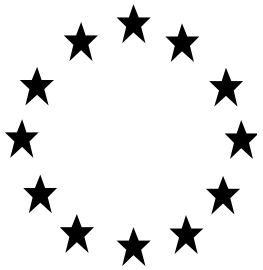
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



BOCHEMIT FORTE PROFI family

Product type 8 (Wood preservatives)

Active substances:
Copper(II) carbonate-copper (II) hydroxide (1:1),
Propiconazole,
Tebuconazole

Case Number in R4BP: BC-MB003424-65

Evaluating Competent Authority: Czech Republic

Date: 08/06/2017

Table of Contents

Document revision

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)	Section
NA-APP	CZ	BC-AN013595-40	9.6.2017	Initial assessment	
NA-AAT	CZ	BC-VS033128-14 BC-GE033269-49 BC-TV041053-19	14.7.2017	Change of expiry date from 9.6.2027 to 9.6.2022. Reason: Mistake correction.	2.1.1.2

1 CONCLUSION

The CZ CA proposes the authorisation of the Bochemit Forte Profi product family as a wood preservative (PT 8) for preventative treatment in Use classes 1, 2, 3 and 4a. The conditions of use and other details about the authorisation are specified in the Summary of the product assessment.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier	**Country**
BOCHEMIT FORTE PROFI family	Czech Republic

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Bochemie a.s.
	Address	Lidická 326, 735 81 Bohumín Czech Republic
Authorisation number	CZ-0003961-0000	
Date of the authorisation	09/06/2017	
Expiry date of the authorisation	09/06/2022	

2.1.1.3 Manufacturer of the products of the family

Name of manufacturer	Bochemie a.s.
Address of manufacturer	Lidická 326, 735 81 Bohumín Czech Republic
Location of manufacturing sites	Lidická 326, 735 81 Bohumín Czech Republic

2.1.1.4 Manufacturers of the active substances

Active substance	Copper(II) carbonate-copper(II) hydroxide (1:1)	Propiconazole	Tebuconazole
Name and address of active substance source	Spiess-Urania Chemicals GmbH Frankenstraβe 18b 20097 Hamburg Germany	Lanxess Deutschland GmbH Kennedyplatz 1 50569 Köln Germany	Lanxess Deutschland GmbH Kennedyplatz 1 50569 Köln Germany
Name and address of manufacturing site	Spiess-Urania Chemicals GmbH c/o AURUBIS AG Hovestrasse 50 20539 Hamburg Germany	Syngenta Crop Protection AG Schwarzwaldalle 215 CH 4002 Basel Switzerland	Bayer CropScience Corp. P.O. box 4913 Hawthorn Road MO 64120-0013 Kansas City United States

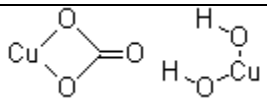
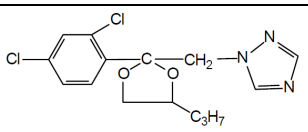
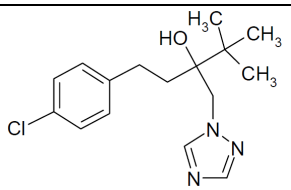
2.1.2 Product family composition and formulation

NB: The full composition of the product according to Annex III Title 1 is 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 constituents			
ISO name	Copper carbonate, basic	Propiconazole	Tebuconazole
IUPAC name	Copper(II) carbonate-copper(II) hydroxide (1:1)	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole	(RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol
EC number	235-113-6	262-104-4	403-640-2
CAS number	12069-69-1	60207-90-1	107534-96-3
Index number in Annex VI of CLP	n.a.	613-205-00-0	603-197-00-7
Minimum purity / content	957 g/kg	930 g/kg	950 g/kg
Structural formula			

2.1.2.2 Candidates for substitution

Propiconazole and tebuconazole are suspected from having endocrine disrupting properties. The Assessment Report for propiconazole states the following (p. 21): "When Member States are authorizing products containing propiconazole the potential of propiconazole to cause endocrine disruption must be considered. This is because propiconazole may have the potential to cause endocrine disruption based on suspected properties for the azole group and that there is not sufficient data." An analogous statement is found in the AR of tebuconazole (p. 22).
However, since the scientific criteria for the determination of endocrine-disrupting properties referred to in Article 5 Paragraph 3 of BPR have not been adopted yet, no definitive conclusion regarding propiconazole and tebuconazole as candidates for substitution can currently be reached.

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

Bochemit Forte Profi product family comprises two products:

- Bochemit Forte Profi
- Bochemit Forte Profi brown

The composition of these products differs only in the presence of a dye compensated for by difference in water content. This difference in composition does not lead to any difference in classification, physico-chemical properties (except for colour), analytical methods, efficacy, risk to human health or risk to the environment.

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Basic copper carbonate	Copper(II) carbonate-copper(II) hydroxide (1:1)	Active substance	12069-69-1	235-113-6	20
Propicona-zole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole	Active substance	60207-90-1	262-104-4	0.3
Tebucona-zole	(RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol	Active substance	107534-96-3	403-640-2	0.3
Monoetha-nolamine	2-aminoethanol	Non-active substance	141-43-5	205-483-3	35

2.1.2.4 Information on technical equivalence

The suppliers of the active substances are identical to the applicants in the active substance approval process under the Directive 98/8/EC. Therefore the CZ CA considers the active substances as technically equivalent to the active substances listed in Annex I to Dir. 98/8/EC.

2.1.2.5 Information on the substances of concern

Please see the confidential annex for further details.

2.1.2.6 Type of formulation

Water-based concentrate

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard categories and the corresponding hazard statements	Acute Tox. 4 (H332) Skin Corr. 1B (H314) Eye Dam. 1 (H318) STOT SE 3 (H335) Aquatic Chronic 1 (H410)
Labelling	
Signal word	Danger
Hazard pictograms	
Hazard statements	H332 Harmful if inhaled. H314 Causes severe skin burns and eye damage. H335 May cause respiratory irritation. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	P260 Do not breathe mist/vapours. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a doctor.
Additional labelling requirements	EUH208 Contains propiconazole. May produce an allergic reaction.

The recommended maximum number of P statements of six (CLP, Article 28) has been exceeded. However, all the P statements listed in the table are considered important by the CZ CA to be included in the label. The following precautionary statements triggered by the classification have been omitted from the label: P261, P264, P271, P304+P340, P312, P363, P321, P391, P403+P233, P405, P501.
The omitted P statements P264, P271, P304+P340, P363, P391, P403+P233, P405 and P501 are included in the instructions given in subsection 2.1.4. The statements P261, P312 and P321 are considered redundant or irrelevant.

Bochemit Forte Profi brown contains a dye, which itself is not classified, but similar reactive dyes may cause sensitization by inhalation (according to the information in the SDS of the dye). In accordance with the precautionary principle, the CZ CA proposes to include appropriate instructions (e.g. the statement P342+P311) on the product label of Bochemit Forte Profi brown.

The classification of the application solution (containing up to 4% of the concentrate) is the following: Skin Irrit. 2 (H315), Eye Irrit. 2 (H319), Aquatic Chronic 2 (H411).
The corresponding P statements are the following: P264, P273, P280, P302+P352, P305+P351+P338, P321, P332+P313, P337+P313, P362+P364, P391 and P501. The relevant P statements are included in the instructions given in subsection 2.1.4.

Classification of the active substances and substances of concern

Substance	Classification	Conc. in the product (%)	Toxicity estimate
Basic copper carbonate	Acute Tox. 4 (H302) Acute Tox. 4 (H332) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	20 Cu: 11.5	LD_{50} 1350 mg/kg bw (oral) LC_{50} >1.03 mg/L air (inhal.) – NOEC 2.2 µg/L (Cu), M=10
Propiconazole	Acute Tox. 4 (H302) Skin Sens. 1 (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	0.3	LD_{50} 1500 mg/kg bw (oral) – ErC_{50} 0.058 mg/L, M=10 NOEC 0.016 mg/L, M=1
Tebuconazole	H302 (Acute Tox. 4) H361d*** (Repr. 2) H400 (Aquatic Acute 1) H410 (Aquatic Chronic 1)	0.3	LD_{50} 1700 mg/kg_{bw} (oral) – M=1 M=10
Monoetha-nolamine	Acute Tox. 4 (H302) Acute Tox. 4 (H312) Acute Tox. 4 (H332) Skin Corr. 1B (H314) STOT SE 3 (H335): C≥ 5%	35	LD_{50} 1515 mg/kg bw (oral) LD_{50} 2504 mg/kg bw (dermal) LC_{50} >1.3 mg/L air (inhal.) – –

2.1.4 Authorised uses

2.1.4.1 Use # 1 – Preventive timber treatment

Use description

Product type	PT08 – Wood preservatives
Where relevant, an exact description of the authorised use	Preventive timber treatment
Target organism (including development stage)	Wood-rotting fungi, hyphae Wood-boring beetles, larvae
Field of use	Use class 1, 2, 3 and 4a (according to EN 335-1), softwood
Application method(s)	Pressure process / vacuum pressure treatment
Application rate(s) and frequency	Use class 1: 5.4 kg/m^3 Use classes 2 and 3: 7.4 kg/m^3 Use class 4a: 14 kg/m^3 Applied once
Category(ies) of users	Industrial
Pack sizes and packaging material	Please see the relevant section

Use specific instructions for use

See the general instructions for use

Use specific risk mitigation measures

See the general risk mitigation measures

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

See the general first aid instructions and emergency measures to protect the environment

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

See the general instructions for disposal

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

See the general conditions of storage

2.1.5 General directions for use

Instructions for use

The product is diluted before use; a 1% to 4% solution is prepared depending on the use class and properties of the timber.

Risk mitigation measures

Use appropriate PPE: protective gloves, protective clothing, eye protection and, when handling the undiluted product, a face shield.
Ensure sufficient ventilation of the workplace. Do not breathe aerosol.
Do not eat, drink or smoke when handling the preparation.
Wash hands thoroughly after handling.
Wash contaminated clothing before use.
The application shall be conducted within a contained area or on impermeable hard standing with building and that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing or both to prevent direct loss to soil, sewer or water, and any losses off the product shall be collected for reuse or disposal.
Treated wood should not be used in places near or above water.
Do not use for wood in direct contact with food, feeding stuffs and drinking water.

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

First aid measures:
Inhalation: If inhaled, remove person to fresh air and keep comfortable for breathing.
Bochemit Forte Profi brown: If experiencing allergic respiratory symptoms, call a doctor.
Skin contamination:
Undiluted product: Take off immediately all contaminated clothing. Rinse skin with water. In case of skin burns, seek medical attention.
Application solution: Wash skin with plenty of water.
Eye contamination: Rinse cautiously with water for several minutes, holding eyelids apart to ensure flushing of the entire surface. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention without delay (undiluted product) or if eye irritation persists (application solution).
Ingestion: Rinse mouth. Do NOT induce vomiting. Seek medical aid immediately and show the container label.

Emergency measures to protect the environment in case of an accident
Contain and collect spillage with a suitable absorbent and put into a labelled lockable container for disposal as hazardous waste. Wear appropriate personal protective equipment. Avoid an accidental discharge into sewers, surface water or soil. Soil contaminated by the undiluted product should be treated as hazardous waste.
In case of an accidental discharge of a large amount of the concentrated product to surface water, groundwater or sewer inform the appropriate authorities according to local regulations.

Instructions for safe disposal of the product and its packaging

The product, empty containers and used sorbents must be treated as hazardous waste.

The product and the application solution must not be released to the environment or to any kind of sewer.

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

Shelf-life: 2 years Store in a well-ventilated place. Keep container tightly closed. Store at temperature from –15 to +30 °C. Protect against direct sunlight. Keep away from food, beverages, drinking water and feed. Prevent unauthorised access. Provide means for cleaning of the area (absorbents) and water supply for first aid in case of skin/eye contamination.

2.1.6 Other information

Application codes

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
IBC	1200 kg	HDPE	Central screw cap, venting with synterised PE tap	Industrial	Yes
IBC	600 kg	HDPE	Central screw cap, venting with synterised PE tap	Industrial	Yes
Drum	60 kg	HDPE	Cap K63 with outlet faucet	Industrial	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substances and substances of concern have been submitted. The studies on the product, submitted for the purpose of product authorisation, are listed in Annex 3.1.

2.1.8.2 Access to documentation

The applicant has submitted the following letters of access:

Spiess-Urania Chemicals GmbH grants the right to refer to the dossier pertaining to Basic Copper Carbonate which Spiess-Urania Chemicals GmbH submitted under Directive 98/8/EC, product type 08.

LANXESS Deutschland GmbH grants the right to refer to the dossier of Propiconazole submitted under Directive 98/8/EC.

LANXESS Deutschland GmbH grants the right to refer to the dossier of Tebuconazole submitted under Directive 98/8/EC.

EURO-Šarm spol. s r.o., Šenov, CZ, as the supplier of 2-aminoethanol used in Bochemit Forte Profi, grants the right to refer to the data contained in their Safety Data Sheet for Monoetanolamin 99% (product code 314014801000), issued on 30 April 2013.

2.2 Assessment of the biocidal product family

2.2.1 Intended uses as applied for by the applicant

Table 1. Intended use # 1 – Preventive timber treatment

Product type	PT08 – Wood preservatives
Where relevant, an exact description of the authorised use	Preventive timber treatment
Target organism (including development stage)	Wood-rotting fungi, hyphae Wood-boring beetles, larvae
Field of use	Use class 1, 2, 3 and 4a (according to EN 335-1), softwood
Application method(s)	Pressure process / vacuum pressure treatment
Application rate(s) and frequency	Use class 1: 5.4 kg/m^3 Use classes 2 and 3: 7.4 kg/m^3 Use class 4a: 14 kg/m^3 Applied once
Category(ies) of users	Industrial
Pack sizes and packaging material	1200 kg IBC (HDPE) 600 kg IBC (HDPE) 60 kg drum (HDPE)

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Results	Reference
Physical state at 20 °C and 101.3 kPa	–	Liquid	SDS
Colour at 20 °C and 101.3 kPa	–	Blue or brown (according to the colour modification of the product)	SDS
Odour at 20 °C and 101.3 kPa	–	Ammonia-like	SDS
Acidity / alkalinity	OECD 122	11.7 (undiluted product) at 19.8°C Alkalinity (as NaOH) 22.4 % (w/w) at ca. 20°C	Štreit and Plodíková, 2013a
Relative density / bulk density	OECD 109; A.3 (Reg. EC 440/2008)	1.240 at 20°C	Štreit and Plodíková, 2013b

Property	Guideline and Method	Results	Reference
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Pre-storage concentrations: Copper 11.2% Propiconazole 0.30% Tebuconazole 0.30% Container: 1 L HDPE bottle **After 2 weeks at 54 °C** Copper 10.7% Propiconazole 0.28% Tebuconazole 0.30% No change in appearance No reactivity towards container material **After 6 months at 40°C** Copper 10.7% Propiconazole 0.27% Tebuconazole 0.28% No change in appearance No reactivity towards container material	Navrátilová, 2009
Storage stability test – **long term storage at ambient temperature**	Guidance on the storage stability by BPU (HSE)[1], p. 5	Pre-storage concentrations: Copper 11.2% Propiconazole 0.30% Tebuconazole 0.30% Container: 1 L HDPE bottle **After 2 years at 20-25 °C** Copper 11.1% Propiconazole 0.27% Tebuconazole 0.29% No change in appearance No reactivity towards container material	Navrátilová, 2009

[1] *Guidance on the storage stability. Data requirements for non-agricultural pesticide products.* BPU (HSE), 2004.

Property	Guideline and Method	Results	Reference
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Pre-storage concentrations: Copper 11.2% Propiconazole 0.30% Tebuconazole 0.30% Container: 1 L HDPE bottle **After 6 months at 1 °C** Copper 11.3% Propiconazole 0.30% Tebuconazole 0.28% No change in appearance No reactivity towards container material **After 6 months at –18 °C** Copper 11.3% Propiconazole 0.30% Tebuconazole 0.30% No change in appearance No reactivity towards container material	Navrátilová, 2009
Effects on content of the active substance and technical characteristics of the biocidal product – **light**	–	Protected from light by the packaging. Should be protected from direct sunlight. None of the a.s. is subject to photolysis according to the respective Assessment Reports.	–
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	CIPAC MT 46.3 CIPAC MT 39.3	Stability at elevated and decreased temperatures confirmed by the respective storage stability test. Should be stored at temperature from –15 °C to +30 °C. Humidity does not affect the properties of the product as the product is water-based.	Navrátilová, 2009
Effects on content of the active substance and technical characteristics of the biocidal product – **reactivity towards container material**	–	No reactivity towards container material was observed in the storage stability studies.	Navrátilová, 2009
Wettability	–	Not applicable (the product is a liquid)	–

Property	Guideline and Method	Results	Reference
Suspensibility, spontaneity and dispersion stability	–	Not applicable (the product is a liquid solution)	–
Wet sieve analysis and dry sieve test	–	Not applicable (the product is a liquid solution)	–
Emulsifiability, re-emulsifiability and emulsion stability	–	Not applicable (the product is a liquid solution)	–
Disintegration time	–	Not applicable (the product is a liquid)	–
Particle size distribution, content of dust/fines, attrition, friability	–	Not applicable (the product is a liquid)	–
Persistent foaming	CIPAC MT 47 (deviation: thickness of the foam measured instead of volume)	Thickness of the foam: 24 mm (corresponds to foam volume of approximately 30 ml); constant for 12 minutes. The test performed only with the lowest concentration. The result is considered acceptable by the CZ CA.[2]	Štreit and Plodíková, 2013c
Flowability / Pourability / Dustability	–	Not applicable (the product is a liquid solution)	–
Burning rate – smoke generators	–	Not applicable	–
Burning completeness – smoke generators	–	Not applicable	–
Composition of smoke – smoke generators	–	Not applicable	–
Spraying pattern – aerosols	–	Not applicable	–

[2] According to the BPR Guidance Vol. IA (p. 99), 'the level of foam generated under the conditions of CIPAC method 47.2 should not exceed 60 ml after 1 minute'. The measurement was performed in a 100ml calibration cylinder, the diameter of which is not specified in the study report. A typical diameter of a 100ml calibration cylinder is up to 4 cm. In a cylinder of 4 cm in diameter, foam thickness of 24 mm corresponds to foam volume of 30 ml.
Another requirement is that the test is performed at both the highest and lowest in use concentrations recommended for use (BPR Guidance Vol. IA, p. 99). The test was performed only at the lowest concentration. However, even if foam volume exceeded 60 ml at the highest application concentration, it should be taken into account that the long-term experience with the product has shown no risk resulting from foam formation during application via vacuum pressure treatment. Therefore no other study is required by the CZ CA.

Property	Guideline and Method	Results	Reference
Physical compatibility	–	Not applicable. Use with other products is not intended.	–
Chemical compatibility	–	Not applicable. Use with other products is not intended.	–
Degree of dissolution and dilution stability	–	Not applicable (the product is a liquid solution)	–
Surface tension	–	Not required. According to TNsG on Product Evaluation (p. 30), surface tension data are to be supplied in order to ensure that the product is classified correctly with regard to aspiration hazard. According to CLP (Annex I, 3.10.3.3), aspiration hazard has only to be considered in case of hydrocarbon content ≥10%. The product is used in a closed system. The long-term experience with the product has not shown any risk resulting from low/high surface tension.	–
Viscosity	–	Not required. According to TNsG on Product Evaluation (p. 30), viscosity data are to be supplied in order to ensure that the product is classified correctly with regard to aspiration hazard. According to CLP (Annex I, 3.10.3.3), aspiration hazard has only to be considered in case of hydrocarbon content ≥10%. The product is used in a closed system. The long-term experience with the product has not shown any risk resulting from low viscosity.	–

Conclusion on the physical, chemical and technical properties of the product
The applicant submitted all required data on the physical, chemical and technical properties of the product except for surface tension and viscosity. The data on surface tension and viscosity are not required by the CZ CA as no increased risk related to these properties has been identified during the long-term use of the product. The storage stability study confirmed the product shelf-life of 2 years in HDPE packaging. The product is also temporarily stable at elevated and decreased temperatures.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Results	Reference
Explosives	–	Not explosive. There are no chemical groups associated with explosive properties.	–
Flammable gases	–	Not applicable	–
Flammable aerosols	–	Not applicable	–
Oxidising gases	–	Not applicable	–
Gases under pressure	–	Not applicable	–
Flammable liquids	–	Not flammable. None of the ingredients classified as flammable.	–
Flammable solids	–	Not applicable	–
Self-reactive substances and mixtures	–	Not self-reactive. There are no chemical groups associated with self-reactive properties.	–
Pyrophoric liquids	–	Not pyrophoric. Not flammable. Experience in manufacture and handling shows no pyrophoric properties.	–
Pyrophoric solids	–	Not applicable	–
Self-heating substances and mixtures	–	Not applicable (the product is a liquid)	–
Substances and mixtures which in contact with water emit flammable gases	–	Not applicable (the product is water-based)	–
Oxidising liquids	–	Not oxidizing. None of the ingredients classified as oxidizing.	–
Oxidising solids	–	Not applicable	–
Organic peroxides	–	Not applicable	–

Property	Guideline and Method	Results	Reference
Corrosive to metals	–	None of the ingredients is classified as corrosive to metals. In addition, the long-term experience with the product does not show any problems related to corrosion of metals. Therefore no testing is required by the CZ CA.	–
Auto-ignition temperatures of products (liquids and gases)	–	Data not available. Not flammable. Experience in manufacture and handling shows no risk associated with autoflammability.	–
Relative self-ignition temperature for solids	–	Not applicable	–
Dust explosion hazard	–	Not applicable	–

Conclusion on the physical hazards and respective characteristics of the product
No risk from physical hazards is anticipated under the normal conditions of use.

2.2.4 Methods for detection and identification

Formulation analysis

Copper content in the products is determined by complexometric titration with the volumetric solution of disodium EDTA, using murexide as an indicator. Propiconazole and tebuconazole are determined by a HPLC-UV method. Monoethanolamine is determined by titration with hydrochloric acid solution in a potentiometric titrator. The methods are described in detail in Hantlová, 2008a and 2008b.

The methods fulfil the criteria for recovery, repeatability, linearity, and specificity set in BPR Guidance Vol. IA (p. 106) and in CIPAC Guidelines on method validation[3] (p. 4, 8) except for low recovery of monoethanolamine (95.5%; at least 98% required). The decreased monoethanolamine recovery is not regarded as significant by the CZ CA as monoethanolamine is not an active substance.

[3] *Guidelines on method validation to be performed in support of analytical methods for agrochemical formulations.* CIPAC, 2003.

Analytical methods for the analysis of the product							
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Linearity**	**Specificity**	**Recovery rate (%)**		**Repeatability**	**Reference**
				Range	Mean		
Copper (active substance)	Complexometric titration	–	No interferants	99.1 – 99.5 (3 samples)	99.4	RSD 0.21% (10 determinations)	Hantlová, 2008a; Navrátilová, 2006a
Propiconazole (active substance)	HPLC-UV	Based on 5 concentrations Range: 0.052 – 0.156 mg/ml R^2 = 0.998 (R = 0.999)	No interferants	98.3 – 102.9 (3 samples)	100.2	RSD 0.68% (5 determinations)	Hantlová, 2008a; Navrátilová, 2006b
Tebuconazole (active substance)	HPLC-UV	Based on 5 concentrations Range: 0.052 – 0.155 mg/ml R^2 = 0.998 (R = 0.999)	No interferants	98.4 – 102.4 (3 samples)	100.1	RSD 0.28% (5 determinations)	Hantlová, 2008a; Navrátilová, 2006b
Monoethanolamine (substance of concern)	Acid-base titration	–	No interferants	95.4 – 95.5 (3 samples)	95.5	RSD 0.19% (8 determinations)	Hantlová, 2008b; Navrátilová, 2006c

Residue analysis

For the methods of active substance residue analysis please refer to the respective sections of the CARs.

Conclusion on the methods for detection and identification
The CZ CA considers the analytical methods submitted as sufficient for the purpose of product authorisation.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Bochemit Forte Profi is a wood preservative for preventive timber treatment for use classes 1, 2, 3 and 4a. The product is applied via vacuum pressure treatment.

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

The target organisms are wood rotting fungi and wood boring beetles.
The object to be protected is timber intended for use in wooden elements indoors and outdoors.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product is lethal to larvae of wood boring beetles upon ingestion. In fungi, the product hinders spore germination and inhibits cell growth.

