CAR for IPBC (PT8), the influent concentration of IPBC is considered to be relevant in order to assess the predicted environmental concentrations in the sewage treatment plant. For further modelling, it is assumed that all of the IPBC in the STP is transformed to iodine species. Hence, the STP risk assessment is based on IPBC influent concentration with no removal/degradation or translocation processes.

The PEC_{STP} value for iodine is calculated based on the worst case PEC_{STP} for IPBC. For iodine only 80 % of the emission is discharged to the surface water, as 20 % of the influent concentration is adsorbed to the sewage sludge (CAR for iodine, 2013).

Therefore, the PEC_{STP} for iodine is calculated according to the following:

$$PEC_{STP} = PEC_{STP,IPBC} * 0.451 * 80\%$$

For the worst case (PEC_{STP}, IPBC = 99.0 µg/L) from the industrial spraying application scenario, this result in the $PEC_{STP,\ iodine}$ of 35.72 µg/L.

This results in the PEC/PNEC of:

$$\frac{35.72 \mu g/L}{2900 \mu g/L} = 1.23 * 10^{-2}$$

Therefore, no unacceptable risk to the STP is identified.

Risk assessment for surface water

For risk assessment of iodine in the surface water, the bridge over pond scenario was chosen as a worst case as it represents an intake into a static water body. Iodine as an inorganic compound is not biodegradable, thus it was assumed that the whole IPBC emissions might accumulate during the service life of the wood. For IPBC this results in a concentration of 1.110 µg/L after 5 years not taking degradation into consideration. Using mole weight transformation this results in a PEC of 0.501 µg/L.
PEC values and PEC/PNEC calculations for all iodine species in the surface water is presented in the table below.

PEC-values and PEC/PNEC calculations for iodine species in surface water		
	PEC_{water} (ug/L)	$PEC/PNEC_{water}$
Iodine (I_2)	0.501	0.839
Iodide(I^-)	0.501	0.604
Iodate (IO_3^-)	0.691	0.012

No uacceptable risk to surface water was identified for any of the iodine species.

Risk assessment for the soil compartment
For risk assessment of iodine in the soil compartment, the house scenario was chosen as a worst case as it represents an intake into the soil. Iodine as an inorganic compound is not biodegradable, thus it was assumed that the whole IPBC emissions might accumulate during the service life of the wood. For IPBC this results in a concentration of 0.630 mg/kg wwt after 5 years not taking degradation into consideration. Using mole weight transformation this results in a PEC of 0.284 mg/kg wwt.
As for the water compartment, iodine may undergo different hydrolytical, photolytical and microbial transformation processes (i.e. speciation) in the soil. The presence of different forms of iodine is largely dependent on redox potential and pH of the surrounding environment. In soil, the prevalent iodine forms are iodide (I-) and iodate (IO3-). As a worst case it is assumed that all iodine will be transformed to iodate, while the total iodine concentration in soil is transformed into 14 % iodide (according to the CAR for iodine and agreed at TMII 2012). The risk assessment therefore covers formation of 100 % iodine, 14 % iodide and 100 % iodate.
PEC values and PEC/PNEC calculations for all iodine species in the soil is presented in the table below.

PEC-values and PEC/PNEC calculations for iodine species in surface water		
	PEC_{soil} (mg/kg wwt)	$PEC/PNEC_{soil}$
Iodine (I_2)	0.283	**24.020**
Iodide(I^-)	0.283	**65.912**
Iodate (IO_3^-)	0.391	**1.285**

An unacceptable risk is identified for the soil compartment, however, the calculated iodine concentration was 0.283 mg/kg wwt (corresponding to 0.7125 mg/kg dwt), which is within the reported background levels of iodine in the environment (0.5-20 mg/kg dwt).

Risk assessment for the sediment compartment
In the CAR (2008) for IPBC the reported PNEC for the sediment was derived using the equilibrium method. Therefore, the risk for the sediment compartment is the same as

that assessed for the surface water. Therefore, the calculation of PECsediment is not necessary.

Risk assessment for the air compartment

Exposure to air is not considered relevant, as iodine speciate into non-volatile iodide and iodate in the different compartments.

Risk to groundwater

The environmental fate and behaviour of IPBC and PBC indicate that the substance is not expected to migrate to groundwater during outdoor service life of treated wood since it is rapidly degraded in soil. However, iodine might reach the groundwater, and thus, an assessment is necessary. IPBC is transformed to PBC (100%), and the total iodine content in soil is transformed to iodide (14 %) and to iodate (100%).

The release of IPBC from treated wood over a service life of 5 years is 329.96 mg/m2 (result from the house scenario). The worst case PEC_{soil} for IPBC at the longer assessment period was $2.84*10^{-4}$ mg/kg wwt. Calculating the $PEC_{local\ soil,porewater}$ according to the Guidance on BPR, Vol IV, Part B+C results in

$$PEC_{local\ soil,porewater} = \frac{PEC_{local,soil} * RHO_{soil}}{k_{soil-water} * 1000}$$

= 0.1342 µg/L

This value is above the drinking water limit of 0.1 µg/L, however, it is still below the background level of iodine in the groundwater. Furthermore, considering the mole weight transformation from IPBC to iodine, the $PEC_{local\ soil,porewater}$ is 0.061 µg iodine/L.

A conservative worst case calculation of the $PEC_{local\ soil,porewater}$ can be based on the PEC_{soil} at time 1, i.e 30 days. Using the same calculation as above, this would result in a $PEC_{local\ soil,porewater}$ of 1.261 µg iodine/L, which, despite being above the water drinking limit, is also below the background level of iodine.