2.2.5.4 Mode of action, including time delay

Basic copper carbonate releases the Cu^{2+} ion. Upon contact with the fungicide, the spores passively take up copper II cations which hinder germination. In insects, copper II cations cause, amongst others, unspecific denaturation of proteins and enzymes.
The mode of action of propiconazole and tebuconazole consists in interfering with the biosynthesis of sterols, lipids essentials for structure and function of the cell membrane of fungi. The final result is inhibition of cell growth.
As the product is used for preventive action, the time delay is not critical.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)					
Field of use	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Use class 1	*Hylotrupes bajulus*	EN 47 + EN 73	Wood: *Pinus sylvestris*, sapwood Retentions: 4.49, 5.18, 5.60, 6.03, 7.17 kg/m^3 Concentrations: 0.72, 0.79, 0.86, 0.90, 1.05% Exposure time: 12 weeks	Toxic value: 5.4 kg/m^3	Fennert and Doblinski, 2007a

Experimental data on the efficacy of the biocidal product against target organism(s)					
Field of use	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Use class 2 (and 4)	*Gloeophyllum trabeum, Coriolus versicolor*	EN 113 + EN 73	Wood (*G. trabeum*): *Pinus sylvestris* Wood (*C. versicolor*): *Fagus sylvatica* Retentions (*G. trabeum*): 4.80, 4.90, 5.48, 6.05, 7.26 kg/m^3 Concentrations (*G. trabeum*): 0.61, 0.65, 0.72, 0.79, 0.95% Retentions (*C. versicolor*): 4.86, 5.39, 5.56, 5.99, 7.22 kg/m^3 Concentrations (*C. versicolor*): 0.73, 0.80, 0.81, 0.89, 1.07% Exposure time: 16 weeks	Toxic value (*G. trabeum*): <4.8 kg/m^3 Toxic value (*C. versicolor*): <4.9 kg/m^3	Fennert and Wessely, 2007a
Use class 2	*Coniophora puteana*	EN 113 + EN 73	Wood: *Pinus sylvestris* Retentions: 7.24, 9.14, 12.13, 15.36, 20.57 kg/m^3 Concentrations: 0.95, 1.20, 1.60, 2.00, 2.70% Exposure time: 16 weeks	Toxic value: <7.2 kg/m^3	Fennert and Wessely, 2008
Use class 2	*Poria placenta*	EN 113 + EN 73	Wood: *Pinus sylvestris*, sapwood Retentions: 5.2, 7.4, 8.9, 14.8, 20.3 kg/m^3 Concentrations: 0.68, 0.95, 1.2, 2.0, 2.7% Exposure time: 16 weeks	Toxic value: 7.4 kg/m^3	Součková, 2009

Experimental data on the efficacy of the biocidal product against target organism(s)					
Field of use	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Use class 3 (and 4)	*Gloeophyllum trabeum, Coriolus versicolor*	EN 113 + EN 84	Wood (*G. trabeum*): *Pinus sylvestris* Wood (*C. versicolor*): *Fagus sylvatica* Retentions: (*G. trabeum*): 4.69, 4.92, 6.21, 6.72, 8.24 kg/m^3 Concentrations (*G. trabeum*): 0.61, 0.65, 0.81, 0.87, 1.09% Retentions (*C. versicolor*): 6.66, 7.21, 8.43, 8.59, 9.51 kg/m^3 Concentrations (*C. versicolor*): 0.98, 1.07, 1.25, 1.30, 1.43% Exposure time: 16 weeks	Toxic value (*G. trabeum*): <4.7 kg/m^3 Toxic value (*C. versicolor*): <6.7 kg/m^3	Fennert and Wessely, 2007b
Use class 3	*Coniophora puteana, Poria placenta*	EN 113 + EN 84	Wood: *Pinus sylvestris* Retentions (*C. puteana*): 4.74, 5.79, 7.89, 9.43, 12.57 kg/m^3 Concentrations (*C. puteana*): 0.61, 0.74, 1.01, 1.21, 1.62% Retentions (*P. placenta*): 4.79, 5.70, 7.99, 9.42, 12.66 kg/m^3 Concentrations (*P. placenta*): 0.61, 0.74, 1.01, 1.21, 1.62% Exposure time: 16 weeks	Toxic value (*C. puteana*): <4.7 kg/m^3 Toxic value (*P. placenta*): 6.85 kg/m^3	Fennert and Wessely, 2010

Experimental data on the efficacy of the biocidal product against target organism(s)					
Field of use	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Use class 3	*Coniophora puteana, Gloeophyllum trabeum*	EN 113 + EN 84	Wood: *Pinus sylvestris* Retentions (*C. puteana*): 2.17, 4.66, 7.87, 11.38 kg/m^3 Retentions (*G. trabeum*): 2.20, 4.37, 7.72, 11.29 Concentrations (*C. puteana* and *G. trabeum*): 0.5, 1.0, 1.75, 2.5% Exposure time: 16 weeks	Toxic value (*C.puteana*): 3.4 kg/m^3 Toxic value (*G. trabeum*): 3.3 kg/m^3	Reinprecht , 2005
Use class 3	*Hylotrupes bajulus*	EN 47 + EN 84	Wood: *Pinus sylvestris*, sapwood Retentions: 4.69, 5.28, 6.01, 7.14, 7.82 kg/m^3 Concentrations: 0.72, 0.79, 0.90, 1.05, 1.15% Exposure time: 12 weeks	Toxic value: 6.6 kg/m^3	Fennert and Doblinski, 2007b
Use class 4	Soft rot micro-fungi	ENV 807	Retentions (Scots pine): 9.0, 11.2, 13.5, 16.7, 18.8 kg/m^3 Concentrations (Scots pine): 1.20, 1.50, 1.80, 2.20, 2.50% Retentions (beech): 15.3, 19.9, 25.3, 30.6, 35.3 kg/m^3 Concentrations (beech): 2.30, 3.00, 3.80, 4.60, 5.30% CC-reference Exposure time: 32 weeks	Toxic value (Scots pine): <37.9 kg/m^3 Toxic value (beech): <45.0 kg/m^3	Fennert and Wessely, 2007c

Experimental data on the efficacy of the biocidal product against target organism(s)					
Field of use	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Use class 4	Soft rot micro-fungi	EN 252	Wood: *Pinus sylvestris*, sapwood Retentions: 11.0, 13.2, 18.1, 23.0, 26.5 kg/m^3 CC-reference and CCA-reference Exposure time: 5 years	Toxic value (CC-reference): 11.7 kg/m^3 Toxic value (CCA-reference): 14.7 kg/m^3	Erdmann and Schumacher, 2014
Use class 4	Soft rot micro-fungi	EN 252	Wood: *Pinus sylvestris*, sapwood Retentions: 11.0, 13.0, 18.0, 23.1, 26.6 kg/m^3 Exposure time: 5 years	The test is ongoing as after 5 years no degradation has occurred in CCA reference stakes	Klamer and Venås, 2014

For Use class 4, the study according to ENV 807 yielded unreasonably high application rates. Therefore two field studies according to EN 252 were initiated in 2009, one of which (Klamer and Venås, 2014) is still ongoing. The results of a field study can be used as a substitute for the results of a study according to ENV 807 if it is confirmed that the wood rot was caused by soft rot and that the rotting of the control stakes cannot be ascribed to *Basidiomycetes* (EN 599-1, 6.4). In the study report of Erdmann and Schumacher (2014) it is stated: "brown rot and soft rot are the dominating forms of rot with white rot occurring as well but less frequently." The activity of soft rot on untreated stakes was confirmed by microscopy.
Regarding the study results of Erdmann and Schumacher (2014) the applicant submitted an expert opinion on efficacy evaluation for UC 4. According to this expert opinion (Ptáček, 2015), the minimum application rate for UC 4 ensuring the required efficacy is 14 kg/m^3. The CZ CA accepted this conclusion.
Efficacy tests were mostly performed on softwood (Scots pine). It is known that wood preservatives may have lower efficacy against fungi when applied on hardwood compared to softwood. Therefore the application rates listed below apply only to softwood.

Conclusion on the efficacy of the product
The efficacy data submitted result in the following recommended application rates (in accordance with EN 599-1) for softwood: Use class 1: 5.4 kg/m^3 Use class 2: 7.4 kg/m^3 Use class 3: 7.4 kg/m^3 Use class 4a: 14 kg/m^3

2.2.5.6 Occurrence of resistance and resistance management

According to the AR for basic copper carbonate, no development of resistance from the target fungi has been reported. There are strains of some species of wood destroying fungi that exhibit tolerance to copper. The growth of these strains is prevented by propiconazole and tebuconazole.
There is no evidence of insects being naturally tolerant or being able to develop resistance to copper at the level of copper used for biocidal purposes in wood preservation.
Development of resistance to triazole fungicides has been reported from agricultural, but not from biocidal use. It is recommended to pay attention to prevention of the evolution of tolerant fungal strains and report to Competent Authorities any new information on development of fungal resistance.

2.2.5.7 Known limitations

For resistance, see the previous subsection.
No undesirable or unintended side effects have been reported.

2.2.5.8 Evaluation of the label claims

For use class 1, the following label claim is justified: "against wood boring beetles".
For use classes 2, 3 and 4a, the following label claim is justified: "against wood rotting fungi and wood boring beetles".
The recommended minimum application rates apply only to softwood.
The respective minimum application rates are specified in subsection 2.2.5.5.

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

The products of Bochemit Forte Profi product family are not intended for use with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on human health

Skin corrosion and irritation

Data waiving	
Information requirement	Skin corrosion / irritation
Justification	According to the BPR (Annex III), testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Reg. (EU) 1272/2008, and synergistic effects between any of the components are not expected. As the classification of the ingredients is sufficient for derivation of product classification, no testing on the product on this endpoint is required.

Conclusion used in risk assessment – Skin corrosion and irritation	
Value/conclusion	Corrosive to skin
Justification for the value/conclusion	The product contains monoethanolamine (35% w/w), which is classified with Skin Corr. 1B. That results in the classification of the product with Skin Corr. 1B. The product further contains a substance which is a skin irritant, but at a concentration insufficient to trigger the product classification.
Classification of the product according to CLP	Skin Corr. 1B (H314)

Eye irritation

Data waiving	
Information requirement	Eye irritation
Justification	According to the BPR (Annex III), testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Reg. (EU) 1272/2008, and synergistic effects between any of the components are not expected. As the classification of the ingredients is sufficient for derivation of product classification, no testing on the product on this endpoint is required.

Conclusion used in risk assessment – Eye irritation	
Value/conclusion	Causes serious eye damage
Justification for the value/conclusion	The product contains monoethanolamine (35% w/w), which is classified as Skin Corr. 1B. That results in the classification of the product as Eye Dam. 1. In addition, the product contains a substance classified as Eye Dam. 1 at a concentration that would trigger classification of the product as Eye Irrit. 2. However, this substance is not considered a substance of concern since due to the presence of monoethanolamine it has no impact on product classification.
Classification of the product according to CLP	Eye Dam. 1 (H318)

Respiratory tract irritation

Data waiving	
Information requirement	Respiratory tract irritation
Justification	Testing on the product is not considered necessary if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Reg. (EU) 1272/2008, and synergistic effects between any of the components are not expected. As the classification of the ingredients is sufficient for derivation of product classification, no testing on the product on this endpoint is required.

Conclusion used in risk assessment – Respiratory tract irritation	
Justification for the conclusion	The product contains monoethanolamine, which is classified as a respiratory irritant with a specific concentration limit (SCL) of 5%. That results in the classification of the product for respiratory irritation.
Classification of the product according to CLP	STOT SE 3 (H335)

Skin sensitization

Data waiving	
Information requirement	Skin sensitization

Justification	According to the BPR (Annex III), testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Reg. (EU) 1272/2008, and synergistic effects between any of the components are not expected. As the classification of the ingredients is sufficient for derivation of product classification and no synergistic effects are expected, no testing on the product on this endpoint is required.

Conclusion used in risk assessment – Skin sensitization	
Value/conclusion	May elicit an allergic reaction in already sensitized individuals upon dermal contact
Justification for the value/conclusion	The product contains propiconazole, which is classified as Skin Sens. 1 (H317). The concentration of propiconazole in the product (0.3%) is not sufficient for classification, but exceeds the trigger value for elicitation in already sensitized individuals.
Classification of the product according to CLP	Not classified, but EUH208 (propiconazole) to be included on the product label.

Respiratory sensitization

Data waiving	
Information requirement	Respiratory sensitization
Justification	According to the BPR (Annex III), testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Reg. (EU) 1272/2008, and synergistic effects between any of the components are not expected. As the classification of the ingredients is sufficient for derivation of product classification and no synergistic effects are expected, no testing on the product on this endpoint is required.

Conclusion used in risk assessment – Respiratory sensitization	
Value/conclusion	Not classified
Justification for the value/conclusion	None of the ingredients is classified for respiratory sensitization. However, Bochemit Forte Profi brown contains a dye, which itself is not classified, but similar reactive dyes may cause sensitization by inhalation (according to the information in the SDS of the dye). In accordance with the precautionary principle, the CZ CA proposes to include appropriate instructions (e.g. the statement P342+P311) on the product label.

Classification of the product according to CLP	Not classified

Acute toxicity

Acute toxicity by oral route

Data waiving	
Information requirement	Acute oral toxicity
Justification	According to the BPR (Annex III), testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Reg. (EU) 1272/2008, and synergistic effects between any of the components are not expected. As there are the respective data available on the individual components and no synergistic effects are expected, no testing on the product on this endpoint is required.

Conclusion used in risk assessment – Acute oral toxicity	
Value	ATE_{mix} (Acute toxicity estimate of the mixture) > 2000 mg/kg bw
Justification for the selected value	The product contains the following ingredients classified for acute oral toxicity (the ingredients below the generic cut-off values as listed in CLP, Annex I, Table 1.1, are not considered): basic copper carbonate (20%; LD_{50} = 1350 mg/kg bw) and monoethanolamine (35%; LD_{50} = 1515 mg/kg bw). The acute toxicity estimate of the mixture has been obtained by the calculation method according to Reg. (EU) 1272/2008 (Annex I, 3.1.3.6.1).
Classification of the product according to CLP	Not classified

Acute toxicity by inhalation

Data waiving	
Information requirement	Acute inhalation toxicity

Justification	According to the BPR (Annex III), testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Reg. (EU) 1272/2008, and synergistic effects between any of the components are not expected. As there are the respective data available on the individual components and no synergistic effects are expected, no testing on the product on this endpoint is required.

Conclusion used in risk assessment – Acute inhalation toxicity	
Value	ATE_{mix} corresponding to Acute Toxicity category 4
Justification for the selected value	Two components of the product are classified for acute inhalation toxicity: basic copper carbonate (LC_{50} > 1.03 mg/L) and monoethanolamine (LC_{50} > 1.3 mg/L). These two compounds differ in their physical state in air (dust/mist vs. vapour), which means that the LC_{50} ranges defining acute toxicity categories (CLP, Annex I, Table 3.3.1) also differ. In addition, for neither of the substances a point LC_{50} value is available. Therefore it has been decided (in accordance with CLP guidance, June 2015, 3.1.6.3.2) that for classification purposes, both compounds will be regarded as dust/mist and will be assigned a point estimate corresponding to the respective acute toxicity category (i.e., 1.5 mg/L for category 4). The resulting point estimate for classification purposes (which should not be regarded as a real value) is 2.7 mg/L (dust/mist). That results in the classification of the product as Acute Tox. 4.
Classification of the product according to CLP	Acute Tox. 4 (H332)

Acute toxicity by dermal route

Data waiving	
Information requirement	Acute dermal toxicity
Justification	According to the BPR (Annex III), testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Reg. (EU) 1272/2008, and synergistic effects between any of the components are not expected. As there are the respective data available on the individual components and only one component is classified for acute dermal toxicity, no testing on the product on this endpoint is required.

Conclusion used in risk assessment – Acute dermal toxicity	
Value	ATE_{mix} (Acute toxicity estimate of the mixture) > 2000 mg/kg bw
Justification for the selected value	The only ingredient classified for acute dermal toxicity is monoethanolamine (LD_{50} = 2504 mg/kg bw). The acute toxicity estimate of the mixture has been obtained by the calculation method according to Reg. (EU) 1272/2008 (Annex I, 3.1.3.6.1).
Classification of the product according to CLP	Not classified

Information on dermal absorption

Value(s) used in the risk assessment – Dermal absorption			
Substance	Copper	Propiconazole	Tebuconazole
Value(s)	Concentrated product: 100% Diluted solutions: 5%	2%	75%
Justification for the selected value(s)	The values have been taken from basic copper carbonate Assessment Report (p. 48).	The dermal absorption value of 2% (propiconazole AR, p. 13) was obtained from a study using a diluted water-based product containing 1% a.s. The concentration in the application solutions of Bochemit Forte Profi ranges from 0.03 to 0.012%. However, the dermal absorption values obtained for other concentrations (1% at 10% a.s., 2% at 0.1% a.s. – AR for PT9) indicate that dermal absorption of propiconazole does not increase significantly with decreasing concentration.	The Assessment Report gives the value of 3.3% for a water-based solution containing 0.64% a.s. Even though there is structural similarity between propiconazole and tebuconazole, there is not enough data available for tebuconazole to allow an analogous inference. Therefore, the default value of 75% given in the EFSA Guidance on Dermal Absorption has been used.

Available toxicological data relating to substance(s) of concern or a mixture that a substance(s) of concern is a component of

Monoethanolamine

Monoethanolamine (ethanolamine, 2-aminoethanol) is classified (CLP, Annex VI) as Acute Tox. 4 (oral), Acute Tox. 4 (dermal), Acute Tox. 4 (inhalation), Skin Corr. 1B and STOT SE 3 (respiratory irritation).

The following information on monoethanolamine (MEA) is based on methanolamine SDS and on the respective SCOEL recommendation[4].
MEA is a colourless liquid with an ammoniacal odour. It has a boiling point of 170°C and a vapour pressure of 50 Pa at 20°C. It has a vapour density of 2.1 times that of air. The odour threshold is 2-3 ppm (5-8 mg/m^3).
The pH of 10% solution in water is 12.1. MEA is corrosive to skin, eyes, and to the respiratory tract and other mucous membranes.
MEA is absorbed through the skin, lungs and gastrointestinal tract. It is a normal constituent of the body and following chemical modifications can be incorporated into cellular membranes. It can be converted into amino acids or deaminated and used as an energy source.
The acute toxicity of ethanolamine is relatively low. Repeated oral administration to rats has indicated a NOAEL of 320 mg/kg/day. The target organs upon inhalation exposure (above 66 ppm) were the lung, liver, kidneys, spleen and testes. Rats exposed to 5 ppm MEA exhibited lethargy after 2-3 weeks exposure. Behavioural changes are therefore concluded to be the critical effect of MEA.
MEA has not been found to be mutagenic in bacteria and did not induce cell transformation. There is evidence for reproductive toxicity at exposure levels much higher than those inducing skin irritation and behavioural effects. MEA has not been tested for immunotoxicity in animals or for carcinogenicity.
Very little information is available on the effects of exposure to monoethanolamine vapour in humans.
The SCOEL used the behavioural LOAEL of 5 ppm (12.7 mg/m^3) to derive a recommended 8-hour TWA (time-weighted average) of 1 ppm (2.5 mg/m^3) and a 15-min STEL (short term exposure limit) of 3 ppm (7.6 mg/m^3) for inhalation exposure. It is assumed that dermal absorption could contribute substantially to the total body burden.

Based on its harmonized classification, monoethanolamine belongs to the band B according to the BPR Guidance (Vol. IIIB, April 2015, p. 371-372). For this class of substances of concern, a qualitative exposure and risk assessment has to be performed in order to determine whether the P-statements normally associated with concerned H-statements are sufficient or whether other risk mitigation measures should be applied.

2.2.6.2 Exposure assessment

The main phases of the product life cycle during which exposure to humans or the environment can occur are:

1. manufacturing of the product
2. application
3. use of the treated wood

The manufacturing phase is already addressed through other pieces of legislation than BPR.[5] Therefore, no risk assessment for the manufacturing phase is considered necessary

[4] Recommendation from Scientific Expert Group on Occupational Exposure Limits for ethanolamine (SCOEL/SUM/24). 1996

[5] See the document 'Exposure associated with manufacture', endorsed at the 22nd meeting of representatives of Member States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (7-8 September 2006).

here. Furthermore the applicant stated that the product formulation takes place under conditions preventing significant exposure (i.e. automated, closed systems). The formulation of the product is supervised by inspection bodies ensuring that required safety measures are followed.

During the product application operator exposure occurs via dermal and inhalation routes. Oral exposure is not expected.

Secondary exposure may occur during mechanical processing of treated wood by sawing, drilling, sanding and similar operations. The highest risk is associated with sanding and the potential inhalation of dust. Sanding can be performed by professionals (chronic exposure) or non-professionals (acute exposure).
Infants may be exposed dermally and orally (mouthing) via residues in playground structures; no mouthing is anticipated in children, who are exposed only via the dermal route. In addition, infants may be exposed orally via mouthing of treated wooden chips.
If the treated timber is used indoors (e.g. indoor cladding), there may be a risk from inhalation exposure to volatile residues of the product. A first-tier assessment has been performed using the criteria given in HEEG Opinion 13.[6] Based on these screening criteria, the risk from inhalation exposure to basic copper carbonate, propiconazole and tebuconazole can be excluded. The risk from inhalation exposure to monoethanolamine cannot be excluded and a further refinement is needed (see the respective scenario).
The risk from dermal exposure to the product contained in wooden components indoors is covered by the dermal exposure in the Sanding scenario.

The main routes of exposure are summarized in the following table.

[6] Basic copper carbonate as an inorganic ionic substance is not volatile, vapour pressure is not applicable (see Assessment Report, p. 5).
Calculation for propiconazole: $0.328 \times MW \times VP / AEL_{long\text{-}term} = 0.328 \times 342 \times 5.6 \cdot 10^{-5} / 0.04 = 0.16 \leq 1$
Calculation for tebuconazole: $0.328 \times 308 \times 1.7 \cdot 10^{-6} / 0.03 = 0.0057 \leq 1$
Calculation for monoethanolamine: $0.410 \times MW \times VP / AEC_{long\text{-}term} = 0.410 \times 61 \times 50 / (2.5/3) = 1500 > 1$
The factor of 3 was applied to the 8-hour TWA of 2.5 mg/m^3 as the indoor exposure at home may last up to 24 hours a day. Such an adaptation is an oversimplification with regard to toxicokinetic principles, but it is considered acceptable for screening purposes.

Indentification 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**			
	Industri-al use	**Profe-ssional use**	**Non-pro-fessional use**	**Industri-al use**	**Profe-ssional use**	**General public**	**Via food**
Inhalation	yes	no	no	no	yes	yes	no
Dermal	yes	no	no	no	yes	yes	no
Oral	no	no	no	no	no	yes	no

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Description of scenario**	**Exposed group**
Primary exposure			
1	Vaccum pressure treatment	Product application by vacuum pressure treatment	Industrial
Secondary exposure			
2	Sanding (professional)	Sanding of the treated wood performed by a professional (dermal and inhalation exposure)	Professionals
3	Sanding (non-professional)	Sanding of the treated wood performed by a non-professional (dermal and inhalation exposure)	Non-professionals
4	Child on a playground structure	A child playing on an outdoor playground structure made of treated wood (dermal exposure)	General public
5	Infant chewing an off-cut	An infant chewing a (treated) wood off-cut (oral exposure)	General public
6	Volatilized residues indoors	Inhalation of volatilized residues from indoor (treated) wooden structures	General public
7	Infant on a playground structure	An infant playing on an outdoor playground structure made of treated wood (dermal and oral exposure)	General public

Industrial exposure

Scenario 1: Vacuum pressure treatment

Description of Scenario 1 – Vacuum pressure treatment
Task description: An operator uses a fork-lift truck to place the wood on the rails of the treatment cylinder. The wood is automatically transferred into the treatment vessel and the vacuum pressure process is performed. When the impregnation process is finished, the door of the cylinder is opened and the wood is transferred by the fork-lift truck to a

storage area where it is placed to dry.
Dermal contamination may occur e.g. when handling restraining straps and treatment machinery, maintaining the door seals of treatment vessels or removing sawdust sludge.

Other operations associated with vacuum pressure treatment (i.e., dilution of the concentrate, re-stacking of fallen wood, cleaning of the treatment cylinder) are discussed below the table. For these operations no exposure calculations are required.

The appropriate model is TNsG Handling model 1 (Biocides Human Health Exposure Methodology, Oct 2015, p. 119), giving the following indicative values:

Body (potential) 8570 mg/cycle
Hands (inside gloves) 1080 mg/cycle
Inhalation 1.9 mg/m^3

3 cycles per day and the cycle duration of 3 hours is assumed. Duration of inhalation exposure is 30 min per day.

A 1% to 4% application solution of the wood preservative is used. The concentration of the active substances and of monoethanolamine in 4% application solution are as follows:

Copper: 0.46%
Propiconazole: 0.012%
Tebuconazole: 0.012%
Monoethanolamine: 1.4%

The application solution is considered a skin and eye irritant. Therefore, in the industrial setting, the use of gloves and protective eyewear is compulsory, and a calculation for the situation without gloves (i.e., Tier 1) would not be meaningful.

PPE required: gloves, protective eyewear, coated coverall (unless the worker is protected from the contact with the preservative e.g. in the closed cab of a fork-lift truck)

The dermal absorption values:

Copper: 5%
Propiconazole: 2%
Tebuconazole: 75%

	Parameters	Value
Tier 2 (gloves, coated coverall)	Number of cycles per day[7]	3
	Cycle duration[7]	3 h
	Duration of inhalation exposure per day[7]	30 min
	Clothing penetration[8]	10%
	Inhalation rate[9]	1.25 m^3/h

Other operations associated with vacuum pressure treatment are the following:

[7] Biocides Human Health Exposure Methodology, October 2015, p. 119-120
[8] HEEG Opinion 9, coated coverall
[9] HEEG Opinion 17

Mixing/loading
In addition, according to TGD (part I, p. 55) for properly labelled corrosives it is not necessary to assess the risk from (systemic) dermal exposure as repeated daily dermal contact is avoided. In addition, the transfer usually takes place in a closed system. Therefore no quantitative risk assessment is required (cf. HEEG Opinion 18).

Storage
According to HEEG Op. 18, at some point in the drying cycle piles of wooden articles in the storage area could fall and the wooden articles will need to be manually re-stacked. It is assumed that in any day one batch of timber from the dipping process will need to be manually re-stacked. However, on any particular day these operations will normally be performed by a person other than the person who performs wood impregnation.
Exposure from occasional re-stacking of the wet or partially dry wood is considered to be equal to or lower than the exposure during the application phase. As the two tasks are not performed by the same person, exposure from storage can be regarded as covered by the exposure from application.

Cleaning of the treatment vessel
As to the cleaning of the treatment equipment, the situation is assumed to be similar to that of dipping tanks. According to HEEG Op. 18, dip tanks are cleaned infrequently, usually less often than once a year. There is not enough information to allow defining an exposure model for the cleaning of the dip tank.
As there is not enough information for exposure calculation and the task is performed infrequently, no quantitative risk assessment will be performed.

Calculations for Scenario 1 – Vacuum pressure treatment
See Annex 3.2.

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated uptake** (mg/kg bw/d)			
		Inhalation	**Dermal**	**Oral**	**Total**
Scenario 1: Vacuum pressure treatment	Tier 2 (gloves, coated coverall)	Cu: $9.1 \cdot 10^{-5}$ Prop.: $2.4 \cdot 10^{-6}$ Teb.: $2.4 \cdot 10^{-6}$	Cu: 0.022 Prop.: $2.3 \cdot 10^{-4}$ Teb.: $8.7 \cdot 10^{-3}$	–	Cu: 0.022 Prop.: $2.4 \cdot 10^{-4}$ Teb.: $8.7 \cdot 10^{-3}$

Combined scenarios
Not relevant.

Professional exposure

Scenario 2: Sanding (professional)

Description of Scenario 2 – Sanding (professional)
Task description: A professional performs machine sanding of the treated wood. For the estimation of inhalation exposure from sanding of the treated wood the TNsG model 'Inhalation of dust – machine sanding preserved wood – adult' has been chosen

(TNsG 2002, part 3, p. 37). Dermal exposure has been estimated using the TNsG model 'Adult (professional) sanding wooden posts' (TNsG 2002, User Guidance, p. 56). The dermal absorption values: Copper: 5% Propiconazole: 2% Tebuconazole: 75%		
	Parameters	Value
Tier 1 (no PPE)	Duration[10]	6 h
	Product retention[11]	14 kg/m^3
	Penetration depth[10]	1 cm
	Article volume[10]	720 cm^3
	Volume of outer 1 cm wood[10]	568 cm^3
	Wood density[12]	0.4 g/m^2
	Inhalation rate[13]	1.25 m^3/h
	Dust concentration in the air[10]	5 mg/m^3
	Hand surface area contaminated[14]	84 cm^2
	Transfer coefficient[15]	2%

Calculations for Scenario 2 – Sanding (professional)
See Annex 3.2.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated uptake** (mg/kg bw/d)			
		Inhalation	**Dermal**	**Oral**	**Total**
Scenario 2: Sanding (professional)	Tier 1 (no PPE)	Cu: $3.2\cdot10^{-3}$ Prop.: $8.3\cdot10^{-5}$ Teb.: $8.3\cdot10^{-5}$	Cu: $2.3\cdot10^{-3}$ Prop.: $2.4\cdot10^{-5}$ Teb.: $8.8\cdot10^{-4}$	–	Cu: $5.4\cdot10^{-3}$ Prop.: $1.1\cdot10^{-4}$ Teb.: $9.7\cdot10^{-4}$

Combined scenarios
Not relevant.

Non-professional exposure

Scenario 3: Sanding (non-professional)

[10] TNsG 2002, part 3, p. 37
[11] Use class 4a
[12] Manual of Technical Agreements, version 6, p. 31
[13] HEEG Opinion 17
[14] TNsG 2002, User guidance, p. 56
[15] Biocides Human Health Exposure Methodology (October 2015, p. 171), rough sawn wood

Description of Scenario 3 – Sanding (non-professional)		
Task description: A non-professional performs sanding of the treated wood. Dermal exposure has been estimated using the TNsG model 'Adult (professional) sanding wooden posts' (TNsG 2002, User Guidance, p. 56), which was also used for professional sanding. For the estimation of inhalation exposure from sanding of the treated wood the TNsG model 'Adult sanding treated wood posts – inhalation route' (TNsG 2002, part 3, p. 50; also User guidance, p. 55) has been chosen. The dermal absorption values: Copper: 5% Propiconazole: 2% Tebuconazole: 75%		
	Parameters	Value
Tier 1 (no PPE)	Duration[16]	1 h
	Product retention[17]	14 kg/m^3
	Article volume[16]	4000 cm^3
	Volume of outer 1 cm wood[16]	3008 cm^3
	Wood density[18]	0.4 g/m^2
	Dust concentration in the air[16]	5 mg/m^3
	Inhalation rate[19]	1.25 m^3/h
	Hand surface area contaminated[20]	84 cm^2
	Transfer coefficient[21]	2%

Calculations for Scenario 3 – Sanding (non-professional)
See Annex 3.2.

Summary table: estimated exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated uptake** (mg/kg bw/d)			
		Inhalation	**Dermal**	**Oral**	**Total**
Scenario 3: Sanding (non-professional)	Tier 1 (no PPE)	Cu: $5.6\cdot10^{-4}$ Prop.: $1.5\cdot10^{-5}$ Teb.: $1.5\cdot10^{-5}$	Cu: $2.3\cdot10^{-3}$ Prop.: $2.4\cdot10^{-5}$ Teb.: $8.8\cdot10^{-4}$	–	Cu: $2.8\cdot10^{-3}$ Prop.: $3.8\cdot10^{-5}$ Teb.: $9.0\cdot10^{-4}$

Combined scenarios
Not relevant.

[16] TNsG 2002, part 3, p. 50
[17] Use class 4a
[18] Manual of Technical Agreements, version 6, p. 31
[19] HEEG Opinion 17
[20] TNsG 2002, User guidance, p. 56
[21] Biocides Human Health Exposure Methodology (October 2015, p. 171), rough sawn wood

Exposure of the general public

Scenario 4: Child on a playground structure

Description of Scenario 4 – Child on a playground structure		
Scenario description: Dermal exposure of a child playing on an outdoor playground structure made of treated wood. The exposure has been estimated using the model 'Child playing on playground structure outdoors – dermal route' (TNsG 2002, part 3, p. 50). The surface concentration has been taken from the 'sanding' scenario (14 mg/cm^2). The dermal absorption values: Copper: 5% Propiconazole: 2% Tebuconazole: 75%		
	Parameters	Value
Tier 1	Surface concentration	14 mg/cm^2
	Hand surface area contaminated[22]	40 cm^2
	Transfer coefficient[23]	2%
	Body weight[22]	15 kg

Calculations for Scenario 4 – Child on a playground structure
See Annex 3.2.

Scenario 5: Infant chewing an off-cut

Description of Scenario 5 – Infant chewing an off-cut		
Scenario description: An infant chewing a treated wood off-cut (oral exposure). The exposure has been estimated using the model 'Infant acute chewing wood off-cut – ingestion route' (TNsG 2002, part 3, p. 50). Absorption from the gastrointestinal tract: Copper[24]: 36% Propiconazole, Tebuconazole: 100%		
	Parameters	Value
Tier 1	Product retention[25]	14 kg/m^3
	Off-cut volume[26]	16 cm^3
	Fraction extracted by chewing[26]	10%
	Body weight[26]	10 kg

[22] TNsG 2002, part 3, p. 50
[23] Biocides Human Health Exposure Methodology (October 2015, p. 171), rough sawn wood
[24] Assessment Report, p. 48
[25] Use class 4a
[26] TNsG 2002, part 3, p. 50

Calculations for Scenario 5 – Infant chewing an off-cut
See Annex 3.2.

Scenario 6: Volatilized residues indoors

Description of Scenario 6 – Volatilized residues indoors		
Scenario description: Inhalation of volatilized residues from treated indoor wooden structures. A first-tier assessment has been performed using the criteria given in HEEG Opinion 13. Based on these screening criteria, the risk from inhalation exposure to basic copper carbonate, propiconazole and tebuconazole can be excluded. However, the risk from inhalation exposure to monoethanolamine cannot be excluded and a further refinement is needed. For the second-tier assessment, the ConsExpo 4.1 model 'Exposure to vapour: evaporation' has been chosen. Volatilization from a timber-cladded ceiling in an unspecified room has been chosen as the model situation as for this situation harmonized default values are available.		
	Parameters	Value
Tier 2	Exposure frequency	1 per year[27]
	Timber surface area[28]	8 m^2
	Surrogate application rate[29]	74 g/m^2
	Room volume[28]	20 m^3
	Ventilation rate[28]	0.6 h^{-1}
	Vapour pressure	50 Pa
	Molecular weight	61 g/mol
	Mass transfer rate approximation model[30]	Langmuir's method
	Molecular weight of matrix[31]	18 g/mol
	Body weight[32]	10 kg
	Inhalation rate[32]	8 m^3/24 h

Calculations for Scenario 6 – Volatilized residues indoors
See Annex 3.2.

[27] It means once a year freshly treated cladding is installed in the room, which is a conservative assumption.
[28] Bremmer, H.J.; Prud'homme de Lodder, L.C.H.; van Engelen, J.G.M. *General fact sheet, limiting conditions and reliability, ventilation, room size, body surface area. Updated version for ConsExpo 4.* RIVM report 320104002/2006.
All values are for an ‚unspecified room'.
[29] Assuming penetration depth 1 cm = thickness of the cladding, and product retention of 7.4 kg/m^3 (Use class 2)
[30] Langmuir's method is more conservative than the Thibodeaux's method.
[31] The molecular weight of water
[32] Toddler, long-term exposure (as the worst case for inhalation exposure)

Scenario 7: Infant on a playground structure

Description of Scenario 7 – Infant on a playground structure		
Scenario description: Dermal and oral exposure of an infant playing on an outdoor playground structure made of treated wood. The exposure has been estimated using the model 'Infant playing on weathered structure and mouthing – dermal and ingestion (TNsG 2002, part 3, p. 51). The dermal absorption values: Copper: 5% Propiconazole: 2% Tebuconazole: 75% Tier 1 In Tier 1, the surface concentration has been taken from the 'sanding' scenario (14 mg/cm^2). No harmonized value is available for the portion extracted by licking. For chewing, 10% is given in the scenario 'Infant acute chewing wood off-cut – ingestion route' (TNsG 2002, part 3, p. 50). 5% is considered as a sufficiently conservative value for licking, especially in the case of vacuum pressure treatment. Tier 2 Tier 1 estimates indicate unacceptable risk (see section 2.2.6.3). However, it should be noted that defaults in the respective TNsG scenario are not based on measured values, so their reliability is rather limited. In addition, in this assessment the TNsG default for product residue on the surface of 0.01 mg/cm^2 has been replaced by a product-specific value of 14 mg/cm^2, i.e. by a value 3 orders of magnitude higher. The second-tier refinement will be based on product-specific values derived from the leaching study (Klamer and Venås, 2013). The leaching rates based on a normalized day, corresponding to 2 mm of precipitation, are considered to cover licking by infants. Conservatively it will be assumed that the timber is freshly treated, not weathered; this corresponds to the initial period of leaching (the first 30 days). For example, the leaching rate for copper is 158 mg/m^2 / 30 d = 5.3 mg/m^2/d.		
	Parameters	Value
Tier 1	Surface concentration	14 mg/cm^2
	Hand surface area contaminated[33]	40 cm^2
	Dermal transfer coefficient[34]	2%
	Surface mouthed[33]	50 cm^2
	Fraction extracted by licking[35]	5%
	Body weight[33]	10 kg
Tier 2	Leaching rate – copper[36]	5.3 mg/m^2/d

[33] TNsG 2002, part 3, p. 51

[34] Biocides Human Health Exposure Methodology (October 2015, p. 171), rough sawn wood

[35] No harmonized value available; 5% is based on 10% extraction effectiveness by chewing in the 'Infant chewing an off-cut' scenario.

[36] Klammer and Venås (2013): the leaching rate for copper (Time 1 = 30 d) is 158 mg/m^2/d

	Leaching rate – propiconazole[37]	0.061 mg/m^2/d
	Leaching rate – tebuconazole[38]	0.099 mg/m^2/d
	Surface mouthed[33]	0.005 m^2

Calculations for Scenario 7 – Child on a playground structure
See Annex 3.2.

Combined scenarios
No combined exposure is foreseen.

Summary table: estimated exposure of the general public					
Exposure scenario	**Tier/ PPE**	**Estimated uptake** (mg/kg bw/d)			
		Inhalation	**Dermal**	**Oral**	**Total**
Scenario 4: Child on a playground structure	Tier 1	–	Cu: $4.3\cdot10^{-3}$ Prop.: $4.5\cdot10^{-5}$ Teb.: $1.7\cdot10^{-3}$	–	Cu: $4.3\cdot10^{-3}$ Prop.: $4.5\cdot10^{-5}$ Teb.: $1.7\cdot10^{-3}$
Scenario 5: Infant chewing an off-cut	Tier 1	-	–	Cu: 0.093 Prop.: $6.7\cdot10^{-3}$ Teb.: $6.7\cdot10^{-3}$	Cu: 0.093 Prop.: $6.7\cdot10^{-3}$ Teb.: $6.7\cdot10^{-3}$
Scenario 6: Volatilized residues indoors	Tier 2	MEA: $2.5\cdot10^{-3}$; $3.1\cdot10^{-3}$ mg/m^3	–	–	MEA: $2.5\cdot10^{-3}$; $3.1\cdot10^{-3}$ mg/m^3
Scenario 7: Infant on a playground structure	Tier 1	–	Cu: $6.4\cdot10^{-3}$ Prop.: $6.7\cdot10^{-5}$ Teb.: $2.5\cdot10^{-3}$	Cu: 0.15 Prop.: 0.011 Teb.: 0.011	Cu: 0.15 Prop.: 0.011 Teb.: 0.013
	Tier 2	–	Cu: $6.4\cdot10^{-3}$ Prop.: $6.7\cdot10^{-5}$ Teb.: $2.5\cdot10^{-3}$	Cu: $1.1\cdot10^{-4}$ Prop.: $9.2\cdot10^{-8}$ Teb.: $1.5\cdot10^{-7}$	Cu: $6.6\cdot10^{-3}$ Prop.: $6.7\cdot10^{-5}$ Teb.: $2.5\cdot10^{-3}$

Dietary exposure
No food, drinking water or livestock exposure is foreseen as the treated wood should not be used for the manufacture of articles coming into contact with food, beverages, drinking water or feed.

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

The manufacturing phase is already addressed through other pieces of legislation than BPR.[39] Therefore, no risk assessment for the manufacturing phase is considered

[37] Klammer and Venås (2013): the leaching rate for propiconazole (Time 1 = 30 d) is 1.83 mg/m^2/d
[38] Klammer and Venås (2013): the leaching rate for tebuconazole (Time 1 = 30 d) is 2.97 mg/m^2/d

necessary. Furthermore the applicant stated that the product formulation takes place under conditions preventing significant exposure (i.e. automated, closed systems). The formulation of the product is supervised by inspection bodies ensuring that required safety measures are followed.

The workers of hazardous waste treatment facilities dealing with the unused biocidal product and with the contaminated packaging are also protected by other pieces of legislation than BPR.

The exposure from disassembling and disposal of the wooden articles at the end of their service life is covered by the dermal exposure for the scenario 'Sanding (professional)' (see above).

Summary of exposure assessment

Scenarios and values to be used in risk assessment				
Scenario number	**Scenario**	**Exposed group**	**Tier/PPE**	**Estimated total uptake** (mg/kg bw/d)
1	Vacuum pressure treatment	Industrial	Tier 2 (gloves, coated coverall)	Cu: 0.022 Prop.: $2.4 \cdot 10^{-4}$ Teb.: $8.7 \cdot 10^{-3}$
2	Sanding (professional)	Professionals	Tier 1 (no PPE)	Cu: $5.4 \cdot 10^{-3}$ Prop.: $1.1 \cdot 10^{-4}$ Teb.: $9.7 \cdot 10^{-4}$
3	Sanding (non-professional)	Non-professionals	Tier 1 (no PPE)	Cu: $2.8 \cdot 10^{-3}$ Prop.: $3.8 \cdot 10^{-5}$ Teb.: $9.0 \cdot 10^{-4}$
4	Child on a playground structure	General public	Tier 1	Cu: $4.3 \cdot 10^{-3}$ Prop.: $4.5 \cdot 10^{-5}$ Teb.: $1.7 \cdot 10^{-3}$
5	Infant chewing an off-cut	General public	Tier 1	Cu: 0.093 Prop.: $6.7 \cdot 10^{-3}$ Teb.: $6.7 \cdot 10^{-3}$
6	Volatilized residues indoors	General public	Tier 2	MEA: $2.5 \cdot 10^{-3}$; $3.1 \cdot 10^{-3}$ mg/m^3
7	Infant on a playground structure	General public	Tier 2	Cu: $6.6 \cdot 10^{-3}$ Prop.: $6.7 \cdot 10^{-5}$ Teb.: $2.5 \cdot 10^{-3}$

[39] See the document 'Exposure associated with manufacture', endorsed at the 22nd meeting of representatives of Member States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (7-8 September 2006).

2.2.6.3 Risk characterisation for human health

Copper: Reference values to be used in risk characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AELshort-term	90d in rat	NOAEL: 16.3 mg/kg bw/d	50*	25%	0.082 mg/kg bw/d
AELmedium-term			50*	25%	0.082 mg/kg bw/d
AELlong-term			100**	25%	0.041 mg/kg bw/d
ARfD	n.a.				
ADI	n.a.				

* Although the inter-species factor is usually set at 10, it was agreed (Assessment Report, p. 22) it could be reduced from 10 to 5 in the case of copper compounds. This factor is composed of an allometric scaling subfactor (which is 4 for rats) and a residual subfactor of 2.5 accounting for the other interspecies variability. Whereas the allometric scaling subfactor was kept unchanged, it was proposed to reduce the residual subfactor from 2.5 to 1.25 on the basis of the extensive toxicokinetic data set both in humans and animals (rats) which demonstrates similarities between the two species in absorption, distribution and excretion of copper compounds.

** Inter-species factor 5, intra-species factor 10, additional factor of 2 for extrapolation from subchronic to chronic exposure

Propiconazole: Reference values to be used in risk characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AELshort-term	Develop-mental in rat	NOAEL: 30 mg/kg bw/d	100	No	0.3 mg/kg bw/d
AELmedium-term	2-generation in rat	NOAEL: 8 mg/kg bw/d	100	No	0.08 mg/kg bw/d
AELlong-term[40]	2-year in rat	NOAEL: 3.6 mg/kg bw/d	100	No	0.04 mg/kg bw/d
ARfD	n.a.				
ADI	n.a.				

[40] From the Assessment Report for PT9. In the AR for PT8 no AELlong-term was derived.

Tebuconazole: Reference values to be used in risk characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AELshort-term	1 year in dog	NOAEL: 3 mg/kg bw/d	100	No	0.03 mg/kg bw/d
AELmedium-term					
AELlong-term					
ARfD	n.a.				
ADI	n.a.				

Risk for industrial users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Vacuum pressure treatment	Tier 2	Cu: 16.3 Prop.: 3.6 Teb.: 3	Cu: 0.041 Prop.: 0.04 Teb.: 0.03	Cu: 0.022 Prop.: $2.4 \cdot 10^{-4}$ Teb.: $8.7 \cdot 10^{-3}$	Cu: 54 Prop.: 0.60 Teb.: 29	Yes

Combined scenarios
Not relevant.

Local effects

Scenario /Task	Effects in terms of classification	Hazard category	Task	Potential exposure route	Frequency and duration of potential exposure
Vacuum pressure treatment – dilution of the product	Skin Corr. 1B (H314) Eye Dam. 1 (H318) STOT SE 3 (H335)	High	Loading product from IBC into a treatment device, dilution with water	skin, eye, inhalation	<few minutes, <1/week
Vacuum pressure treatment – application	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	Low	Handling treated wood, mainly using a fork-lift truck; restacking fallen wood	skin, eye	<1 h/day, daily

Table continued

Scenario /Task	Degree of potential exposure	RMMs	Necessary PPE	Conclusion on risk
Vacuum pressure treatment – dilution of the product	n.r.	Labelling according to the respective classification, transfer in closed system, good ventilation	Appropriate gloves, coated coverall, eye protection, face shield	Acceptable: +Trained workers +Use of appropriate PPE +Low task frequency and duration +Low likelihood of exposure
Vacuum pressure treatment – application	Body potential ~ 25 g/day, hands inside gloves ~ 3 g/day	Transfer using a fork-lift truck, good ventilation	Gloves, coverall, eye protection	Acceptable: +Reversible effects +Trained workers +Use of appropriate PPE

Conclusion

The risk for industrial users is acceptable provided that appropriate PPE is used, i.e.:

- For dilution of the concentrate: gloves, eye protection, face shield, coated coverall
- For application: gloves, coverall, eye protection (unless the operator is protected e.g. in the closed cab of a fork-lift truck)

Risk for professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Sanding	Tier 1	Cu: 16.3 Prop.: 3.6 Teb.: 3	Cu: 0.041 Prop.: 0.04 Teb.: 0.03	Cu: $5.4 \cdot 10^{-3}$ Prop.: $1.1 \cdot 10^{-4}$ Teb.: $9.7 \cdot 10^{-4}$	Cu: 13 Prop.: 0.28 Teb.: 3.2	Yes

Combined scenarios

Not relevant.

Local effects

There are no local effects anticipated from sanding and other processing of the treated wood.

Conclusion

The risk for professional users is acceptable.

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Sanding	Tier 1	Cu: 16.3 Prop.: 30 Teb.: 3	Cu: 0.082 Prop.: 0.3 Teb.: 0.03	Cu: $2.8 \cdot 10^{-3}$ Prop.: $3.8 \cdot 10^{-5}$ Teb.: $9.0 \cdot 10^{-4}$	Cu: 3.4 Prop.: 0.013 Teb.: 3.0	Yes

Combined scenarios
Not relevant.

Local effects
There are no local effects anticipated from sanding and other processing of the treated wood.

Conclusion
The risk for non-professional users is acceptable.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Child on a playground structure	Tier 1	Cu: 16.3 Prop.: 3.6 Teb.: 3	Cu: 0.041 Prop.: 0.04 Teb.: 0.03	Cu: $4.3 \cdot 10^{-3}$ Prop.: $4.5 \cdot 10^{-5}$ Teb.: $1.7 \cdot 10^{-3}$	Cu: 10 Prop.: 0.11 Teb.: 5.7	Yes
Infant chewing an off-cut	Tier 1	Cu: 16.3 Prop.: 30 Teb.: 3	Cu: 0.082 Prop.: 0.3 Teb.: 0.03	Cu: 0.093 Prop.: $6.7 \cdot 10^{-3}$ Teb.: $6.7 \cdot 10^{-3}$	Cu: 113 Prop.: 2.2 Teb.: 22	Yes[41]
Volatilized residues indoors[42]	Tier 2	MEA: 12.7 mg/m^3	MEA: AEL not defined; limit for workplace exposure: 2.5 mg/m^3	MEA: $2.5 \cdot 10^{-3}$; $3.1 \cdot 10^{-3}$ mg/m^3	–	Yes[43]

[41] The extraction of 10% of wood preservative by chewing is considered to be an overestimation in the case of vacuum pressure treatment. In addition, this scenario is considered as an accidental, uncommon occurrence as parents usually do not allow children to chew preservative treated wood.
[42] For monoethanolamine only qualitative risk assessment is required
[43] The estimated concentration is much lower than the limit for workplace exposure

Infant on a playground structure	Tier 1	Cu: 16.3 Prop.: 3.6 Teb.: 3	Cu: 0.041 Prop.: 0.04 Teb.: 0.03	Cu: 0.15 Prop.: 0.011 Teb.: 0.013	Cu: 370 Prop.: 28 Teb.: 43	No
	Tier 2	Cu: 16.3 Prop.: 3.6 Teb.: 3	Cu: 0.041 Prop.: 0.04 Teb.: 0.03	Cu: $6.6 \cdot 10^{-3}$ Prop.: $6.7 \cdot 10^{-5}$ Teb.: $2.5 \cdot 10^{-3}$	Cu: 16 Prop.: 0.17 Teb.: 8.3	Yes

Combined scenarios
No combined exposure is foreseen.

Local effects
For the scenario 'Child on a playground structure' no local effects are anticipated.
In the case of an infant chewing an off-cut or licking a playground structure, light and transient irritation of oral mucosa is not excluded due to the content of monoethanolamine. However, this effect is of minor importance. In addition, these scenarios are considered uncommon occurrences as parents usually do not allow children to chew preservative treated wood or to lick larger areas on a daily basis.
The estimated indoor concentration of monoethanolamine due to volatilized residues (0.0031 mg/m^3) is much lower than the limit for workplace exposure (2.5 mg/m^3). Therefore no respiratory irritation is expected.