Usually a $PEC_{local\ soil,porewater}$ above 0.1 µg/L would result in having to conduct a groundwater assessment using the FOCUS Pearl modelling. Since the value is below the background level in the groundwater, no such assessment is considered necessary.

3.4 New information on the active substance

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3.5 Residue behaviour

3.6 Summaries of the efficacy studies

see IUCLID file & section 2.2.5

3.7 Confidential annex

Please refer to the separate document "Confidential Annex to the PAR"

3.8 Other

Description of vacumat application

A "Vacumat" is an application machine for superficial application like "Automated spraying", "Dipping" and "flowcoat", and is not for penetrative application like the "Vacuum pressure treatment" and the "Double vacuum pressure treatment", where the wood preservative is "pressed" into the wood.
A vacumat is an application machine designed for use in the treatment of a wide number of different types of wooden items.
Several models have been designed to perform these tasks e.g.:

- For shiplay boards, mouldings, round wheels, picture frames, window frames, external doors and for floor boards (with UV lacquer).

- For items used internally e.g. doors, frames, base mouldings and coating profiles.

- For the treatment of edges, e.g. doors, tabletops and laminate boards.

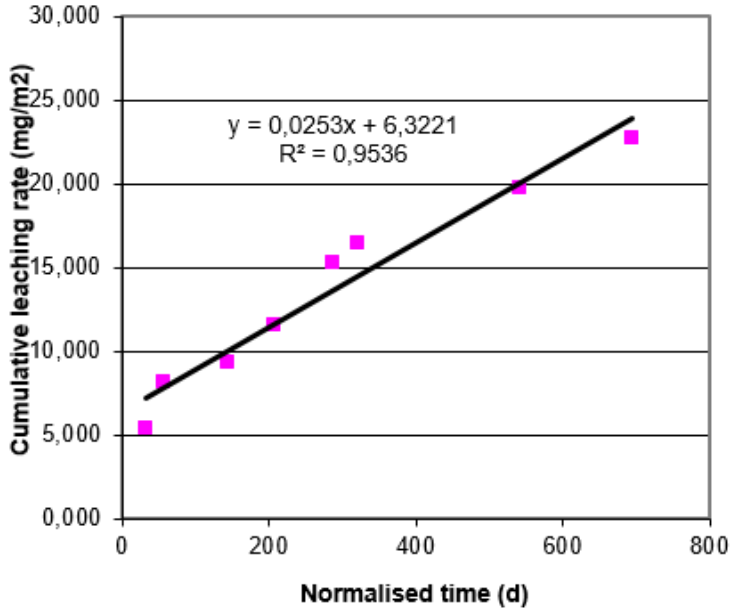
All types of vacumat work on the same basic principle. Conveyor belts transport the items into a chamber with low pressure created by powerful vacuum pumps.

The vacuum system (which can be combined with jets) first ensures that the items receive a more than adequate amount of treatment, and then that the protective liquid is sucked away. The excess liquid passes through a filter back to the liquid tank.
The vacumat can work with preservative, priming liquids, undercoat liquids and UV lacquers.
For long items, especially shiplay boards, it is important that the materials do not buckle, but are straight (due to the matrix/vac system).

A matrix/template must be made for each type of profile used.

3.9 Comparison of leaching and subsequent risk from treated wood with and without a top coat

The applicant has submitted a leaching study, which was not used in the leaching calculations, as the study was conducted using a top coat containing IPBC, and it would thus not be possible to distinguish between the IPBC leached from the topcoat or from TEKNOL AQUA 1411-01. However, the data can be used to compare the amount of propiconazole leached from the treated wood with and without a top coat, and thus quantify the impact of the use of a top coat.
Plotting the data points for propiconazole in the study with a top coat, the best fit is a linear regression. Although this is not a realistic, it is worst-case for the service life and will be used in the assessment.



The leaching rates for propiconazole has been derived similarly for this study as for the study without the use of a top coat, i.e. taking into consideration the difference in active substance concentration and the application rate.

The table below shows the leaching rates derived from the study without the top coat and the study with the top coat, respectively.

Comparison of leaching rates for propiconazole from study without top coat and with top coat		
	Without top coat	With top coat
Time 1 (30 days)	1.3522	0.1309
Time 2 (5 years)	0.1331	0.0319
Time 2 (15 years)	0.0543	0.1039

Generally, the leaching rates of propiconazole are lower for the studies without the top coat, expect at 15 years, which is to be expected as the leaching rates with a top coat is based on a linear regression as opposed to the leaching rates from the study without a top coat which is a logarithmic regression. Furthermore, assessment factors of 2 and 5 have been applied to the leaching rate with the top coat to account for the stability of the top coat, cf. the 2nd Leaching Workshop.
To further investigate the impact of a top coat the risks to the environment can be calculated for propiconazole. Unacceptable risks were identified for the terrestrial compartment, and therefore this is the relevant compartment for comparison.

PECsoil and PEC/PNECsoil propiconazole from study with top coat		
	PECsoil	PEC/PNECsoil
In service - House - Time 1 (30 days)	$1.96*10^{-2}$	0.196
In service - House - Time 2 (5 years)	$2.10*10^{-2}$	0.210
In service - House - Time 2 (15 years)	$6.91*10^{-2}$	0.691

These calculations show acceptable risks from propiconazole in the terrestrial compartment for the service life of treated wood at all evaluated time points. The risk assessment for propiconazole based on leaching study without a top coat showed an unacceptable risk for time 1 (PEC/PNEC 0f 2.03), and this PEC/PNEC is much lower based on the data with a top coat.
Acceptable risks have been identified for all time points and taking into consideration that it is based on a linear regression, we believe it is justified to conclude that the top coat does indeed result in less TEKNOL AQUA 1411-01 leached from the treated wood.