Conclusion
The risk for the general public is acceptable.

Risk for consumers via residues in food

No residues in food are anticipated as the treated wood should not be used for the manufacture of articles coming into contact with food, beverages, drinking water or feed.

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

Tier 1[44]

Risk characterisation from combined exposure: Tier 1						
Scenario number	**Scenario**	**PPE**	**Estimated uptake / AEL (%)**			**Acceptable (yes/no)**
			Copper	Propi-conazole	Tebu-conazole	
1	Vacuum pressure treatment	Gloves, coverall, eye protection	54	0.60	29	Yes
2	Sanding (professional)	No	13	0.28	3.2	Yes
3	Sanding (non-professional)	No	3.4	0.013	3.0	Yes

[44] Tier 1, 2 and 3 as defined in the Guidance on BPR Vol. IIIB, section 4.4.1

Risk characterisation from combined exposure: Tier 1						
4	Child on a playground structure	Not relevant	10	0.11	5.7	Yes
5	Infant chewing an off-cut	Not relevant	113	2.2	22	Yes[41]
7	Infant on a playground structure	Not relevant	16	0.17	8.3	Yes

Conclusion on Tier 1
Risk assessment is acceptable for each substance individually in the product (with or without PPE as specified in the table).

Tier 2

No information on synergy of combinations of copper with azole fungicides has been found. In the lack of information, additivity of effects will be assumed.

Risk characterisation from combined exposure: Tier 2					
Scenario number	**Scenario**	**PPE**	**Estimated uptake / AEL**	**Hazard quotient**	**Acceptable (yes/no)**
			Copper + Propiconazole + Tebuconazole	Copper + Propiconazole + Tebuconazole	
1	Vacuum pressure treatment	Gloves, coverall, eye protection	84	0.84	Yes
2	Sanding (professional)	No	16	0.16	Yes
3	Sanding (non-professional)	No	6.4	0.06	Yes
4	Child on a playground structure	n.r.	16	0.16	Yes
5	Infant chewing an off-cut	n.r.	**137**	**1.37**	No
7	Infant on a playground structure	n.r.	24	0.24	Yes

Conclusion on Tier 2
Risk assessment is not acceptable for the scenario 'Infant chewing an off-cut'. It has been noted that the extraction factor used in the respective scenario is likely to be an overestimation and that the scenario is considered as an accidental, uncommon occurrence. Nevertheless, a Tier 3 assessment will be performed.
For the remaining scenarios the risk is acceptable.

Tier 3

In tier 3 primarily the copper and tebuconazole NOAELs have to be investigated as the contribution of propiconazole to Σ HI is insignificant.
The AELacute for copper was derived from a subchronic study and the AELacute for tebuconazole was derived from a chronic study. This indicates that the AELacute values for both compounds may an overestimation. In addition, for tebuconazole an allometric scaling factor of 4 was used, although for extrapolation from a dog study a factor of 1.4 would be more appropriate (BPR guidance, vol. IIIB, April 2015, p. 177).

The NOAELs for individual organs		
Target organ / Mode of action	**NOAEL (AEL)**	
	Copper (subchronic)	Tebuconazole (chronic)
Liver	34 mg/kg bw/d (0.68 mg/kg bw/d)	–
Kidney	16.3 mg/kg bw/d (0.082 mg/kg bw/d)	–
Spleen	15.2-35.2 mg/kg bw/d (0.076-0.176 mg/kg bw/d)	–
Adrenals	–	3 mg/kg bw/d (0.03 mg/kg bw/d)
Overall AEL	0.082 mg/kg bw/d (kidney effect)	0.03 mg/kg bw/d (histopathological alterations in the adrenal cortex)

Tier 3A
As the target organs used for AEL derivation differ, the HQs do not have to be summed up. Therefore the risk is deemed acceptable.

2.2.7 Risk assessment for animal health

The treated wood is not intended for the manufacture of articles coming into contact with feed or drinking water.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

PNEC	Copper	Propiconazole	Tebuconazole
$PNEC_{STP}$	0.23 mg/l	1.0 mg/l	0.32 mg/l
$PNEC_{surface\ water}$	7.8 µg/l	1.6 µg/l	1.0 µg/l
$PNEC_{sediment}$	18.9 mg/kg wwt	0.054 mg/kg wwt	0.55 mg/kg wwt
$PNEC_{soil}$[45]	40.35 mg/kg wwt	0.1 mg/kg wwt	0.10 mg/kg wwt

Bioaccumulation: Because of the homeostasis of metals, copper is not considered bioaccumulative.
The bioaccumulation potential of propiconazole and tebuconazole is low. Experimentally derived bioconcentration factors in fish are 180 and 78 with relatively short depuration half-lives of 0.48 d and 0.44 days, respectively.

Information relating to the ecotoxicity of the biocidal product necessary for product classification

There are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected. Therefore the classification of the mixture can be made according to the rules laid down in Reg. (EC) 1272/2008.

Active substance / Substance of concern	**Classification**	**Toxicity estimate**	**Readily biode-gradable (yes/no)**	**M-factor**	**Concen-tration in the product**
Basic copper carbonate	Aquatic Acute 1 (H400)	Not available	No	–	20% Cu: 11.5%
	Aquatic Chronic 1 (H410)	NOEC 2.2 µg/l (Cu)		M=10	
Propiconazole	Aquatic Acute 1 (H400)	ErC_{50} 0.058 mg/l	No	M=10	0.3%
	Aquatic Chronic 1 (H410)	NOEC 0.016 mg/l		M=1	
Tebuconazole	Aquatic Acute 1 (H400)	ErC_{50} 0.237 mg/l	No	M=1	0.3%
	Aquatic Chronic 1 (H410)	NOEC 0.01 mg/l		M=10	

The resulting environmental classification of the product: Aquatic Chronic 1 (H410)

Further toxicological studies

No data is available. The data on the active substances give sufficient information.

[45] For propiconazole the more recent $PNEC_{soil}$ from AR PT 9 will be used.

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

Please refer to the subsection *Fate and distribution in exposed environmental compartments* under 2.2.8.2.

Further studies on fate and behaviour in the environment

No data is available. The fate of the components in the product is covered by the data provided for the active substances.

Leaching behaviour

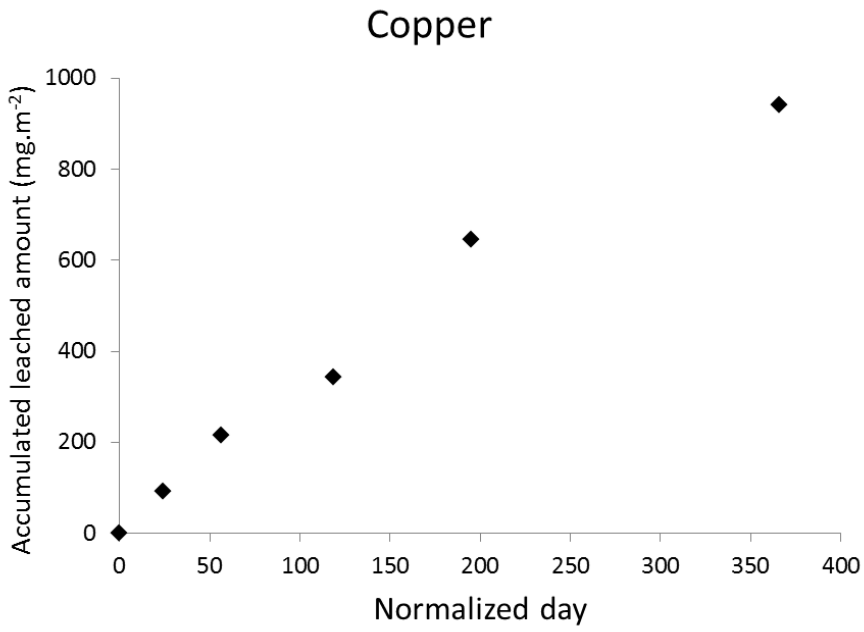
Two leaching studies have been submitted by the applicant: one for the part above ground and one for the part below ground. The latter study was submitted in 2017 to refine the exposure assessment for use class 4.

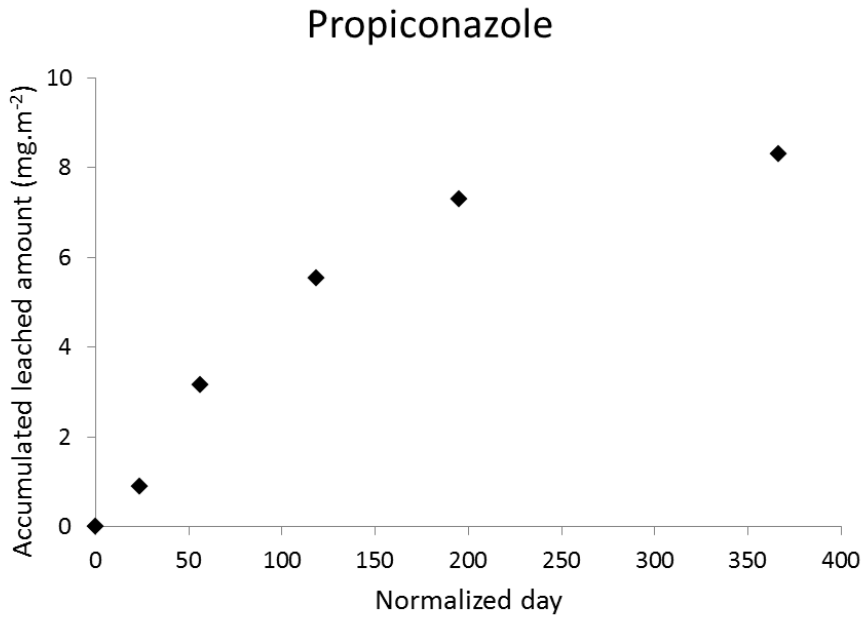
Leaching study for the part above ground

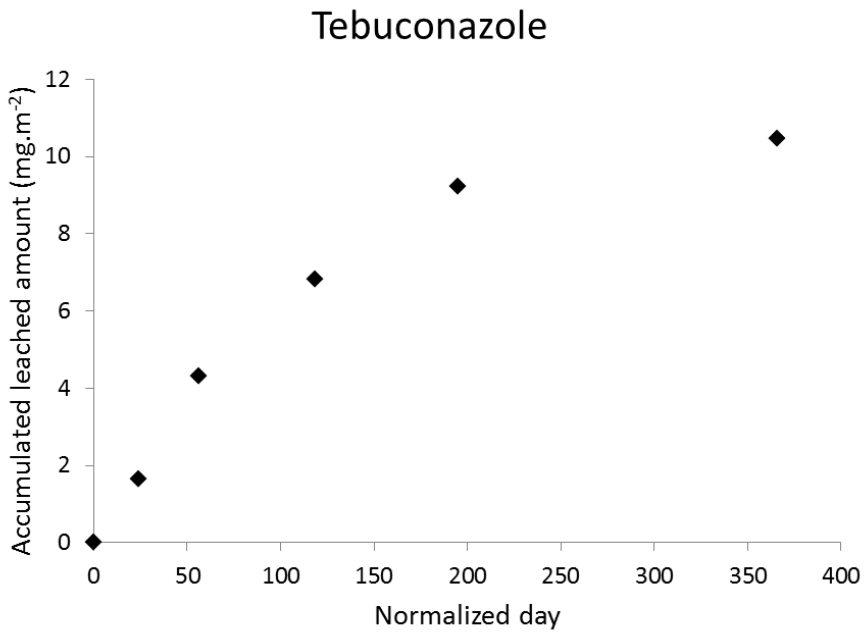
The leaching behaviour of the active substances from treated timber above ground was investigated in a semi-field leaching study (Klamer et Venås, 2013) carried out according to NT BUILD 509. The study was performed on vacuum pressure treated wood test specimens. The average product retention was 10.1 kg/m^3.

The duration of the study was 554 days, during which 702.9 mm of rain accumulated. Concetrations of the active substances in the leachate solutions were determined after 46, 108, 227, 375, and 703 mm of rainfall. From a.s. concentrations and leachate volumes the leached amounts were calculated. A graphic representation of the data is shown below the table. 'Normalized days' are proportional to accumulated rainfall; the standard annual rainfall is 700 mm (TGD part II, p. 88).

Results of the leaching study					
Days since start	**Accumulated rainfall (mm)**	**Normalized days**	**Leached amount of active substance (mg.m^{-2})**		
			Copper	Propiconazole	Tebuconazole
48	46.0	24	91.1	0.893	1.64
linear interpolation		*30*	*114*	*1.32*	*2.14*
63	107.7	56.2	124	2.27	2.67
153	227.3	118.5	128	2.37	2.51
248	375.4	195	302	1.76	2.40
554	702.9	366.2	297	1.0	1.24
Total amount leached (mg.m^{-2})			944	8.29	10.46


Copper
Accumulated leached amount (mg.m-2)
1000
800
600
400
200
0
0
50
100
150
200
250
300
350
400
Normalized day


Propiconazole
Accumulated leached amount (mg.m-2)
10
8
6
4
2
0
0
50
100
150
200
250
300
350
400
Normalized day



Leaching rates for Time 1 (the first 30 days) have been calculated using linear interpolation. An example calculation for copper is given below:

$91.1 + (30–24)/(56.2–24) \times 124 = 114$ mg.m^{-2}

The simplest method of leaching rate calculation for Time 2 (20 years = 7300 days) is linear extrapolation. It is assumed that the flux during the last period of the study (normalized days 195 to 366) remains constant during the whole remaining period (days 367 to 7300). This assumption is conservative as the flux tends to decrease with time.
Example calculations for copper:

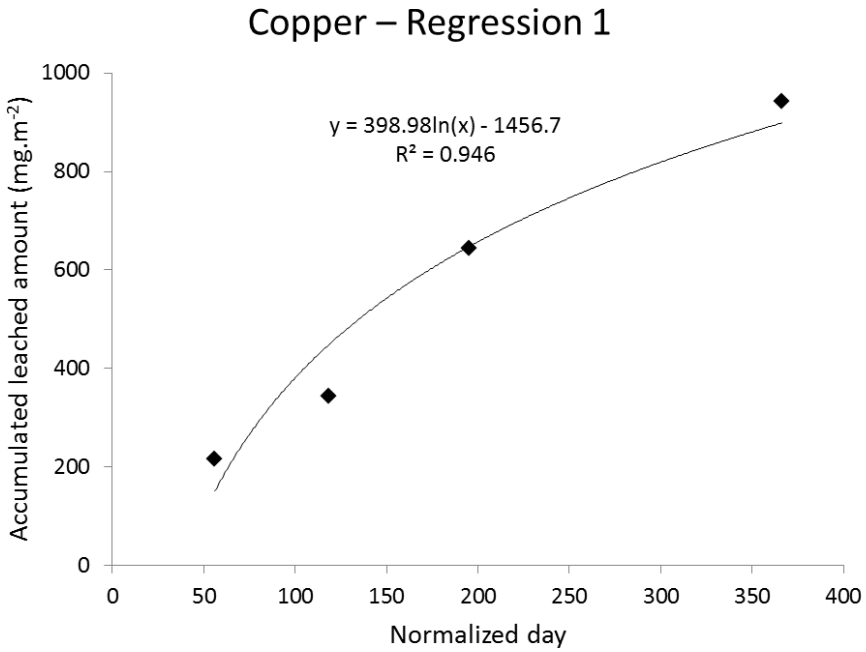
Flux: $297/(366.2–195) = 1.73$ mg.m^{-2}.d^{-1}

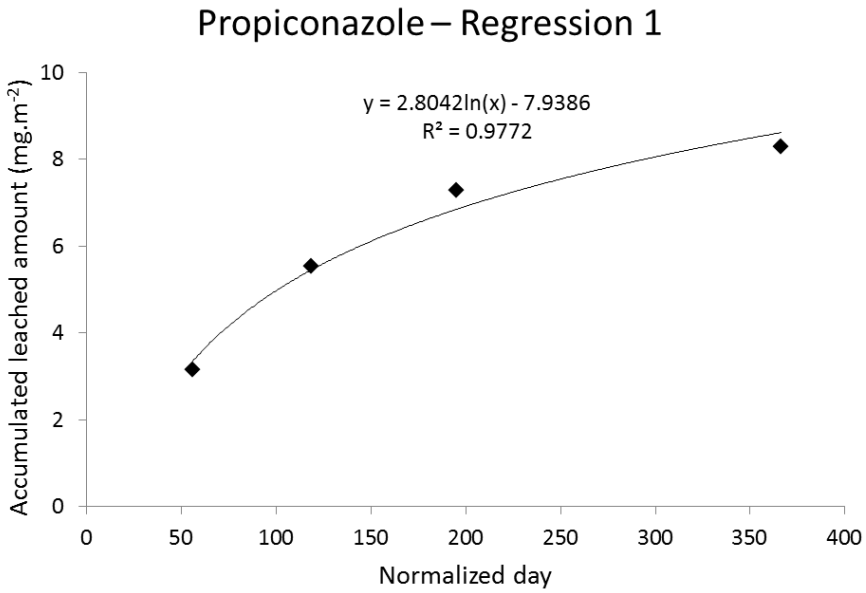
Amount leached: $944 + 1.73 \times (7300–366.2) = 12\,939$ mg.m^{-2}

A more refined approach, further referred to as Regression 1, was suggested by the applicant. The accumulated leached amount has been plotted versus normalised time and fitted with logarithmic regression in the following form:

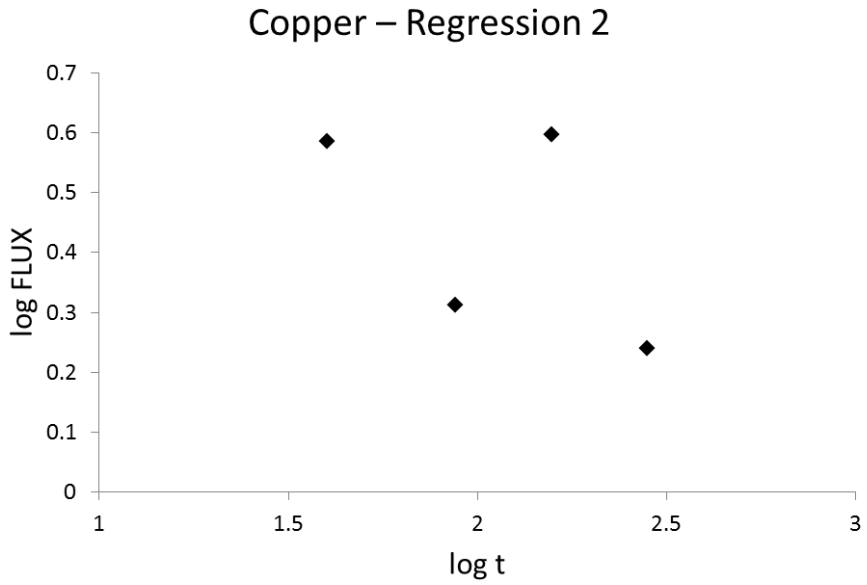
$$y = a \cdot \ln t + b \ .$$

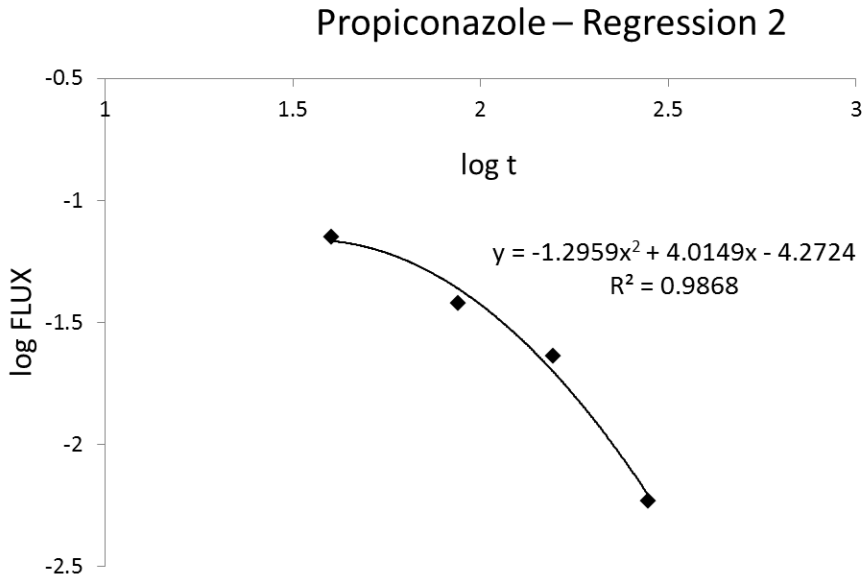
The first point (normalized day 24) has not been included. The amount leached during Time 2 has been calculated from the regression function. The graphs for copper and propiconazole are shown in Figure 2; the plot for tebuconazole is similar to that of propiconazole. The plot for copper indicates that for copper this model may lead to emission underestimation. On the other hand, for propiconazole and tebuconazole the regression curve fits the data satisfactorily. This conclusion could only be drawn from visual inspection as there are not enough data points for appropriate statistical procedures to be performed.

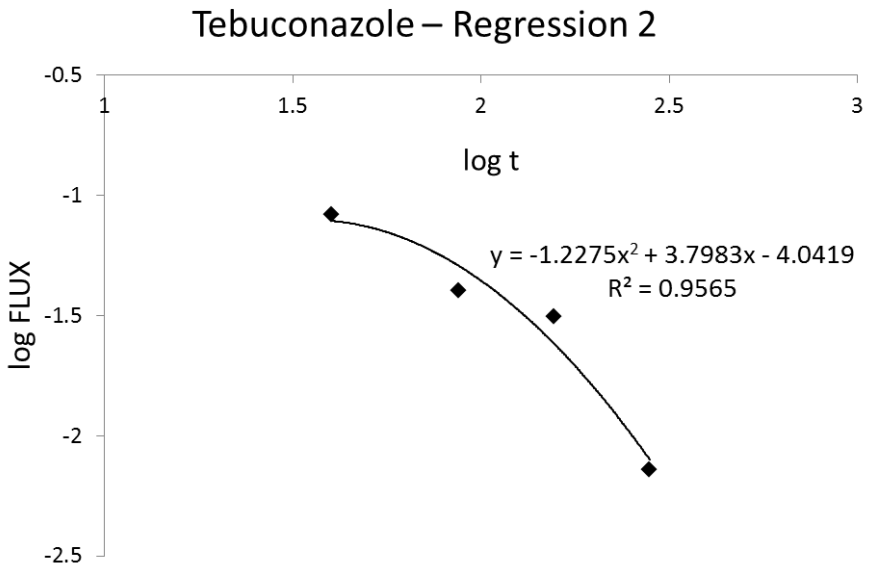




Yet another empirical model for extrapolation beyond the testing period, further referred to as Regression 2, is described in ESD (p. 149-154). The procedure consists of calculating the daily flux, plotting the flux vs. time on a logaritmic scale, and fitting the data with a second-order polynomial regression. The final estimate is obtained by numerical integration. The plots are shown below. The first point (normalized day 24) has not been included.


Copper – Regression 2
log FLUX
log t
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
1
1.5
2
2.5
3


Propiconazole – Regression 2
log FLUX
log t
y = -1.2959x² + 4.0149x - 4.2724
R² = 0.9868
-0.5
-1
-1.5
-2
-2.5
1
1.5
2
2.5
3



The flux values for copper are too scattered to allow fitting with a regression function. For propiconazole and tebuconazole the model is appropriate. According to ESD, the resultant function *FLUX(t)* does not yield reliable results when *t* approaches zero (the artefact of 'zero region'; see ESD, p. 153). Therefore, the total amount leached during the leaching study is used for days 1 to 366, and the flux values from the regression model for days 367 to 7 300 are added. The results are listed in the following table.

Leached amounts for Time 1 and 2: product retention 10.1 kg/m^3			
Time	**Total amount leached (mg.m^{-2})**		
	Copper	Propiconazole	Tebuconazole
Time 1	114	1.32	2.14
Time 2 (linear extrapolation)	12 900	49.0	60.7
Time 2 (Regression 1)	2 090	17.0	20.9
Time 2 (Regression 2)	–	8.85	11.3

Regression 1 gives approximately 3 times lower results for propiconazole and tebuconazole than linear extrapolation; in case of Regression 2 the decrease is 5-fold. The value for copper from Regression model 1 is not sufficiently reliable as it may lead to emission underestimation.
Conservatively, the linear extrapolation values will be used in the risk assessment. If the results lead to an unacceptable risk, use of values from Regression models 1 and 2 will be considered.

As a higher amount of the product was applied in the test (10.1 kg/m^3) than that recommended for Use class 3 (7.4 kg/m^3), and lower than that recommended for Use class 4a (14 kg/m^3), corrections have to be made for the respective application rates.
However, for Use class 4a the leaching rates are applicaple only for the part above ground. For the part below ground no leaching study has been submitted and, as a result, only conservative Tier 1 emission calculations could be performed.

The corrected values are given in the following tables.

Leached amounts for Time 1 and 2: product retention 7.4 kg/m^3			
Time	**Total amount leached (mg.m^{-2})**		
	Copper	Propiconazole	Tebuconazole
Time 1	83.5	0.97	1.57
Time 2 (linear extrapolation)	9 450	35.9	44.5
Time 2 (Regression 1)	1 530	12.5	15.3
Time 2 (Regression 2)	–	6.48	8.28

Leached amounts for Time 1 and 2: product retention 14 kg/m^3			
Time	**Total amount leached (mg.m^{-2})**		
	Copper	Propiconazole	Tebuconazole
Time 1	158.02	1.83	2.97
Time 2 (linear extrapolation)	17 935.25	67.92	84.14
Time 2 (Regression 1)	2 897.03	23.56	28.97
Time 2 (Regression 2)	–	12.27	15.66

Leaching study for the part below ground

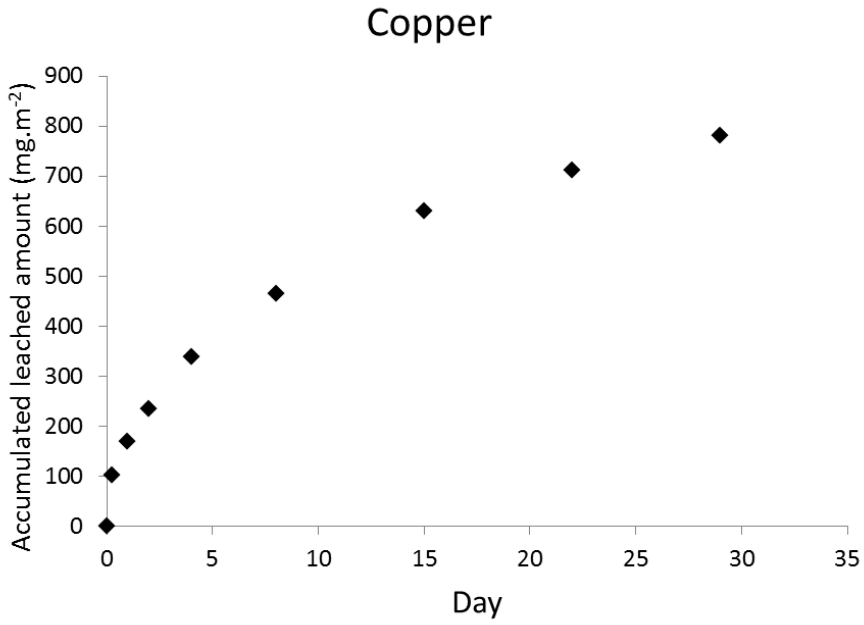
Leaching behaviour of the active substances from treated wood below ground was investigated in a laboratory leaching study according to CEN/TS 15119-2 (Vaněk and Ptáček, 2016; Samsonek and Gerych, 2016). This study was commissioned by the applicant in order to refine the emission estimates for use class 4a.

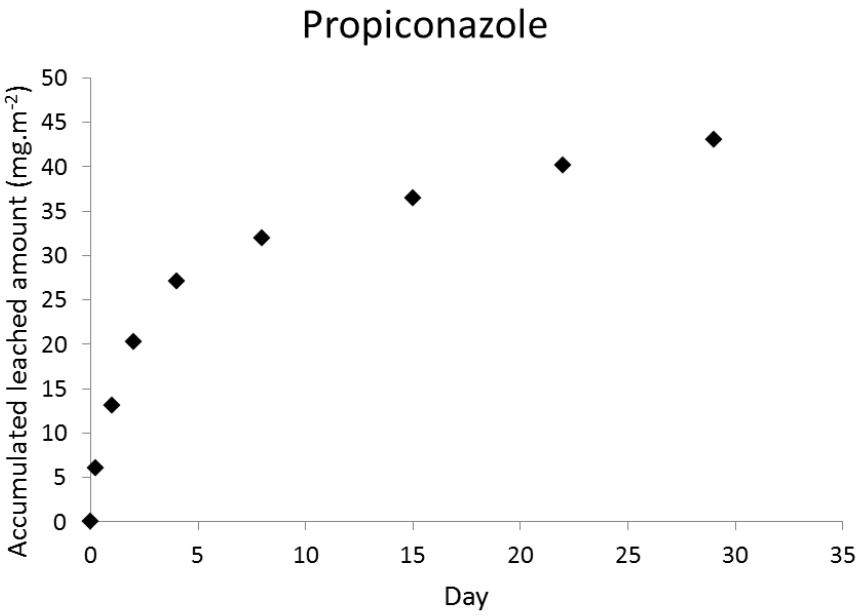
Two sets of of treated specimens (5 pieces per set, exposed surface 200 cm^2 per set) had been treated by a vacuum pressure process. The retentions achieved (mean 14.6 kg/m^3) were slightly higher than the recommended application rate for use class 4 of 14 kg/m^3, but no correction for application rate is considered necessary as the difference is small and the correction would lead to a lower emission estimate.

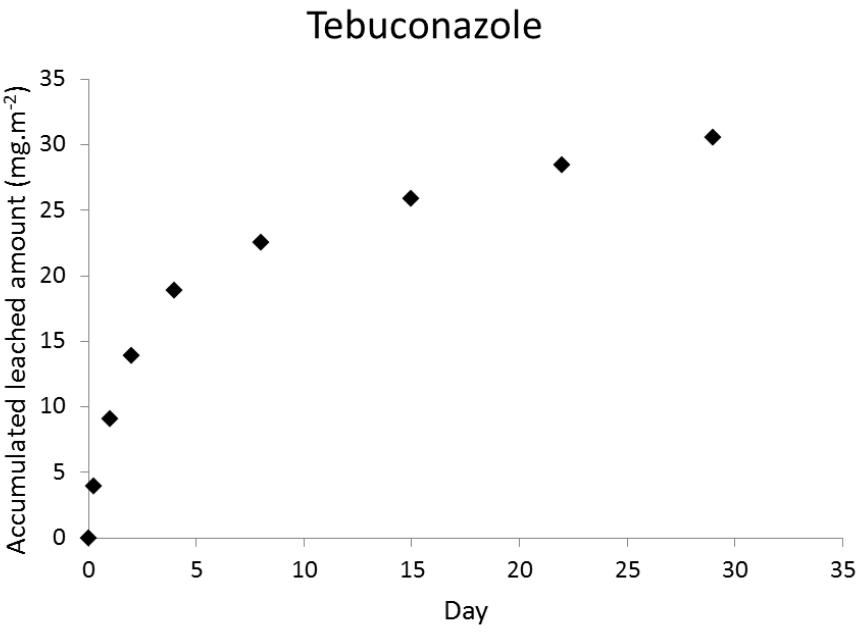
Each set was immersed in 500 ml of distilled water. The water was replaced at the following time points: 6 hours, 1 day, 2 days, 4 days, 8 days, 15 days, 22 days and 29 days. The leachates were analysed for the content of the active substances. Calculation of leaching rates is given in Annex 3.2. Results are presented in the table below.

Results of the leaching study			
Time (day)	**Leached amount of the active substance(mg.m^{-2})**		
	Copper	Propiconazole	Tebuconazole
0.25	102.8	6.067	3.929
1	66.5	7.075	5.138
2	65.8	7.188	4.813
4	104.3	6.738	4.963
8	126.1	4.838	3.700
15	164.3	4.550	3.338
22	82.6	3.663	2.538
29	68.3	2.975	2.163
Total amount leached (mg.m^{-2})	780.6	43.092	30.579

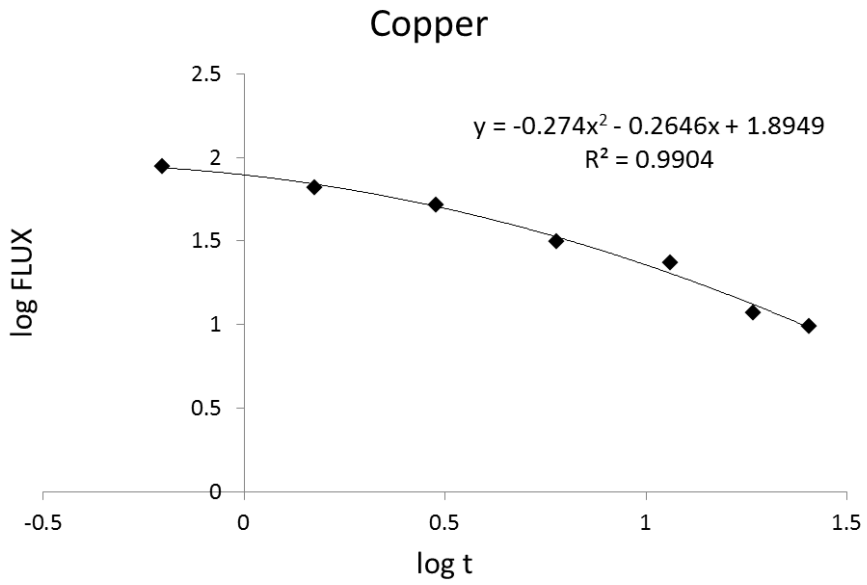
Cumulative leached amounts are plotted in the following graphs.

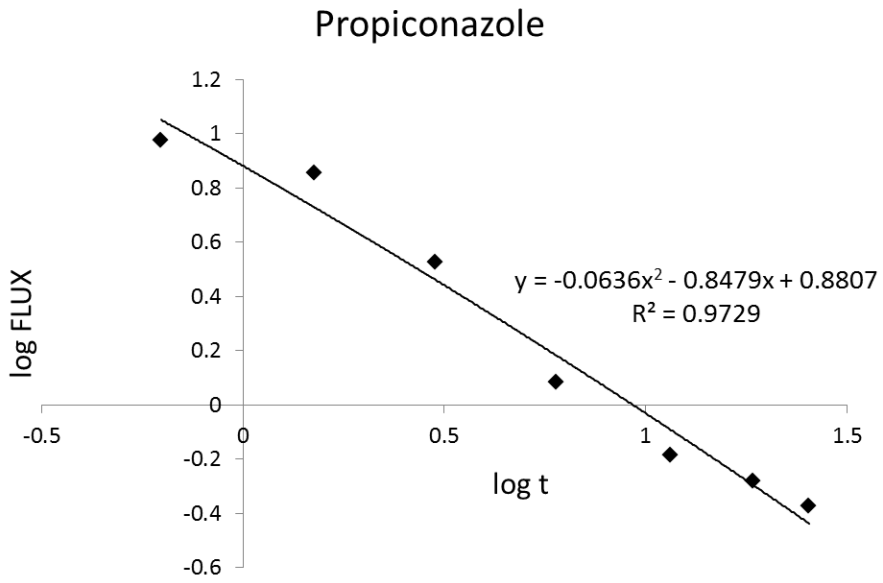


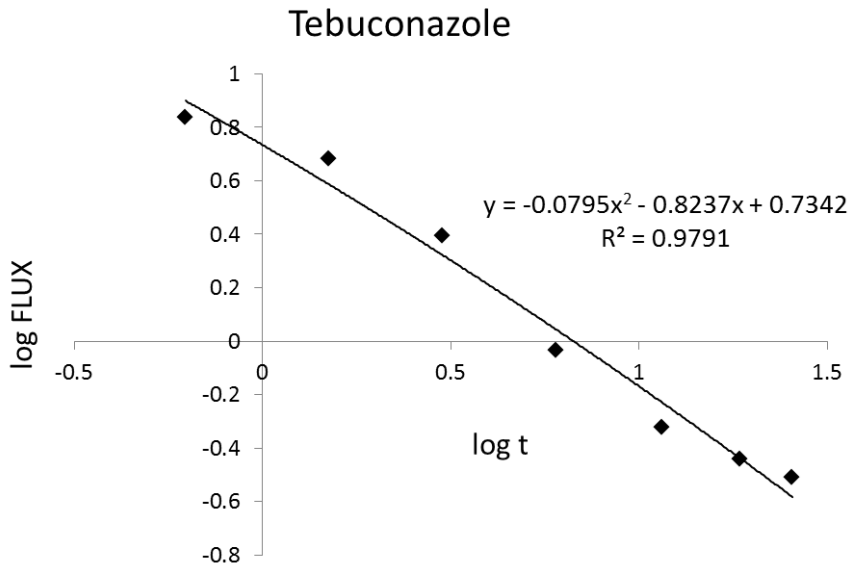




Extrapolation to Time 1 (30 days) and Time 2 (20 years = 7300 days) has been performed according to the procedure described in the ESD (p. 149-154), referred to as Regression 2 in the previous leaching study. The plots are shown below. The first point (0.25 d) has not been included.


Copper
y = -0.274x² - 0.2646x + 1.8949
R² = 0.9904
log FLUX
log t
2.5
2
1.5
1
0.5
0
-0.5
0
0.5
1
1.5


Propiconazole
y = -0.0636x² - 0.8479x + 0.8807
R² = 0.9729
log FLUX
log t
1.2
1
0.8
0.6
0.4
0.2
0
-0.2
-0.4
-0.6
-0.5
0
0.5
1
1.5



As the model does not give reliable results when time approaches zero, for days 1 to 29 the experimentally measured values have been used ('total amount leached'), and for days 30 to 7300 the extrapolated values from the regression model have been added. The results are listed in the following table.

Leached amounts for Time 1 and 2			
Time	**Total amount leached (mg.m^{-2})**		
	Copper	Propiconazole	Tebuconazole
Time 1	789	43.4	30.8
Time 2	1330	79.7	54.3

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 8
Assessed scenarios	Scenario 1: House Scenario 2: Noise barrier Scenario 3: Transmission pole
ESD(s) used	Revised emission scenario document for wood preservatives, 2013
Approach	Scenarios 1, 2: Leaching rates Scenarios 3: Leaching rates, in tier 1 alsoapplied amount
Distribution in the environment	Calculated based on TGD 2003
Groundwater simulation	Scenario 1: FOCUS PEARL 4.4.4 Scenarios 2, 3: not required

Confidential Annexes	No
Life cycle steps assessed	Scenarios 1, 2, 3: Production: No Formulation: No Use: No Service life: Yes
Remarks	–

Emissions during individual life cycle stages

Emissions to the environment can occur during the following product life-cycle stages:

1. application
2. storage
3. mechanical processing of treated wood
4. service life of the treated wood
5. disposal of the treated wood

Application

The product is intended exclusively for industrial application via vacuum pressure treatment. The Annex I inclusion directives for all the active substances state that any losses from the application of the product must be collected for reuse or disposal. According to the EU waste legislation, the application solutions as well as the product are considered hazardous waste and they must not be released to soil, surface water or any kind of sewer. These obligations shall be indicated on the product label and in safety data sheets. The prohibition of release of the collected waste water to a sewage treatment plant in the EU is also reflected in the ESD (p. 38, 46, 52). Emissions via volatilization can be regarded as negligible as vapour pressure of all the active substances is below 0.005 Pa (see ESD, p. 43). Consequently, the application phase is not considered as relevant for the environmental exposure assessment.

Storage

The Annex I inclusion directives for all the active substances state that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water. This obligation must be indicated on the product label and in safety data sheets. Therefore no exposure calculations are required for the storage phase.

Mechanical processing of treated wood

During mechanical processing of the treated wood all the remains should be collected and disposed of as waste. Thus no significant emissions are expected at this stage.

Service life

PECs related to the service life of the treated wood are to be calculated. Only PEC values for Use classes 3 and 4 have to be estimated as the potential emissions to the outer environment from treated wood in Use classes 1 and 2 are considered negligible (ESD, p. 66).

Disposal of the treated wood

Wood waste at the end of its life cycle is burned or stored in landfills. Its direct discarding into the environment is prohibited. Thus waste is not a significant source of the active ingredients of the active substances to the environment.

Emission scenarios

For Use class 1 and 2 the potential emissions from treated wood to the outer environment are considered negligible (ESD, p. 66).

For Use class 3 four basic emission scenarios are described in the ESD: House, Fence, Bridge over pond, and Noise barrier (ESD, p. 22). The Fence scenario for Use class 3 is covered by the House scenario (ESD, p. 69). The Bridge over pond scenario will not be included in the assessment as basic copper carbonate use in outdoor constructions near or above water is prohibited by the respective Annex I inclusion directive. This restriction must be indicated on the product label.

For Use class 4a (wood in contact with ground) there are two scenarios in ESD: Transmission pole and Fence post. The Fence post scenario is covered by the Transmission pole scenario (i.e. the Fence post scenario always yields lower emission estimates than the Transmission pole scenario; ESD, p. 77). Therefore the Fence post scenario has not been included in the present assessment.

Emission estimation according to the Transmission pole scenario was performed in two tiers. In the first tier, due to an initial absence of a leaching study for the part below ground default assumptions for leached amount had to be employed, i.e. 50% of the applied amount from the part below ground during Time 1 and 100% during Time 2. As the resulting PEC/PNEC in soil was above 1 for propiconazole and tebuconazole at Time 1 and for mixture toxicity at Time 2, the applicant commissioned a leaching study for the part below ground according to an appropriate method. The leaching rates from this study (Vaněk and Ptáček, 2016) were used to obtain a refined (tier 2) emission estimate.

The treated wood is not intended to be used in Use classes 4b and 5.

An overview of the emission scenarios used and of the corresponding environmental compartments is given in the table below. PECs only have to be calculated for the compartments written in bold as they are considered the worst-case scenarios for the respective compartments. According to ESD, groundwater assessment is only necessary for the house scenario, which can be regarded as the worst-case for soil exposure (ESD, p. 176).

Use class	Emission scenario	Compartments affected
UC 3	House	**Soil**
		Groundwater (leaching from soil)
	Noise barrier	Soil (direct)
		Soil (via STP sludge)
		Groundwater (leaching from soil)
		STP
		Surface water (via STP effluent)
		Sediment (via STP effluent)
UC 4a	Transmission pole	**Soil**
		Groundwater (leaching from soil)

Emission estimation

Scenario 1a: House (for calculation of PECsoil)

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario: House				
Leachable wood area	$AREA_{house}$	125	m^2	ESD, Table 4.15
Duration of the initial assessment period	TIME1	30	d	ESD, Table 4.15
Duration of the long-term assessment period	TIME2	7300	d	ESD, p. 68
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the initial assessment period	$Q^*_{leach,time1}$	Cu: 83.5 Prop.: 0.97 Teb.: 1.57	$mg.m^{-2}$	See 'Leaching behaviour'
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the longer assessment period	$Q^*_{leach,time2}$	Cu: 9 450 Prop.: 35.9 Teb.: 44.5	$mg.m^{-2}$	See 'Leaching behaviour'
Soil volume (wet)	V_{soil}	13	m^3	ESD, Table 4.15
Bulk density of wet soil	RHO_{soil}	1700	$kg_{wwt}.m^{-3}$	ESD, Table 4.15

Calculations for Scenario 1a – House

Output	**Symbol**	**Value**	**Unit**	**Equation No.**
Cumulative quantity of substance, leached over the initial assessment period	$Q_{leach,time1}$	Cu: 10 438 Prop.: 121.3 Teb.: 196.3	mg	ESD, (4.43)
Cumulative quantity of substance, leached over the longer assessment period	$Q_{leach,time2}$	Cu: 1 181 250 Prop.: 4 488 Teb.: 5 563	mg	ESD, (4.44)
Concentration in local soil at the end of the initial assessment period	$Clocal_{soil,leach,time1}$	Cu: 0.472 Prop.: $5.49 \cdot 10^{-3}$ Teb.: $8.88 \cdot 10^{-3}$	$mg.kg_{wwt}^{-1}$	ESD, (4.45)
Concentration in local soil at the end of the longer assessment period	$Clocal_{soil,leach,time2}$	Cu: 53.5 Prop.: 0.203 Teb.: 0.252	$mg.kg_{wwt}^{-1}$	ESD, (4.46)

Output	Symbol	Value	Unit	Equation No.
Average daily emission of substance due to leaching over the initial assessment period	$E_{soil,leach,time1}$	Cu: 347.9 Prop.: 4.042 Teb.: 6.542	$mg.d^{-1}$	ESD, (3.5)
Average daily emission of substance due to leaching over the longer assessment period	$E_{soil,leach,time1}$	Cu: 161.8 Prop.: 0.615 Teb.: 0.762	$mg.d^{-1}$	ESD, (3.6)

Scenario 1b: House (for calculation of PECgroundwater using FOCUS PEARL)

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario: House (groundwater)				
Leachable wood area per hectare	$AREA_{total}$	2000	$m^2.ha^{-1}$	ESD, p. 176
Duration of the longer assessment period	TIME2	20	y	ESD, p. 177
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the longer assessment period	$Q^*_{leach,time2}$	Prop.: 0.0359 Teb.: 0.0445	$g.m^{-2}$	See 'Leaching behaviour'
Fraction of house surface exposed to weather	$F_{weatherside}$	0.5	–	ESD, p. 177

Calculations for Scenario 1b – House (groundwater)

Output	Symbol	Value	Unit	Equation
Annual application rate per hectar	–	Prop.: 1.80 Teb.: 2.23	$g.ha^{-1}.y^{-1}$	$(AREA_{total} \times Q^*_{leach,time2} / TIME2) \times F_{weatherside}$

Scenario 2: Noise barrier

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario: Noise barrier				
Leachable wood area	$AREA_{noise\text{-}barrier}$	3000	m^2	ESD, Table 4.17
Duration of the initial assessment period	TIME1	30	d	ESD, Table 4.17

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Duration of the long-term assessment period	TIME2	7300	d	ESD, p. 68
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the initial assessment period	$Q^*_{leach,time1}$	Cu: 83.5 Prop.: 0.97 Teb.: 1.57	$mg.m^{-2}$	See 'Leaching behaviour'
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the longer assessment period	$Q^*_{leach,time2}$	Cu: 9 450 Prop.: 35.9 Teb.: 44.5	$mg.m^{-2}$	See 'Leaching behaviour'
Fraction released to the STP	F_{STP}	0.7	–	ESD, Table 4.17

Calculations for Scenario 2 – Noise barrier

Output	**Symbol**	**Value**	**Unit**	**Equation No.**
Local daily emission rate to the STP following leaching from treated wood during the initial assessment period	$E_{STP,time1}$	Cu: 5 845 Prop.: 67.90 Teb.: 109.9	$mg.d^{-1}$	ESD, (4.55)
Local daily emission rate to the STP following leaching from treated wood during the longer assessment period	$E_{STP,time2}$	Cu: 2 718 Prop.: 10.33 Teb.: 12.80	$mg.d^{-1}$	ESD, (4.56)

Scenario 3: Transmission pole (tier 1)

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario: Transmission pole				
Leachable wood area above soil	$AREA_{pole,above}$	5.5	m^2	ESD, Table 4.19
Leachable wood area below soil	$AREA_{pole,below}$	1.6	m^2	ESD, Table 4.19
Duration of the initial assessment period	TIME1	30	d	ESD, Table 4.19
Duration of the long-term assessment period	TIME2	7300	d	ESD, p. 68

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the initial assessment period	$Q^*_{leach,time1}$	Cu: 158.02 Prop.: 1.83 Teb.: 2.97	$mg.m^{-2}$	See 'Leaching behaviour'
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the longer assessment period	$Q^*_{leach,time2}$	Cu: 17 935.25 Prop.: 67.92 Teb.: 84.14	$mg.m^{-2}$	See 'Leaching behaviour'
Soil volume (wet)	V_{soil}	2.97	m^3	ESD, Table 4.19
Bulk density of wet soil	RHO_{soil}	1700	$kg_{wwt}.m^{-3}$	ESD, Table 4.19
Volume of the part below soil	$V_{pole,below}$	0.098	m^3	Calculated using the dimensions in ESD, p. 77
Application rate of the product	AR	14	kg/m^3	Use class 4a
Active substance content in the product	F_{ai}	Cu: 11.5 Prop.: 0.3 Teb.: 0.3	%	–
Fraction of the applied amount leached out of the part below soil over the initial assessment period	$F_{leach,time1}$	50	%	Tier 1
Fraction of the applied amount leached out of the part below soil over the longer assessment period	$F_{leach,time2}$	100	%	Tier 1

Calculations for Scenario 3 – Transmission pole (tier 1)

Output	**Symbol**	**Value**	**Unit**	**Equation**
Cumulative quantity of substance, leached over the initial assessment period from the part above ground	$Q_{leach,above,time1}$	Cu: 869.11 Prop.: 10.065 Teb.: 16.335	mg	$AREA_{pole,above} \times Q^*_{leach,time1}$

Output	Symbol	Value	Unit	Equation
Cumulative quantity of substance, leached over the longer assessment period from the part above ground	$Q_{leach,above,time2}$	Cu: 98 643.88 Prop.: 373.56 Teb.: 462.77	mg	$AREA_{pole,above} \times Q^*_{leach,time2}$
Cumulative quantity of substance, leached over the initial assessment period from the part below ground	$Q_{leach,below,time1}$	Cu: 78 890 Prop.: 2 058 Teb.: 2 058	mg	$V_{pole,below} \times AR \times (F_{ai}/100) \times (F_{leach,time1}/100) \times 10^6$
Cumulative quantity of substance, leached over the longer assessment period from the part below ground	$Q_{leach,below,time2}$	Cu: 157 780 Prop: 4 116 Teb.: 4 116	mg	$V_{pole,below} \times AR \times (F_{ai}/100) \times (F_{leach,time2}/100) \times 10^6$
Cumulative quantity of substance, leached over the initial assessment period	$Q_{leach,time1}$	Cu: 79 759.11 Prop.: 2 068.065 Teb.: 2 074.335	mg	$Q_{leach,above,time1} + Q_{leach,below,time1}$
Cumulative quantity of substance, leached over the longer assessment period	$Q_{leach,time2}$	Cu: 256 423.9 Prop.: 4 489.56 Teb.: 4 578.77	mg	$Q_{leach,above,time2} + Q_{leach,below,time2}$
Concentration in local soil at the end of the initial assessment period	$Clocal_{soil,leach,time1}$	Cu: $1.58 \cdot 10^1$ Prop.: $4.10 \cdot 10^{-1}$ Teb.: $4.11 \cdot 10^{-1}$	$mg.kg_{wwt}^{-1}$	ESD, (4.69)
Concentration in local soil at the end of the longer assessment period	$Clocal_{soil,leach,time2}$	Cu: $5.08 \cdot 10^1$ Prop.: $8.89 \cdot 10^{-1}$ Teb.: $9.07 \cdot 10^{-1}$	$mg.kg_{wwt}^{-1}$	ESD, (4.70)
Average daily emission of substance due to leaching over the initial assessment period	$E_{soil,leach,time1}$	Cu: $2.66 \cdot 10^3$ Prop.: 68.9355 Teb.: 69.1445	$mg.d^{-1}$	$Q_{leach,time1}$ / TIME1

Output	Symbol	Value	Unit	Equation
Average daily emission of substance due to leaching over the longer assessment period	$E_{soil,leach,time1}$	Cu: $3.51 \cdot 10^{1}$ Prop.: 0.615 Teb.: 0.6272	$mg.d^{-1}$	$Q_{leach,time2}$ / TIME2

Scenario 3: Transmission pole (tier 2)

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario: Transmission pole				
Leachable wood area above soil	$AREA_{pole,above}$	5.5	m^2	ESD, Table 4.19
Leachable wood area below soil	$AREA_{pole,below}$	1.6	m^2	ESD, Table 4.19
Duration of the initial assessment period	TIME1	30	d	ESD, Table 4.19
Duration of the long-term assessment period	TIME2	7300	d	ESD, p. 68
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the initial assessment period for the part above ground	$Q^*_{leach,above,time1}$	Cu: 158 Prop.: 1.83 Teb.: 2.97	$mg.m^{-2}$	See 'Leaching behaviour'
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the longer assessment period for the part above ground	$Q^*_{leach,above,time2}$	Cu: 17 935 Prop.: 67.9 Teb.: 84.1	$mg.m^{-2}$	See 'Leaching behaviour'
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the initial assessment period for the part below ground	$Q^*_{leach,below,time1}$	Cu: 789 Prop.: 43.4 Teb.: 30.8	$mg.m^{-2}$	See 'Leaching behaviour'
Cumulative quantity of substance leached out of 1 m^2 of treated wood over the longer assessment period for the part below ground	$Q^*_{leach,\ below,time2}$	Cu: 1330 Prop.: 79.7 Teb.: 54.3	$mg.m^{-2}$	See 'Leaching behaviour'
Soil volume (wet)	V_{soil}	2.97	m^3	ESD, Table 4.19
Bulk density of wet soil	RHO_{soil}	1700	$kg_{wwt}.m^{-3}$	ESD, Table 4.19

Calculations for Scenario 3 – Transmission pole (tier 2)

Output	Symbol	Value	Unit	Equation
Cumulative quantity of substance, leached over the initial assessment period from the part above ground	$Q_{leach,above,time1}$	Cu: 869 Prop.: 10.065 Teb.: 16.335	mg	$AREA_{pole,above}$ × $Q^*_{leach,above,time1}$
Cumulative quantity of substance, leached over the longer assessment period from the part above ground	$Q_{leach,above,time2}$	Cu: 98 642.5 Prop.: 373.45 Teb.: 462.55	mg	$AREA_{pole,above}$ × $Q^*_{leach,above,time2}$
Cumulative quantity of substance, leached over the initial assessment period from the part below ground	$Q_{leach,below,time1}$	Cu: 1262.4 Prop.: 69.44 Teb.: 49.28	mg	$AREA_{pole,below}$ × $Q^*_{leach,below,time1}$
Cumulative quantity of substance, leached over the longer assessment period from the part below ground	$Q_{leach,below,time2}$	Cu: 2128 Prop: 127.52 Teb.: 86.88	mg	$AREA_{pole,below}$ × $Q^*_{leach,below,time2}$
Cumulative quantity of substance, leached over the initial assessment period	$Q_{leach,time1}$	Cu: 2131.4 Prop.: 79.505 Teb.: 65.615	mg	$Q_{leach,above,time1}$ + $Q_{leach,below,time1}$
Cumulative quantity of substance, leached over the longer assessment period	$Q_{leach,time2}$	Cu: 100770.5 Prop.: 500.97 Teb.: 549.43	mg	$Q_{leach,above,time2}$ + $Q_{leach,below,time2}$
Concentration in local soil at the end of the initial assessment period	$Clocal_{soil,leach,time1}$	Cu: 0.422 Prop.: $1.57 \cdot 10^{-2}$ Teb.: $1.30 \cdot 10^{-2}$	$mg.kg_{wwt}^{-1}$	ESD, (4.69)

Output	Symbol	Value	Unit	Equation
Concentration in local soil at the end of the longer assessment period	$Clocal_{soil,leach,time2}$	Cu: 20.0 Prop.: $9.92 \cdot 10^{-2}$ Teb.: 0.109	$mg.kg_{wwt}^{-1}$	ESD, (4.70)
Average daily emission of substance due to leaching over the initial assessment period	$E_{soil,leach,time1}$	Cu: 71.0 Prop.: 2.65 Teb.: 2.187	$mg.d^{-1}$	$Q_{leach,time1}$ / TIME1
Average daily emission of substance due to leaching over the longer assessment period	$E_{soil,leach,time1}$	Cu: 13.8 Prop.: 0.0686 Teb.: 0.0753	$mg.d^{-1}$	$Q_{leach,time2}$ / TIME2

Fate and distribution in exposed environmental compartments

For identification of relevant receiving compartments please refer to the subsection 'Emission scenarios' above.

Copper: Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Vapour pressure	not measurable	Pa	–
Partition coefficitent in soil ($K_{p,soil}$)	2 120	$l.kg^{-1}$	–
Partition coefficient in suspended matter ($K_{p,susp}$)	30 246	$l.kg^{-1}$	–
Leaching-ageing factor in soil	2	–	To be applied only for Time 2
Regional background concentration in surface water	2.9	$\mu g.l^{-1}$	–
Regional background concentration in groundwater	2.9	$\mu g.l^{-1}$	–
Regional background concentration in soil	21.6	$mg.kg_{wwt}^{-1}$	–
Regional background concentration in sediment	14.7	$mg.kg_{wwt}^{-1}$	–

Propiconazole: Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	342.2	$g.mol^{-1}$	–
Vapour pressure (at 25°C)	$5.6 \cdot 10^{-5}$	Pa	–
Water solubility (at 20°C)	100	$mg.l^{-1}$	–
Log Octanol/water partition coefficient	3.72	Log 10	–
Organic carbon/water partition coefficient (K_{OC})	944	$l.kg^{-1}$	–
Henry's law constant	$9.2 \cdot 10^{-5}$	$Pa.m^3.mol^{-1}$	
Biodegradability	Not readily biodegradable	–	–
DT_{50} in the water-sediment system	1206	d (at 12°C)	
DT_{50} for hydrolysis in surface water	No remarkable hydrolysis	–	–
DT_{50} for photolysis in surface water	No remarkable photolysis	–	–
DT_{50} for degradation in soil	129	d	Field study
Major metabolites above 10% in the water-sediment system	None	–	–
Major metabolites above 10% in soil	1,2,4-triazole, CGA 118 245	–	–

Both soil degradation products above 10%, i.e. 1,2,4-triazole and CGA 118 245, are degraded faster than the parent compound in soil (DT_{50} 9.3 days and 1 day respectively) and are more mobile in soil (K_{OC} 69 and 129, respectively). Both of them also show lower toxicity to earthworms (LC_{50} > 299 $mg.kg_{wwt}^{-1}$) than propiconazole (LC_{50} = 205 $mg.kg_{wwt}^{-1}$). Thus no risk assessment for the degradation products is necessary.

Tebuconazole: Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	307.8	$g.mol^{-1}$	–
Vapour pressure (at 20°C)	$1.7 \cdot 10^{-6}$	Pa	–
Water solubility (at 20°C)	29	$mg.l^{-1}$	–
Log Octanol/water partition coefficient	3.49	Log 10	–
Organic carbon/water partition coefficient (K_{OC})	992	$l.kg^{-1}$	–
Henry's law constant	$1 \cdot 10^{-5}$	$Pa.m^3.mol^{-1}$	
Biodegradability	Not readily biodegradable	–	–
DT_{50} for degradation in surface water (water phase)	43	d	Outdoor microcosm study

Tebuconazole: Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
DT_{50} for hydrolysis in surface water	No significant hydrolysis	–	–
DT_{50} for photolysis in surface water	No significant photolysis	–	–
DT_{50} for degradation in soil	77	d	Field study
Major metabolites above 10% in the water-sediment system	None	–	–
Major metabolites above 10% in soil	1,2,4-triazole (9%)	–	–

Calculated fate and distribution in the STP		
Compartment	**Percentage**	**Remarks**
	Scenario 2	
Air	Cu: 0% Prop.: 0% Teb.: 0%	–
Water	Cu: 16% Prop.: 89% Teb.: 89%	Cu: 100% used in the risk assessment
Sludge	Cu: 84% Prop.: 11% Teb.: 11%	–
Degraded in STP	Cu: 0% Prop.: 0% Teb.: 0%	–

The distribution for propiconazole and tebuconazole was obtained from the SimpleTreat model as contained in EUSES 2.1.2 (K_{OC} used as input).
In order to estimate $Fstp_{sludge}$ for copper, a hypothetical K_{OC} value of 75 600 has been derived from $K_{p,susp}$ using TGD equations (23) and (24) and the default values in TGD Table 5. The resulting percentage of copper adsorbed to sludge is 84%. However, in the risk assessment the portion of copper remaining in water will conservatively be assumed 100%.

Calculations of the distribution in exposed environmental compartments
Scenarios 1a, 2, 3 – See Annex 3.2.

The FOCUS PEARL model is not applicable to inorganic substances such as copper. Therefore, in accordance with TGD (part II, p. 86), the concentration in porewater of soil below the house has been used as $PEC_{groundwater}$. For the calculations see Annex 3.2.

Input parameters for Scenario 1b – groundwater exposure assessment for propiconazole, its degradation product 1,2,4-triazole and for tebuconazole, using FOCUS PEARL 4.4.4:

Parameter	Value	Unit	Remarks
Molecular weight	Propiconazole: 342.2 1,2,4-triazole: 69.1 Tebuconazole: 307.8	$g.mol^{-1}$	–
Application rate	Propiconazole: 1.8 1,2,4-triazole[46]: 0.37 Tebuconazole: 2.3	$g.ha^{-1}.y^{-1}$	–
Organic carbon/water partition coefficient (K_{OC})	Propiconazole: 944 1,2,4-triazole: 69 Tebuconazole: 992	$l.kg^{-1}$	–
Organic matter/water partition coefficient (K_{OM})	Propiconazole: 548 1,2,4-triazole: 40 Tebuconazole: 575	$l.kg^{-1}$	Calculated: $K_{OM}=0.58\times K_{OC}$
DT_{50} in soil at 20°C	Propiconazole[47]: 43 1,2,4-triazole: 9.3 Tebuconazole: 77	d	–
Vapour pressure	Propiconazole: $5.6\cdot10^{-5}$ 1,2,4-triazole: 0.22 Tebuconazole: $1.7\cdot10^{-6}$	Pa	–
Solubility in water	Propiconazole: 100 1,2,4-triazole: 700 000 Tebuconazole: 29	$mg.l^{-1}$	–
Application events per year	10	–	See ESD, p. 178
Amount applied per application event	Propiconazole: 0.18 1,2,4-triazole: 0.037 Tebuconazole: 0.23	$g.ha^{-1}$ per event	–
Application type	To the soil surface	–	–
Crop	Grass (=alfalfa)	–	–
Scenarios calculated	All nine FOCUS scenarios	–	–
Additional assumptions	No interception, fallow soil, no plant uptake	–	–

Calculated PEC values

Summary table on calculated PEC values – Time 1					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
Scenario 1a	–	–	–	Cu: 22.1 Prop.: $5.07\cdot10^{-3}$ Teb.: $7.78\cdot10^{-3}$	–

[46] Conservatively, 100% conversion of propiconazole to 1,2,4-triazole was assumed
[47] From the Assessment Report for PT9

Summary table on calculated PEC values – Time 1					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
Scenario 1b	–	–	–	–	–
Scenario 2	Cu: $2.92 \cdot 10^{-3}$ Prop.: $3.02 \cdot 10^{-5}$ Teb.: $4.89 \cdot 10^{-5}$	Cu: $3.10 \cdot 10^{-3}$ Prop.: $3.02 \cdot 10^{-6}$ Teb.: $4.88 \cdot 10^{-6}$	Cu: 16.0 Prop.: $6.43 \cdot 10^{-5}$ Teb.: $1.09 \cdot 10^{-4}$	–	–
Scenario 3 (tier 1)	–	–	–	Cu: 37.4 Prop.: $3.78 \cdot 10^{-1}$ Teb.: $3.60 \cdot 10^{-1}$	–
Scenario 3 (tier 2)	–	–	–	Cu: 22.0 Prop.: $1.45 \cdot 10^{-2}$ Teb.: $1.14 \cdot 10^{-2}$	–

Summary table on calculated PEC values – Time 2					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
Scenario 1a	–	–	–	Cu: 37.5 Prop.: $5.18 \cdot 10^{-3}$ Teb.: $3.83 \cdot 10^{-3}$	32
Scenario 1b	–	–	–	–	Prop.: $<10^{-6}$ 1,2,4-triazole: $<10^{-6}$ Teb.: $<10^{-6}$
Scenario 2	Cu: $1.36 \cdot 10^{-3}$ Prop.: $4.60 \cdot 10^{-6}$ Teb.: $5.70 \cdot 10^{-6}$	Cu: $2.99 \cdot 10^{-3}$ Prop.: $4.59 \cdot 10^{-7}$ Teb.: $5.69 \cdot 10^{-7}$	Cu: 15.3 Prop.: $9.78 \cdot 10^{-6}$ Teb.: $1.27 \cdot 10^{-5}$	–	–
Scenario 3 (tier 1)	–	–	–	Cu: 36.2 Prop.: $2.27 \cdot 10^{-2}$ Teb.: $1.38 \cdot 10^{-2}$	–
Scenario 3 (tier 2)	–	–	–	Cu: 20.8 Prop.: $2.53 \cdot 10^{-3}$ Teb.: $1.66 \cdot 10^{-3}$	–

Primary and secondary poisoning

Primary poisoning
For PT 8 primary poisoning is not relevant.

Secondary poisoning
Because of the homeostasis of metals, copper is not considered bioaccumulative.

Propiconazole and tebuconazole show slight potential for bioaccumulation. However, according to the Assessment Report for propiconazole, the degree of bioaccumulation potential does not require risk assessment for secondary poisoning.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: Due to the low volatility of the active substances, air is not the compartment of concern.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values – Time 1	
	PEC/PNEC$_{STP}$
Scenario 2	Cu: 0.013 Prop.: $3.0 \cdot 10^{-5}$ Teb.: $1.5 \cdot 10^{-4}$

Summary table on calculated PEC/PNEC values – Time 2	
	PEC/PNEC$_{STP}$
Scenario 2	Cu: $5.9 \cdot 10^{-3}$ Prop.: $4.6 \cdot 10^{-6}$ Teb.: $1.8 \cdot 10^{-5}$

Conclusion: As the PEC/PNEC$_{STP}$ < 1 in all cases, the risk to the STP is acceptable.

Aquatic compartment

Summary table on calculated PEC/PNEC values – Time 1		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 2	Cu: 0.40 Prop.: $1.9 \cdot 10^{-3}$ Teb.: $4.9 \cdot 10^{-3}$	Cu: 0.85 Prop.: $1.2 \cdot 10^{-3}$ Teb.: $2.0 \cdot 10^{-4}$

Summary table on calculated PEC/PNEC values – Time 2		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 2	Cu: 0.38 Prop.: $2.9 \cdot 10^{-4}$ Teb.: $5.7 \cdot 10^{-4}$	Cu: 0.81 Prop.: $1.8 \cdot 10^{-4}$ Teb.: $2.3 \cdot 10^{-5}$

Conclusion: As the PEC/PNEC$_{STP}$ < 1 in all cases, the risk to the aquatic compartment is acceptable.

Terrestrial compartment

Summary table on calculated PEC/PNEC values – Time 1	
	PEC/PNEC$_{soil}$
Scenario 1a	Cu: 0.55 Prop.: 0.051 Teb.: 0.078
Scenario 3 (tier 1)	Cu: 0.927 Prop.: **3.78** Teb.: **3.60**
Scenario 3 (tier 2)	Cu: 0.546 Prop.: 0.145 Teb.: 0.114

Summary table on calculated PEC/PNEC values – Time 2	
	PEC/PNEC$_{soil}$
Scenario 1a	Cu: 0.93 Prop.: 0.052 Teb.: 0.038
Scenario 3 (tier 1)	Cu: 0.897 Prop.: 0.227 Teb.: 0.138
Scenario 3 (tier 2)	Cu: 0.515 Prop.: 0.0253 Teb.: 0.0166

Conclusion: For Use class 3 (Scenario 1a) the risk to the terrestrial compartment is acceptable as the PEC/PNEC$_{soil}$ < 1 in all cases.
For use class 4 (Scenario 3) the tier 2 estimates result in PEC/PNEC$_{soil}$ < 1 for each active substance, therefore the risk to the soil compartment is acceptable.
The tier 1 estimates indicated unacceptable risk especially in Time 1. This was mainly due to the conservative assumption that 50% of the a.s. leaches out within the first 30 days. The subsequent leaching study showed that the default assumption was not realistic in this case.
Overall, the risk to soil is acceptable.

Groundwater

The PEC$_{GW}$ for copper (0.032 mg/l) complies with the limit for drinking water of 2 mg/l according to Dir. 98/83/EC.
The PEC$_{GW}$ for propiconazole, tebuconazole and 1,2,4-triazole (<10^{-6} µg/l) complies with the limit for pesticides of 0.10 µg/l according to Dir. 98/83/EC.

Primary and secondary poisoning

Primary poisoning
For PT 8 primary poisoning is not relevant.

Secondary poisoning
Because of the homeostasis of metals, copper is not considered bioaccumulative.
Propiconazole and tebuconazole show slight potential for bioaccumulation. However, according to the Assessment Report for propiconazole, the degree of bioaccumulation potential does not require risk assessment for secondary poisoning.

Conclusion: The risk assessment for primary or secondary poisoning is not considered relevant.

Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments.

An exposure of the environment is likely. The PEC/PNEC values indicate a need to perform mixture toxicity assessment for the terrestrial compartment.
Mixture toxicity assessment for the remaining compartments is performed too although the PEC/PNEC values of propiconazole and tebuconazole for groundwater and sediment are low, so practically nothing is added to the copper concentrations. In the STP and in groundwater, the PEC/PNEC values are very low for all active substances.

Screening Step 2: Identification of relevant substances

Besides the active substances, the product contains only monoethanolamine. Monoethanolamine does not bear an environmental classification according to CLP, Annex IV.

Screening Step 3: Screen on synergistic interactions

There are no synergistic effects reported in the literature for a mixture containing both copper and azole fungicides. Therefore no synergism is not anticipated.

Screening step	
1	Significant exposure of environmental compartments? Yes
2	Number of relevant substances >1? Yes
3	Indication for synergistic effects for the product? No

Tiered approach

Tier 1 (PEC/PNEC summation) was sufficient to demonstrate acceptable risk.

Tier 1. PEC/PNEC summation

Sewage treatment plant (STP)

Use class 3

Use class 3 (Scenario 2: Noise barrier)			
Compartment	RQ product	Acceptable risk for the environment? (Y/N)	Remarks
STP, Time 1	$1.32 \cdot 10^{-2}$	Yes	–
STP, Time 2	$5.92 \cdot 10^{-3}$	Yes	–

RQ values for sewage treated plant are below 1 therefore the risk is considered acceptable.

Aquatic compartment

Use class 3

Use class 3 (Scenario 2: Noise barrier)			
Compartment	RQ product	Acceptable risk for the environment? (Y/N)	Remarks
Water, Time 1	$4.07 \cdot 10^{-1}$	Yes	–
Water, Time 2	$3.81 \cdot 10^{-1}$	Yes	–
Sed, Time 1	$8.51 \cdot 10^{-1}$	Yes	–
Sed, Time 2	$8.10 \cdot 10^{-1}$	Yes	–

RQ values for aquatic compartment are below 1 therefore the risk is considered acceptable.

Terrestrial compartment

Use class 3

Use class 3 (Scenario 1a: House)			
Compartment	RQ product	Acceptable risk for the environment? (Y/N)	Remarks
Soil, Time 1	0.68	Yes	–
Soil, Time 2	**1.02**	No	–

As the sum of PEC/PNEC is slightly above 1 at Time 2, the emission estimates in the house scenario will be refined by using higher-tier estimates of cumulative leached amount for propiconazole and tebuconazole. These higher-tier estimates have been obtained by an extrapolation procedure recommended in the ESD (p. 149-154). They have been presented in the subsection 'Leaching study for the part above ground' and are repeated below. The ESD extrapolation procedure was not applicable to copper data, so no refinement for copper was possible.

Leached amounts for Time 2: product retention 14 kg/m^3			
Time	**Total amount leached (mg.m^{-2})**		
	Copper	Propiconazole	Tebuconazole
Time 2 (linear extrapolation)	17 935	67.92	84.14
Time 2 (Regression 2 = procedure according to ESD)	–	12.27	15.66

Calculations of the refined PEC values are given in Annex 3.2. The PEC_{soil} values together with the corresponding $PEC/PNEC_{soil}$ ratios and risk quotients are summarized in the two tables below. As the risk quotients are below 1, the risk is considered acceptable.

	PEC_{soil} [mg/kg$_{wwt}$], Time 2	**$PEC/PNEC_{soil}$, Time 2**
Before refinement		
Scenario 1a	Cu: 37.5 Prop.: $5.18 \cdot 10^{-3}$ Teb.: $3.83 \cdot 10^{-3}$	Cu: 0.93 Prop.: 0.052 Teb.: 0.038
After refinement		
Scenario 1a	Cu: 37.5 Prop.: $9.34 \cdot 10^{-4}$ Teb.: $7.13 \cdot 10^{-4}$	Cu: 0.93 Prop.: $9.3 \cdot 10^{-3}$ Teb.: $7.1 \cdot 10^{-3}$

Use class 3 (Scenario 1a: House – after refinement)			
Compartment	RQ product	Acceptable risk for the environment? (Y/N)	Remarks
Soil, Time 1	0.68	Yes	–
Soil, Time 2	0.95	Yes	–

Use class 4

Use class 4a (Scenario 3: Transmission pole)			
Compartment	RQ product	Acceptable risk for the environment? (Y/N)	Remarks
tier 1			
Soil, Time 1	**8.31**	No	–
Soil, Time 2	**1.26**	No	–
tier 2			
Soil, Time 1	0.81	Yes	–
Soil, Time 2	0.56	Yes	–

As the tier 2 risk quotients are below 1, the risk is considered acceptable.

Conclusion: In use class 3 and 4a the risk is acceptable for all exposed compartments.

Overall conclusion on the risk assessment for the environment of the product
For use class 3 and 4a, no unacceptable risk to the environment from the use of the product has been identified provided that the treated wood is not used in the proximity of water and appropriate risk mitigation measures are implemented during application and storage stages (freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water; any losses must be collected for reuse or disposal).

2.2.9 Measures to protect man, animals and the environment

Please refer to sections 2.1.4 and 2.1.5.

2.2.10 Assessment of a combination of biocidal products

The product is not intended for use with other biocidal products.

3 ANNEXES

3.1 List of studies for the biocidal product family

Author	Year	Title	Testing laboratory	Owner of data
Štreit, V.; Plodíková, P.	2013a	Bochemit Forte Profi. Determination of pH, acidity and alkalinity (Study No. 359/13/pH)	Research Institute for Organic Syntheses, Rybitví, CZ	Bochemie a.s., Bohumín, CZ
Štreit, V.; Plodíková, P.	2013b	Bochemit Forte Profi. Relative density (Study No. 359/13/43)	Research Institute for Organic Syntheses, Rybitví, CZ	Bochemie a.s., Bohumín, CZ
Štreit, V.; Plodíková, P.	2013c	Bochemit Forte Profi. Persistent foaming (Study No. 359/13/CIPAC MT 47)	Research Institute for Organic Syntheses, Rybitví, CZ	Bochemie a.s., Bohumín, CZ
Navrátilová, Y.	2009	Storage stability test report for Bochemit Forte Profi (Study No. 5910/BFP/2007)	Bochemie a.s., Bohumín, CZ	Bochemie a.s., Bohumín, CZ
Hantlová, E.	2008a	Bochemit Forte Profi. ZKN PND 50-2130-05	Bochemie a.s., Bohumín, CZ	Bochemie a.s., Bohumín, CZ
Hantlová, E.	2008b	ZKP MOK č.9 BOCHEMIT FORTE PROFI 3/2008. Stanovení MEA. (in Czech) [Determination of monoethanolamine.]	Bochemie a.s., Bohumín, CZ	Bochemie a.s., Bohumín, CZ
Navrátilová, Y.	2006a	Validation of *Determination of the copper content in the product Bochemit Forte Profi* method	Bochemie a.s., Bohumín, CZ	Bochemie a.s., Bohumín, CZ
Navrátilová, Y.	2006b	Validation of *Determination of the tebuconazole and propiconazole content in the product Bochemit Forte Profi* method	Bochemie a.s., Bohumín, CZ	Bochemie a.s., Bohumín, CZ

Author	Year	Title	Testing laboratory	Owner of data
Navrátilová, Y.	2006c	Validační protokol pro metodu *Stanovení monoethanolaminu ve výrobku Bochemit Forte Profi.* Č. Protokolu VP-04/06. (in Czech) [Validation report for the method *Determination of the monoethanolamine content in the product Bochemit Forte Profi.* Report No. VP-04/06]	Bochemie a.s., Bohumín, CZ	Bochemie a.s., Bohumín, CZ
Fennert, E.-M.; Doblinski, M.	2007a	Determination of the toxic values against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 47 (06/2005) in combination with evaporative ageing procedure according to EN 73 (04/90). (Report No. 32/06/8870/03)	Materialprüfanstalt Brandenburg, Eberswalde, DE	Bochemie a.s., Bohumín, CZ
Fennert, E.-M.; Wessely, S.	2007a	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (11/96) after evaporative ageing procedure according to EN 73 (04/90). (Report No. 32/06/8870/01A)	Materialprüfanstalt Brandenburg, Eberswalde, DE	Bochemie a.s., Bohumín, CZ
Fennert, E.-M.; Wessely, S.	2008	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (11/96) after evaporative ageing procedure according to EN 73 (04/90). (Report No. 32/06/8870/09a)	Materialprüfanstalt Brandenburg, Eberswalde, DE	Bochemie a.s., Bohumín, CZ

Author	Year	Title	Testing laboratory	Owner of data
Součková, A.	2009	Determination of the toxic values against wood destroying fungus Poria placenta according to ČSN EN 113 in the combination with ČSN EN 73 of the preparation Bochemit Forte Profi. (Report No. VZL-72/08/4)	Timber-wood research and development institute, Prague, CZ	Bochemie a.s., Bohumín, CZ
Fennert, E.-M.; Wessely, S.	2007b	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (11/96) after leaching procedure according to EN 84 (05/97). (Report No. 32/06/8870/02A)	Materialprüfanstalt Brandenburg, Eberswalde, DE	Bochemie a.s., Bohumín, CZ
Fennert, E.-M.; Wessely, S.	2010	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (11/96) after leaching procedure according to EN 84 (05/97). (Report No. 32/06/8870/12)	Materialprüfanstalt Brandenburg, Eberswalde, DE	Bochemie a.s., Bohumín, CZ
Reinprecht, L.	2005	Testing of the fungicide effectiveness of three preservatives from Bochemie Bohumín	Technical University in Zvolen, Zvolen, SK	Bochemie a.s., Bohumín, CZ
Fennert, E.-M.; Doblinski, M.	2007b	Determination of the toxic values against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 47 (06/2005) in combination with leaching procedure according to EN 84 (05/97). (Report No. 32/06/8870/04a)	Materialprüfanstalt Brandenburg, Eberswalde, DE	Bochemie a.s., Bohumín, CZ

Author	Year	Title	Testing laboratory	Owner of data
Fennert, E.-M.; Wessely, S.	2007c	Determination of the protective effectiveness against soft rotting micro-fungi and other soil-inhabiting micro-organisms according to ENV 807 (12/2001). (Report No. 32/06/8870/05)	Materialprüfanstalt Brandenburg, Eberswalde, DE	Bochemie a.s., Bohumín, CZ
Erdmann, M.; Schumacher, P.	2014	Report No. 32/06/8870/07/f	Materialprüfanstalt Brandenburg, Eberswalde, DE	Bochemie a.s., Bohumín, CZ
Klamer, M.; Venås, T. M.	2014	Test Report EN 252 (stakes in ground contact). (Order no. 313170)	Danish Technological Institute, Taastrup, DK	Bochemie a.s., Bohumín, CZ
Klamer, M.; Venås, T. M.	2013	Leaching of copper, tebuconazole and propiconazole from wood treated with Bochemit Forte Profi – 1.5 years of exposure. (Order no. 454070)	Danish Technological Institute, Taastrup, DK	Bochemie a.s., Bohumín, CZ
Ptáček, P.	2015	Hodnocení účinnosti Bochemit Forte Profi, typ 8 (in Czech) [Efficacy evaluation Bochemit Forte Profi, product type 8]	Institute for testing and certification, Zlín, CZ	Bochemie a.s., Bohumín, CZ
Vaněk, P.; Ptáček, P.	2016	Test report No. 463500065/2016	Institute for testing and certification, Zlín, CZ	Bochemie a.s., Bohumín, CZ
Samsonek, J.; Gerych, P.	2016	Accredited laboratory test report ref. No. 46352265/01	Institute for testing and certification, Zlín, CZ	Bochemie a.s., Bohumín, CZ

3.2 Output tables from exposure assessment tools

Scenario 1: Vacuum pressure treatment

Scenario	Vacuum pressure treatment	
Active substance	Copper	
	Units	**Tier 2**
Active substance concentration	%	0.46
Body exposure		
Clothing type		coated coverall
Indicative value	mg/cycle	8570
Duration	cycles/day	3
Potential body deposit	mg/day	25710
Clothing penetration	%	10
Actual dermal deposit (product)	mg/day	2571
Hand exposure		
Gloves worn		yes
Indicative value	mg/cycle	1080
Duration	cycles/day	3
Actual hand deposit (product)	mg/day	3240
Total dermal exposure		
Product	mg/day	5811
Active substance	mg/day	26.7306
Dermal absorption		
Dermal penetration	%	5
Absorbed dose (dermal)	mg/day	1.33653
Inhalation exposure		
Indicative value	mg/m^3	1.9
Duration	hr/day	0.5
Inhalation rate	m^3/hr	1.25
Mitigation by RPE		none
Inhaled (product)	mg/day	1.1875
Inhaled (active substance)	mg/day	0.0054625
Systemic dose		
Total absorbed dose	mg/day	1.3419925
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**2.24E-02**

Scenario 1: Vacuum pressure treatment – continued

Scenario **Active substance**	Vacuum pressure treatment Propiconazole	
	Units	**Tier 2**
Active substance concentration	%	0.012
Body exposure		
clothing type		coated coverall
indicative value	mg/cycle	8570
duration	cycles/day	3
potential body deposit	mg/day	25710
clothing penetration	%	10
actual dermal deposit (product)	mg/day	2571
Hand exposure		
gloves worn		yes
indicative value	mg/cycle	1080
duration	cycles/day	3
actual hand deposit (product)	mg/day	3240
Total dermal exposure		
Product	mg/day	5811
Active substance	mg/day	0.69732
Dermal absorption		
Dermal penetration	%	2
Absorbed dose (dermal)	mg/day	0.0139464
Inhalation exposure		
Indicative value	mg/m^3	1.9
Duration	hr/day	0.5
Inhalation rate	m^3/hr	1.25
Mitigation by RPE		none
Inhaled (product)	mg/day	1.1875
Inhaled (active substance)	mg/day	0.0001425
Systemic dose		
Total absorbed dose	mg/day	0.0140889
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**2.35E-04**

Scenario 1: Vacuum pressure treatment – continued

Scenario **Active substance**	Vacuum pressure treatment Tebuconazole	
	Units	**Tier 2**
Active substance concentration	%	0.012
Body exposure		
clothing type		coated coverall
indicative value	mg/cycle	8570
duration	cycles/day	3
potential body deposit	mg/day	25710
clothing penetration	%	10
actual dermal deposit (product)	mg/day	2571
Hand exposure		
gloves worn		yes
indicative value	mg/cycle	1080
duration	cycles/day	3
actual hand deposit (product)	mg/day	3240
Total dermal exposure		
Product	mg/day	5811
Active substance	mg/day	0.69732
Dermal absorption		
Dermal penetration	%	75
Absorbed dose (dermal)	mg/day	0.52299
Inhalation exposure		
Indicative value	mg/m^3	1.9
Duration	hr/day	0.5
Inhalation rate	m^3/hr	1.25
Mitigation by RPE		none
Inhaled (product)	mg/day	1.1875
Inhaled (active substance)	mg/day	0.0001425
Systemic dose		
Total absorbed dose	mg/day	0.5231325
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**8.72E-03**

Scenario 1: Vacuum pressure treatment – continued

Scenario / Tier	Vacuum pressure treatment, Tier 2			
	Estimated uptake (mg/kg bw/d)			
	Inhalation	Dermal	Oral	Total
Copper	9.10E-05	2.23E-02	0.00E+00	2.24E-02
Propiconazole	2.38E-06	2.32E-04	0.00E+00	2.35E-04
Tebuconazole	2.38E-06	8.72E-03	0.00E+00	8.72E-03

Scenario 2: Sanding (professional)

Scenario **Active substance**	Sanding (professional) Copper	
	Units	**Tier 1**
Active substance concentration	%	11.5
Hand exposure		
Product retention	kg/m^3	14
Surface concentration	mg/cm^2	14
Hand surface area contaminated	cm^2	84
Transfer coefficient	%	2
Amount on hands (product)	mg	23.52
Amount on hands (a.s.)	mg	2.7048
Dermal absorption		
Dermal penetration	%	5
Absorbed dose (dermal)	mg	0.13524
Inhalation exposure		
Indicative value	mg/m^3	5
Duration	hr/day	6
Inhalation rate	m^3/hr	1.25
Inhaled (wood dust)	mg/day	37.5
Product fraction in the wood		
Product retention	$kg/m^3 = mg/cm^3$	14
Article volume	cm^3	720
Volume of outer 1 cm wood	cm^3	568
Product retention in outer 1 cm	$mg_{product}/cm_{wood}^3$	17.74647887
Wood density	mg_{wood}/cm_{wood}^3	400
Weight fraction of the product in the wood	-	0.044366197
Inhaled (product)	mg/day	1.663732394
Inhaled (active substance)	mg/day	0.191329225
Systemic dose		
Total absorbed dose	mg/day	0.326569225
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**5.44E-03**

Scenario 2: Sanding (professional) – continued

Scenario **Active substance**	Sanding (professional) Propiconazole	
	Units	**Tier 1**
Active substance concentration	%	0.3
Hand exposure		
Product retention	kg/m^3	14
Surface concentration	mg/cm^2	14
Hand surface area contaminated	cm^2	84
Transfer coefficient	%	2
Amount on hands (product)	mg	23.52
Amount on hands (a.s.)	mg	0.07056
Dermal absorption		
Dermal penetration	%	2
Absorbed dose (dermal)	mg	0.0014112
Inhalation exposure		
Indicative value	mg/m^3	5
Duration	hr/day	6
Inhalation rate	m^3/hr	1.25
Inhaled (wood dust)	mg/day	37.5
Product fraction in the wood		
Product retention	$kg/m^3 = mg/cm^3$	14
Article volume	cm^3	720
Volume of outer 1 cm wood	cm^3	568
Product retention in outer 1 cm	$mg_{product}/cm_{wood}^3$	17.74647887
Wood density	mg_{wood}/cm_{wood}^3	400
Weight fraction of the product in the wood	-	0.044366197
Inhaled (product)	mg/day	1.663732394
Inhaled (active substance)	mg/day	0.004991197
Systemic dose		
Total absorbed dose	mg/day	0.006402397
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**1.07E-04**

Scenario 2: Sanding (professional) – continued

Scenario **Active substance**	Sanding (professional) Tebuconazole	
	Units	**Tier 1**
Active substance concentration	%	0.3
Hand exposure		
Product retention	kg/m^3	14
Surface concentration	mg/cm^2	14
Hand surface area contaminated	cm^2	84
Transfer coefficient	%	2
Amount on hands (product)	mg	23.52
Amount on hands (a.s.)	mg	0.07056
Dermal absorption		
Dermal penetration	%	75
Absorbed dose (dermal)	mg	0.05292
Inhalation exposure		
Indicative value	mg/m^3	5
Duration	hr/day	6
Inhalation rate	m^3/hr	1.25
Inhaled (wood dust)	mg/day	37.5
Product fraction in the wood		
Product retention	$kg/m^3 = mg/cm^3$	14
Article volume	cm^3	720
Volume of outer 1 cm wood	cm^3	568
Product retention in outer 1 cm	$mg_{product}/cm_{wood}^3$	17.74647887
Wood density	mg_{wood}/cm_{wood}^3	400
Weight fraction of the product in the wood	-	0.044366197
Inhaled (product)	mg/day	1.663732394
Inhaled (active substance)	mg/day	0.004991197
Systemic dose		
Total absorbed dose	mg/day	0.057911197
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**9.65E-04**

Scenario / Tier	Sanding (professional), Tier 1			
	Estimated uptake (mg/kg bw/d)			
	Inhalation	Dermal	Oral	Total
Copper	3.19E-03	2.25E-03	0.00E+00	5.44E-03
Propiconazole	8.32E-05	2.35E-05	0.00E+00	1.07E-04
Tebuconazole	8.32E-05	8.82E-04	0.00E+00	9.65E-04

Scenario 3: Sanding (non-professional)

Scenario **Active substance**	Sanding (non-professional) Copper	
	Units	**Tier 1**
Active substance concentration	%	11.5
Hand exposure		
Product retention	kg/m^3	14
Surface concentration	mg/cm^2	14
Hand surface area contaminated	cm^2	84
Transfer coefficient	%	2
Amount on hands (product)	mg	23.52
Amount on hands (a.s.)	mg	2.7048
Dermal absorption		
Dermal penetration	%	5
Absorbed dose (dermal)	mg	0.13524
Inhalation exposure		
Indicative value	mg/m^3	5
Duration	hr/day	1
Inhalation rate	m^3/hr	1.25
Inhaled (wood dust)	mg/day	6.25
Product fraction in the wood		
Product retention	$kg/m^3 = mg/cm^3$	14
Article volume	cm^3	4000
Volume of outer 1 cm wood	cm^3	3008
Product retention in outer 1 cm	$mg_{product}/cm_{wood}^3$	18.61702128
Wood density	mg_{wood}/cm_{wood}^3	400
Weight fraction of the product in the wood	-	0.046542553
Inhaled (product)	mg/day	0.290890957
Inhaled (active substance)	mg/day	0.03345246
Systemic dose		
Total absorbed dose	mg/day	0.16869246
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**2.81E-03**

Scenario 3: Sanding (non-professional) – continued

Scenario **Active substance**	Sanding (non-professional) Propiconazole	
	Units	**Tier 1**
Active substance concentration	%	0.3
Hand exposure		
Product retention	kg/m^3	14
Surface concentration	mg/cm^2	14
Hand surface area contaminated	cm^2	84
Transfer coefficient	%	2
Amount on hands (product)	mg	23.52
Amount on hands (a.s.)	mg	0.07056
Dermal absorption		
Dermal penetration	%	2
Absorbed dose (dermal)	mg	0.0014112
Inhalation exposure		
Indicative value	mg/m^3	5
Duration	hr/day	1
Inhalation rate	m^3/hr	1.25
Inhaled (wood dust)	mg/day	6.25
Product fraction in the wood		
Product retention	$kg/m^3 = mg/cm^3$	14
Article volume	cm^3	4000
Volume of outer 1 cm wood	cm^3	3008
Product retention in outer 1 cm	$mg_{product}/cm_{wood}^3$	18.61702128
Wood density	mg_{wood}/cm_{wood}^3	400
Weight fraction of the product in the wood	-	0.046542553
Inhaled (product)	mg/day	0.290890957
Inhaled (active substance)	mg/day	0.000872673
Systemic dose		
Total absorbed dose	mg/day	0.002283873
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**3.81E-05**

Scenario 3: Sanding (non-professional) – continued

Scenario **Active substance**	Sanding (non-professional) Tebuconazole	
	Units	**Tier 1**
Active substance concentration	%	0.3
Hand exposure		
Product retention	kg/m^3	14
Surface concentration	mg/cm^2	14
Hand surface area contaminated	cm^2	84
Transfer coefficient	%	2
Amount on hands (product)	mg	23.52
Amount on hands (a.s.)	mg	0.07056
Dermal absorption		
Dermal penetration	%	75
Absorbed dose (dermal)	mg	0.05292
Inhalation exposure		
Indicative value	mg/m^3	5
Duration	hr/day	1
Inhalation rate	m^3/hr	1.25
Inhaled (wood dust)	mg/day	6.25
Product fraction in the wood		
Product retention	$kg/m^3 = mg/cm^3$	14
Article volume	cm^3	4000
Volume of outer 1 cm wood	cm^3	3008
Product retention in outer 1 cm	$mg_{product}/cm_{wood}^3$	18.61702128
Wood density	mg_{wood}/cm_{wood}^3	400
Weight fraction of the product in the wood	-	0.046542553
Inhaled (product)	mg/day	0.290890957
Inhaled (active substance)	mg/day	0.000872673
Systemic dose		
Total absorbed dose	mg/day	0.053792673
Body weight	kg	60
Total systemic dose	mg/kg bw/day	**8.97E-04**

Scenario / Tier	Sanding (non-professional), Tier 1			
	Estimated uptake (mg/kg bw/d)			
	Inhalation	Dermal	Oral	Total
Copper	5.58E-04	2.25E-03	0.00E+00	2.81E-03
Propiconazole	1.45E-05	2.35E-05	0.00E+00	3.81E-05
Tebuconazole	1.45E-05	8.82E-04	0.00E+00	8.97E-04

Scenario 4: Child on a playground structure

Scenario	Child on a playground structure	
Active substance	Copper	
	Units	**Tier 1**
Active substance concentration	%	11.5
Hand exposure		
Surface concentration	mg/cm^2	14
Hand surface area contaminated	cm^2	40
Transfer coefficient	%	2
Amount on hands (product)	mg	11.2
Amount on hands (a.s.)	mg	1.288
Dermal absorption		
Dermal penetration	%	5
Absorbed dose (dermal)	mg	0.0644
Systemic dose		
Total absorbed dose	mg/day	0.0644
Body weight	kg	15
Total systemic dose	mg/kg bw/day	**4.29E-03**

Scenario	Child on a playground structure	
Active substance	Propiconazole	
	Units	**Tier 1**
Active substance concentration	%	0.3
Hand exposure		
Surface concentration	mg/cm^2	14
Hand surface area contaminated	cm^2	40
Transfer coefficient	%	2
Amount on hands (product)	mg	11.2
Amount on hands (a.s.)	mg	0.0336
Dermal absorption		
Dermal penetration	%	2
Absorbed dose (dermal)	mg	0.000672
Systemic dose		
Total absorbed dose	mg/day	0.000672
Body weight	kg	15
Total systemic dose	mg/kg bw/day	**4.48E-05**

Scenario 4: Child on a playground structure – continued

Scenario **Active substance**	Child on a playground structure Tebuconazole	
	Units	**Tier 1**
Active substance concentration	%	0.3
Hand exposure		
Surface concentration	mg/cm^2	14
Hand surface area contaminated	cm^2	40
Transfer coefficient	%	2
Amount on hands (product)	mg	11.2
Amount on hands (a.s.)	mg	0.0336
Dermal absorption		
Dermal penetration	%	75
Absorbed dose (dermal)	mg	0.0252
Systemic dose		
Total absorbed dose	mg/day	0.0252
Body weight	kg	15
Total systemic dose	mg/kg bw/day	**1.68E-03**

Scenario / Tier	Child playing on playground structure outdoors, Tier 1			
	Estimated uptake (mg/kg bw/d)			
	Inhalation	Dermal	Oral	Total
Copper	0.00E+00	4.29E-03	0.00E+00	4.29E-03
Propiconazole	0.00E+00	4.48E-05	0.00E+00	4.48E-05
Tebuconazole	0.00E+00	1.68E-03	0.00E+00	1.68E-03

Scenario 5: Infant chewing an off-cut

Scenario **Active substance**	Infant chewing an off-cut Copper	
	Units	**Tier 1**
Active substance concentration	%	11.5
Oral exposure		
Product retention	$kg/m^3 = mg/cm^3$	14
Off-cut volume	cm^3	16
Amount of product in the off-cut	mg	224
Fraction extracted by chewing	%	10
Amount ingested (product)	mg	22.4
Amount ingested (active substance)	mg	2.576
Absorption		
Absorption from GIT	%	36
Absorbed dose	mg	0.92736
Systemic dose		
Total absorbed dose	mg/day	0.92736
Body weight	kg	10
Total systemic dose	mg/kg bw/day	**9.27E-02**

Scenario **Active substance**	Infant chewing an off-cut Propiconazole	
	Units	**Tier 1**
Active substance concentration	%	0.3
Oral exposure		
Product retention	$kg/m^3 = mg/cm^3$	14
Off-cut volume	cm^3	16
Amount of product in the off-cut	mg	224
Fraction extracted by chewing	%	10
Amount ingested (product)	mg	22.4
Amount ingested (active substance)	mg	0.0672
Absorption		
Absorption from GIT	%	100
Absorbed dose	mg	0.0672
Systemic dose		
Total absorbed dose	mg/day	0.0672
Body weight	kg	10
Total systemic dose	mg/kg bw/day	**6.72E-03**

Scenario 5: Infant chewing an off-cut – continued

Scenario **Active substance**	Infant chewing an off-cut Tebuconazole	
	Units	**Tier 1**
Active substance concentration	%	0.3
Oral exposure		
Product retention	$kg/m^3 = mg/cm^3$	14
Off-cut volume	cm^3	16
Amount of product in the off-cut	mg	224
Fraction extracted by chewing	%	10
Amount ingested (product)	mg	22.4
Amount ingested (active substance)	mg	0.0672
Absorption		
Absorption from GIT	%	100
Absorbed dose	mg	0.0672
Systemic dose		
Total absorbed dose	mg/day	0.0672
Body weight	kg	10
Total systemic dose	mg/kg bw/day	**6.72E-03**

Scenario / Tier	Infant chewing an off-cut, Tier 1			
	Estimated uptake (mg/kg bw/d)			
	Inhalation	Dermal	Oral	Total
Copper	0.00E+00	0.00E+00	9.27E-02	9.27E-02
Propiconazole	0.00E+00	0.00E+00	6.72E-03	6.72E-03
Tebuconazole	0.00E+00	0.00E+00	6.72E-03	6.72E-03

Scenario 6: Volatilized residues indoors

ConsExpo 4.1 report

Product

Bochemit Forte Profi

Compound

Compound name :	Monoethanolamine	
CAS number :		
molecular weight	61	g/mol
vapour pressure	50	Pascal
KOW	-1.9	10Log

General Exposure Data

exposure frequency	1	1/year
body weight	10	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	0.35	fraction
exposure duration	1	year
room volume	20	m3
ventilation rate	0.6	1/hr
applied amount	592	gram
release area	8	m2
application duration	1	minute
mol weight matrix	18	g/mol
mass transfer rate	4.78E3	m/min

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	8	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.00307	mg/m3
inhalation mean concentration on day of exposure:	0.00307	mg/m3
inhalation air concentration year average :	8.4E-6	mg/m3/day
inhalation acute (internal) dose :	0.897	mg/kg
inhalation chronic (internal) dose :	0.00246	mg/kg/day

Integrated (point estimates)

total external dose:	0.897	mg/kg
total acute dose (internal):	0.897	mg/kg
total chronic dose (internal):	0.00246	mg/kg/day

Scenario 7: Infant playing on a playground structure outdoors

Scenario **Active substance**	Infant on a playground structure Copper	
	Units	**Tier 1**
Active substance concentration	%	11.5
Surface concentration	mg/cm^2	14
Hand exposure		
Hand surface area contaminated	cm^2	40
Transfer coefficient	%	2
Amount on hands (product)	mg	11.2
Amount on hands (a.s.)	mg	1.288
Dermal absorption		
Dermal penetration	%	5
Absorbed dose (dermal)	mg	0.0644
Oral exposure		
Surface mouthed	cm^2	50
Fraction extracted by licking	%	5
Amount ingested (product)	mg	35
Amount ingested (a.s.)	mg	4.025
Oral absorption		
Absorption from GIT	%	36
Absorbed dose (oral)	mg	1.449
Systemic dose		
Total absorbed dose	mg/day	1.5134
Body weight	kg	10
Total systemic dose	mg/kg bw/day	**1.51E-01**

Scenario 7: Infant playing on a playground structure outdoors – continued

Scenario **Active substance**	Infant on a playground structure Propiconazole	
	Units	**Tier 1**
Active substance concentration	%	0.3
Surface concentration	mg/cm^2	14
Hand exposure		
Hand surface area contaminated	cm^2	40
Transfer coefficient	%	2
Amount on hands (product)	mg	11.2
Amount on hands (a.s.)	mg	0.0336
Dermal absorption		
Dermal penetration	%	2
Absorbed dose (dermal)	mg	0.000672
Oral exposure		
Surface mouthed	cm^2	50
Fraction extracted by licking	%	5
Amount ingested (product)	mg	35
Amount ingested (a.s.)	mg	0.105
Oral absorption		
Absorption from GIT	%	100
Absorbed dose (oral)	mg	0.105
Systemic dose		
Total absorbed dose	mg/day	0.105672
Body weight	kg	10
Total systemic dose	mg/kg bw/day	**1.06E-02**

Scenario 7: Infant playing on a playground structure outdoors – continued

Scenario **Active substance**	Infant on a playground structure Tebuconazole	
	Units	**Tier 1**
Active substance concentration	%	0.3
Surface concentration	mg/cm^2	14
Hand exposure		
Hand surface area contaminated	cm^2	40
Transfer coefficient	%	2
Amount on hands (product)	mg	11.2
Amount on hands (a.s.)	mg	0.0336
Dermal absorption		
Dermal penetration	%	75
Absorbed dose (dermal)	mg	0.0252
Oral exposure		
Surface mouthed	cm^2	50
Fraction extracted by licking	%	5
Amount ingested (product)	mg	35
Amount ingested (a.s.)	mg	0.105
Oral absorption		
Absorption from GIT	%	100
Absorbed dose (oral)	mg	0.105
Systemic dose		
Total absorbed dose	mg/day	0.1302
Body weight	kg	10
Total systemic dose	mg/kg bw/day	**1.30E-02**

Scenario 7: Infant playing on a playground structure outdoors – continued

Scenario **Active substance**	Infant on a playground structure Copper	
	Units	**Tier 2**
Active substance concentration	%	11.5
Surface concentration	mg/cm^2	14
Hand exposure		
Hand surface area contaminated	cm^2	40
Transfer coefficient	%	2
Amount on hands (product)	mg	11.2
Amount on hands (a.s.)	mg	1.288
Dermal absorption		
Dermal penetration	%	5
Absorbed dose (dermal)	mg	0.0644
Oral exposure		
Surface mouthed	m^2	0.005
Leaching rate	mg/m^2/day	5.3
Amount ingested (product)	mg	0.0265
Amount ingested (a.s.)	mg	0.0030475
Oral absorption		
Absorption from GIT	%	36
Absorbed dose (oral)	mg	0.0010971
Systemic dose		
Total absorbed dose	mg/day	0.0654971
Body weight	kg	10
Total systemic dose	mg/kg bw/day	**6.55E-03**

Scenario 7: Infant playing on a playground structure outdoors – continued

Scenario **Active substance**	Infant on a playground structure Propiconazole	
	Units	**Tier 2**
Active substance concentration	%	0.3
Surface concentration	mg/cm^2	14
Hand exposure		
Hand surface area contaminated	cm^2	40
Transfer coefficient	%	2
Amount on hands (product)	mg	11.2
Amount on hands (a.s.)	mg	0.0336
Dermal absorption		
Dermal penetration	%	2
Absorbed dose (dermal)	mg	0.000672
Oral exposure		
Surface mouthed	m^2	0.005
Leaching rate	mg/m^2/day	0.061
Amount ingested (product)	mg	0.000305
Amount ingested (a.s.)	mg	0.000000915
Oral absorption		
Absorption from GIT	%	100
Absorbed dose (oral)	mg	0.000000915
Systemic dose		
Total absorbed dose	mg/day	0.000672915
Body weight	kg	10
Total systemic dose	mg/kg bw/day	**6.73E-05**

Scenario 7: Infant playing on a playground structure outdoors – continued

Scenario **Active substance**	Infant on a playground structure Tebuconazole	
	Units	**Tier 2**
Active substance concentration	%	0.3
Surface concentration	mg/cm^2	14
Hand exposure		
Hand surface area contaminated	cm^2	40
Transfer coefficient	%	2
Amount on hands (product)	mg	11.2
Amount on hands (a.s.)	mg	0.0336
Dermal absorption		
Dermal penetration	%	75
Absorbed dose (dermal)	mg	0.0252
Oral exposure		
Surface mouthed	m^2	0.005
Leaching rate	mg/m^2/day	0.099
Amount ingested (product)	mg	0.000495
Amount ingested (a.s.)	mg	0.000001485
Oral absorption		
Absorption from GIT	%	100
Absorbed dose (oral)	mg	0.000001485
Systemic dose		
Total absorbed dose	mg/day	0.025201485
Body weight	kg	10
Total systemic dose	mg/kg bw/day	**2.52E-03**

Scenario / Tier	Infant playing on playground structure outdoors, Tier 1			
	Estimated uptake (mg/kg bw/d)			
	Inhalation	Dermal	Oral	Total
Copper	0.00E+00	6.44E-03	1.45E-01	1.51E-01
Propiconazole	0.00E+00	6.72E-05	1.05E-02	1.06E-02
Tebuconazole	0.00E+00	2.52E-03	1.05E-02	1.30E-02

Scenario / Tier	Infant playing on playground structure outdoors, Tier 2			
	Estimated uptake (mg/kg bw/d)			
	Inhalation	Dermal	Oral	Total
Copper	0.00E+00	6.44E-03	1.10E-04	6.55E-03
Propiconazole	0.00E+00	6.72E-05	9.15E-08	6.73E-05
Tebuconazole	0.00E+00	2.52E-03	1.49E-07	2.52E-03

Leaching study for the part below ground – calculation of leaching rates:

Time	Leachate volume	
day	ml	
	set 1	set 2
0,25	480	475
1	500	500
2	500	500
4	500	500
8	500	500
15	500	500
22	500	500
29	500	500

Exposed area: 0.02 m^2

Copper

Time	Conc. in leachate		Amount in leachate			L.rate (Qd)
day	mg/l		mg			mg/m^2
	set 1	set 2	set 1	set2	mean	mean
0,25	4,61	4,00	2,2128	1,9	2,0564	102,82
1	3,00	2,32	1,5	1,16	1,33	66,5
2	2,95	2,31	1,475	1,155	1,315	65,75
4	4,41	3,93	2,205	1,965	2,085	104,25
8	5,11	4,98	2,555	2,49	2,5225	126,125
15	6,53	6,61	3,265	3,305	3,285	164,25
22	2,91	3,70	1,455	1,85	1,6525	82,625
29	2,50	2,96	1,25	1,48	1,365	68,25

Propiconazole

Time	Conc. in leachate		Amount in leachate			L.rate (Qd)
day	mg/l		mg			mg/m^2
	set 1	set 2	set 1	set2	mean	mean
0,25	0,276	0,232	0,13248	0,1102	0,12134	6,067
1	0,256	0,310	0,128	0,155	0,1415	7,075
2	0,317	0,258	0,1585	0,129	0,14375	7,1875
4	0,283	0,256	0,1415	0,128	0,13475	6,7375
8	0,188	0,199	0,094	0,0995	0,09675	4,8375
15	0,191	0,173	0,0955	0,0865	0,091	4,55
22	0,155	0,138	0,0775	0,069	0,07325	3,6625
29	0,121	0,117	0,0605	0,0585	0,0595	2,975

Tebuconazole

Time	Conc. in leachate		Amount in leachate			L.rate (Qd)
day	mg/l		mg			mg/m^2
	set 1	set 2	set 1	set2	mean	mean
0,25	0,178	0,151	0,08544	0,07173	0,07858	3,929125
1	0,167	0,244	0,0835	0,122	0,10275	5,1375
2	0,215	0,170	0,1075	0,085	0,09625	4,8125
4	0,220	0,177	0,11	0,0885	0,09925	4,9625
8	0,145	0,151	0,0725	0,0755	0,074	3,7
15	0,133	0,134	0,0665	0,067	0,06675	3,3375
22	0,108	0,095	0,054	0,0475	0,05075	2,5375
29	0,088	0,085	0,044	0,0425	0,04325	2,1625

Scenario 1a: House – copper, distribution in exposed compartments

$PECregional_{soil}$ Ageing factor	21.6 2	$mg.kg_{wwt}^{-1}$ (-)	AR, p. 32
$PEClocal_{soil,time1}$ $PEClocal_{soil,time2}$ (with ageing)	**2.21E+01** **3.75E+01**	$mg.kg_{wwt}^{-1}$ $mg.kg_{wwt}^{-1}$	

Scenario 1a: House – propiconazole, distribution in exposed compartments

$DT50_{soil}$ k	129 0.0053732	d d^{-1}	 TGD, II, Eq. (29)
$Clocal_{soil,time1}$ (with degr., time-weighted avg.)	**2.60E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.7), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., time-weighted avg.)	**5.04E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.8), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time1}$ (with degr., at the end of time 1)	**5.07E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.11), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., at the end of time 2)	**5.18E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.12), $Clocal_{soil,applic}$ = 0

Scenario 1a: House – tebuconazole, distribution in exposed compartments

$DT50_{soil}$ k	77 0.0090019	d d^{-1}	 TGD, II, Eq. (29)
$Clocal_{soil,time1}$ (with degr., time-weighted avg.)	**4.07E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.7), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., time-weighted avg.)	**3.77E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.8), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time1}$ (with degr., at the end of time 1)	**7.78E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.11), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., at the end of time 2)	**3.83E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.12), $Clocal_{soil,applic}$ = 0

Scenario 1a: House – propiconazole, calculation with a refined leaching rate (Regression 2) for Time 2

Scenario

$AREA_{house}$	125	m^2	ESD, Table 4.15
TIME1	30	d	ESD, Table 4.15
TIME2 (years)	20	y	ESD, p. 68
TIME2 (days)	7300	d	
$Q^*_{leach,time1}$	0.97	$mg.m^{-2}$	
$Q^*_{leach,time2}$	6.48	$mg.m^{-2}$	
V_{soil}	13	m^3	ESD, Table 4.15
RHO_{soil}	1700	$kg_{wwt}.m^{-3}$	ESD, Table 4.15
$Q_{leach,time1}$	121.25	mg	ESD Eq. (4.43)
$Q_{leach,time2}$	810	mg	ESD Eq. (4.44)
$Clocal_{soil,leach,time1}$ (without degradation)	5.49E-03	$mg.kg_{wwt}^{-1}$	ESD Eq. (4.45)
$Clocal_{soil,leach,time2}$ (without degradation)	3.67E-02	$mg.kg_{wwt}^{-1}$	ESD Eq. (4.46)
$E_{soil,leach,time1}$	4.0416667	$mg.d^{-1}$	ESD Eq. (3.5)
$E_{soil,leach,time2}$	0.1109589	$mg.d^{-1}$	ESD Eq. (3.6)

Distribution in exposed compartments

$DT50_{soil}$	129	d	
k	0.0053732	d^{-1}	TGD, II, Eq. (29)
$Clocal_{soil,time1}$ (with degr., time-weighted avg.)	**2.60E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.7), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., time-weighted avg.)	**9.11E-04**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.8), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time1}$ (with degr., at the end of time 1)	**5.07E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.11), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., at the end of time 2)	**9.34E-04**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.12), $Clocal_{soil,applic}$ = 0

Scenario 1a: House – tebuconazole, calculation with a refined leaching rate (Regression 2) for Time 2

Scenario

$AREA_{house}$	125	m^2	ESD, Table 4.15
TIME1	30	d	ESD, Table 4.15
TIME2 (years)	20	y	ESD, p. 68
TIME2 (days)	7300	d	
$Q^*_{leach,time1}$	1.57	$mg.m^{-2}$	
$Q^*_{leach,time2}$	8.28	$mg.m^{-2}$	
V_{soil}	13	m^3	ESD, Table 4.15
RHO_{soil}	1700	$kg_{wwt}.m^{-3}$	ESD, Table 4.15
$Q_{leach,time1}$	196.25	mg	ESD Eq. (4.43)
$Q_{leach,time2}$	1035	mg	ESD Eq. (4.44)
$Clocal_{soil,leach,time1}$ (without degradation)	8.88E-03	$mg.kg_{wwt}^{-1}$	ESD Eq. (4.45)
$Clocal_{soil,leach,time2}$ (without degradation)	4.68E-02	$mg.kg_{wwt}^{-1}$	ESD Eq. (4.46)
$E_{soil,leach,time1}$	6.5416667	$mg.d^{-1}$	ESD Eq. (3.5)
$E_{soil,leach,time2}$	0.1417808	$mg.d^{-1}$	ESD Eq. (3.6)

Distribution in exposed compartments

$DT50_{soil}$	77	d	
k	0.0090019	d^{-1}	TGD, II, Eq. (29)
$Clocal_{soil,time1}$ (with degr., time-weighted avg.)	**4.07E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.7), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., time-weighted avg.)	**7.02E-04**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.8), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time1}$ (with degr., at the end of time 1)	**7.78E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.11), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., at the end of time 2)	**7.13E-04**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.12), $Clocal_{soil,applic}$ = 0

Scenario 1b: House – copper, concentration in groundwater

$PEClocal_{soil,time2}$	53.5	$mg.kg_{wwt}^{-1}$	See Calculations for scenario 1a in section 2.2.8.2
$Fwater_{soil}$	0.2	–	TGD, II, Table 5 (p. 43)
$Fsolid_{soil}$	0.6	–	TGD, II, Table 5 (p. 43)
RHO_{solid}	2500	$kg.m^{-3}$	TGD, II, p. 47
Kp_{soil}	2120	$l.kg^{-1}$	–
$K_{soil\text{-}water}$	3180	$m^3.m^{-3}$	TGD, II, Eq. (24)
RHO_{soil}	1700	$kg.m^{-3}$	ESD
$PEClocal_{soil,\ porew}$	0.0286	$mg.l^{-1}$	TGD, II, Eq. (67)
$PECregional_{groundwater}$	0.0029	$mg.l^{-1}$	–
$PEClocal_{groundwater}$	**0.032**	$mg.l^{-1}$	–

Scenario 2: Noise barrier – copper, distribution in exposed compartments

STP			
$CAPACITY_{stp}$	10000	eq	TGD, II, Table 9 (p. 62)
WASTEWinhab	200	$l.d^{-1}.eq^{-1}$	TGD, II, Table 9 (p. 62)
$EFFLUENT_{stp}$	2000000	$l.d^{-1}$	TGD, II, Eq. (34)
$Clocal_{inf,time1}$	0.0029225	$mg.l^{-1}$	TGD, II, Eq. (32)
$Clocal_{inf,time2}$	0.0013592	$mg.l^{-1}$	TGD, II, Eq. (32)
$Fstp_{water}$	1	(-)	EUSES/SimpleTreat, using K_{OC}
$Fstp_{sludge}$	0	(-)	EUSES/SimpleTreat, using K_{OC}
$PECstp_{time1} = Clocal_{eff,time1}$	**2.92E-03**	$mg.l^{-1}$	TGD, II, Eq. (33), (38)
$PECstp_{time2} = Clocal_{eff,time2}$	**1.36E-03**	$mg.l^{-1}$	TGD, II, Eq. (33), (38)
Surface water			
Kp_{susp}	30246	$l.kg^{-1}$	AR, p. 28
$SUSP_{water}$	15	$mg.l^{-1}$	TGD, II, p. 76
DILUTION	10	(-)	TGD, II, p. 76
$Clocal_{water,time1}$	2.01E-04	$mg.l^{-1}$	TGD, II, Eq. (45)
$Clocal_{water,time2}$	9.35E-05	$mg.l^{-1}$	TGD, II, Eq. (45)
$PECregional_{water}$	0.0029	$mg.l^{-1}$	AR, p. 32
$PEClocal_{water,time1}$	**3.10E-03**	$mg.l^{-1}$	TGD, II, Eq. (48)
$PEClocal_{water,time2}$	**2.99E-03**	$mg.l^{-1}$	TGD, II, Eq. (48)
Sediment			
$Fwater_{susp}$	0.9	(-)	TGD, II, Table 5 (p. 43)
$Fsolid_{susp}$	0.1	(-)	TGD, II, Table 5 (p. 43)
RHOsolid	2500	$kg.m^{-3}$	TGD, II, p. 47
$K_{susp\text{-}water}$	7562.4	$m^3.m^{-3}$	TGD, II, Eq. (24)
RHO_{susp}	1150	$kg.m^{-3}$	TGD, II, p. 44
$Clocal_{sed,time1}$	1.32E+00	$mg.kg_{wwt}^{-1}$	TGD, II, Eq. (50)
$Clocal_{sed,time2}$	6.15E-01	$mg.kg_{wwt}^{-1}$	TGD, II, Eq. (50)
$PECregional_{sediment}$	14.7	$mg.kg_{wwt}^{-1}$	AR, p. 32
$PEClocal_{sed,time1}$	**1.60E+01**	$mg.kg_{wwt}^{-1}$	
$PEClocal_{sed,time2}$	**1.53E+01**	$mg.kg_{wwt}^{-1}$	

Scenario 2: Noise barrier – propiconazole, distribution in exposed compartments

STP			
$CAPACITY_{stp}$	10000	eq	TGD, II, Table 9 (p. 62)
WASTEWinhab	200	$l.d^{-1}.eq^{-1}$	TGD, II, Table 9 (p. 62)
$EFFLUENT_{stp}$	2000000	$l.d^{-1}$	TGD, II, Eq. (34)
$Clocal_{inf,time1}$	3.395E-05	$mg.l^{-1}$	TGD, II, Eq. (32)
$Clocal_{inf,time2}$	5.164E-06	$mg.l^{-1}$	TGD, II, Eq. (32)
$Fstp_{water}$	0.89	(-)	EUSES/SimpleTreat, using K_{OC}
$Fstp_{sludge}$	0.11	(-)	EUSES/SimpleTreat, using K_{OC}
$PECstp_{time1} = Clocal_{eff,time1}$	**3.02E-05**	$mg.l^{-1}$	TGD, II, Eq. (33), (38)
$PECstp_{time2} = Clocal_{eff,time2}$	**4.60E-06**	$mg.l^{-1}$	TGD, II, Eq. (33), (38)
Surface water			
Foc_{susp}	0.1	(-)	TGD, II, Table 5 (p. 43)
Koc	944	$l.kg^{-1}$	
Kp_{susp}	94.4	$l.kg^{-1}$	TGD, II, Eq. (23)
$SUSP_{water}$	15	$mg.l^{-1}$	TGD, II, p. 76
DILUTION	10	(-)	TGD, II, p. 76
$Clocal_{water,time1}$	**3.02E-06**	$mg.l^{-1}$	TGD, II, Eq. (45)
$Clocal_{water,time2}$	**4.59E-07**	$mg.l^{-1}$	TGD, II, Eq. (45)
Sediment			
$Fwater_{susp}$	0.9	(-)	TGD, II, Table 5 (p. 43)
$Fsolid_{susp}$	0.1	(-)	TGD, II, Table 5 (p. 43)
RHOsolid	2500	$kg.m^{-3}$	TGD, II, p. 47
$K_{susp\text{-}water}$	24.5	$m^3.m^{-3}$	TGD, II, Eq. (24)
RHO_{susp}	1150	$kg.m^{-3}$	TGD, II, p. 44
$PEClocal_{sed,time1}$	**6.43E-05**	$mg.kg_{wwt}^{-1}$	TGD, II, Eq. (50)
$PEClocal_{sed,time2}$	**9.78E-06**	$mg.kg_{wwt}^{-1}$	TGD, II, Eq. (50)

Scenario 2: Noise barrier – tebuconazole, distribution in exposed compartments

STP			
$CAPACITY_{stp}$	10000	eq	TGD, II, Table 9 (p. 62)
WASTEWinhab	200	$l.d^{-1}.eq^{-1}$	TGD, II, Table 9 (p. 62)
$EFFLUENT_{stp}$	2000000	$l.d^{-1}$	TGD, II, Eq. (34)
$Clocal_{inf,time1}$	5.495E-05	$mg.l^{-1}$	TGD, II, Eq. (32)
$Clocal_{inf,time2}$	6.401E-06	$mg.l^{-1}$	TGD, II, Eq. (32)
$Fstp_{water}$	0.89	(-)	EUSES/SimpleTreat, using K_{OC}
$Fstp_{sludge}$	0.11	(-)	EUSES/SimpleTreat, using K_{OC}
$PECstp_{time1} = Clocal_{eff,time1}$	**4.89E-05**	$mg.l^{-1}$	TGD, II, Eq. (33), (38)
$PECstp_{time2} = Clocal_{eff,time2}$	**5.70E-06**	$mg.l^{-1}$	TGD, II, Eq. (33), (38)
Surface water			
Foc_{susp}	0.1	(-)	TGD, II, Table 5 (p. 43)
Koc	992	$l.kg^{-1}$	
Kp_{susp}	99.2	$l.kg^{-1}$	TGD, II, Eq. (23)
$SUSP_{water}$	15	$mg.l^{-1}$	TGD, II, p. 76
DILUTION	10	(-)	TGD, II, p. 76
$Clocal_{water,time1}$	**4.88E-06**	$mg.l^{-1}$	TGD, II, Eq. (45)
$Clocal_{water,time2}$	**5.69E-07**	$mg.l^{-1}$	TGD, II, Eq. (45)
Sediment			
$Fwater_{susp}$	0.9	(-)	TGD, II, Table 5 (p. 43)
$Fsolid_{susp}$	0.1	(-)	TGD, II, Table 5 (p. 43)
RHOsolid	2500	$kg.m^{-3}$	TGD, II, p. 47
$K_{susp\text{-}water}$	25.7	$m^3.m^{-3}$	TGD, II, Eq. (24)
RHO_{susp}	1150	$kg.m^{-3}$	TGD, II, p. 44
$PEClocal_{sed,time1}$	**1.09E-04**	$mg.kg_{wwt}^{-1}$	TGD, II, Eq. (50)
$PEClocal_{sed,time2}$	**1.27E-05**	$mg.kg_{wwt}^{-1}$	TGD, II, Eq. (50)

Scenario 3: Transmission pole (tier1) – copper, distribution in exposed compartments

$PECregional_{soil}$ Ageing factor	21.6 2	$mg.kg_{wwt}^{-1}$ (-)	AR, p. 32
$PEClocal_{soil,time1}$ $PEClocal_{soil,time2}$ (with ageing)	**3.74E+01** **3.62E+01**	$mg.kg_{wwt}^{-1}$ $mg.kg_{wwt}^{-1}$	

Scenario 3: Transmission pole (tier 1) – propiconazole, distribution in exposed compartments

$DT50_{soil}$ k	129 0.00537323	d d^{-1}	 TGD, II, Eq. (29)
$Clocal_{soil,time1}$ (with degr., time-weighted avg.)	**1.94E-01**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.7), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., time-weighted avg.)	**2.21E-02**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.8), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time1}$ (with degr., at the end of time 1)	**3.78E-01**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.11), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., at the end of time 2)	**2.27E-02**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.12), $Clocal_{soil,applic}$ = 0

Scenario 3: Transmission pole (tier 1) – tebuconazole, distribution in exposed compartments

$DT50_{soil}$ k	77 0.00900191	d d^{-1}	 TGD, II, Eq. (29)
$Clocal_{soil,time1}$ (with degr., time-weighted avg.)	**1.88E-01**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.7), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., time-weighted avg.)	**1.36E-02**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.8), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time1}$ (with degr., at the end of time 1)	**3.60E-01**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.11), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., at the end of time 2)	**1.38E-02**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.12), $Clocal_{soil,applic}$ = 0

Scenario 3: Transmission pole (tier 2) – copper, distribution in exposed compartments

$PECregional_{soil}$ Ageing factor	21,6 2	$mg.kg_{wwt}^{-1}$ (-)	AR, p. 32
$PEClocal_{soil,time1}$ $PEClocal_{soil,time2}$ (with ageing)	**2,20E+01** **2,08E+01**	$mg.kg_{wwt}^{-1}$ $mg.kg_{wwt}^{-1}$	

Scenario 3: Transmission pole (tier 2) – propiconazole, distribution in exposed compartments

$DT50_{soil}$ k	129 0,00537323	d d^{-1}	 TGD, II, Eq. (29)
$Clocal_{soil,time1}$ (with degr., time-weighted avg.)	**7,47E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.7), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., time-weighted avg.)	**2,47E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.8), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time1}$ (with degr., at the end of time 1)	**1,45E-02**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.11), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., at the end of time 2)	**2,53E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.12), $Clocal_{soil,applic}$ = 0

Scenario 3: Transmission pole (tier 2) – tebuconazole, distribution in exposed compartments

$DT50_{soil}$ k	77 0,00900191	d d^{-1}	 TGD, II, Eq. (29)
$Clocal_{soil,time1}$ (with degr., time-weighted avg.)	**5,95E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.7), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., time-weighted avg.)	**1,63E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.8), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time1}$ (with degr., at the end of time 1)	**1,14E-02**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.11), $Clocal_{soil,applic}$ = 0
$Clocal_{soil,time2}$ (with degr., at the end of time 2)	**1,66E-03**	$mg.kg_{wwt}^{-1}$	ESD Eq. (3.12), $Clocal_{soil,applic}$ = 0

3.3 New information on the active substance

No new data on the active substance have been submitted.

3.4 Residue behaviour

No other data on residue behaviour have been submitted.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Please refer to the IUCLID file.

3.6 Confidential annex I

3.6.1 Product family composition and formulation

NB: This information is confidential and should not be disclosed to third parties

Qualitative and quantitative information on the composition of the biocidal product family are given in a confidential annex I.

3.6.2 Qualitative and quantitative information on the composition of the members of the biocidal product family

Qualitative and quantitative information on the composition of the members of the biocidal product family are given in a confidential annex I.

3.6.3 Information on the substance(s) of concern

Information on the substance(s) of concern are given in confidential annex I.

3.7 Other

No other relevant information.