HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 3 april 2015 tot toelating van het middel Tanalith E 3462, toelatingnummer 14634 N

Product Assessment Report

Tanalith E 3462

3rd of April 2015

Internal registration/file no:	20130952 TNB
Authorisation/Registration no:	14634N
Granting date/entry into force of authorisation/ registration:	3[rd]of April 2015
Expiry date of authorisation/ registration:	3rd of April 2020
Active ingredient:	Basic copper carbonate, propiconazole and tebuconazole
Product type:	PT08

Biocidal product assessment report related to product authorisation under Regulation (EU) 528/2012

Contents

1 General information about the product application

1.1 Applicant

Company Name:	Arch Timber Protection
Address:	Wheldon Road
City:	Castleford
Postal Code:	WF10 2JT
Country:	United Kingdom
Telephone:	+44 1977 714166
Fax:	N/a
E-mail address:	advice@archchemicals.com

1.1.1 Person authorised for communication on behalf of the applicant

Name:	Mr. Kerry Helligar
Function:	Regulatory specialist
Address:	Wheldon Road
City:	Castleford
Postal Code:	WF10 2JT
Country:	United Kingdom
Telephone:	+44 1977 714024
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E-mail address:	timberprotectionadvice.ukca@lonza.com

1.2 Current authorisation holder

Product is currently not auhorised in the Netherlands.

1.3 Proposed authorisation holder

Company Name:	Arch Timber Protection
Address:	Wheldon Road
City:	Castleford
Postal Code:	WF10 2JT
Country:	United Kingdom
Telephone:	+44 1977 714166
Fax:	N/a
E-mail address:	timberprotectionadvice.ukca@lonza.com
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	N/a

1.4 Information about the product application

Application received:	9th of July 2013
Application reported complete:	28th of April 2014
Type of application:	National authorisation
Further information:	N/a

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	Tanalith E 3462
Manufacturer's development code number(s), if appropriate:	3462, 3475 Tanalith 3463 Tanalith E 3474 Tanalith E 3475
Product type:	PT08
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Basic copper carbonate (Copper(II) carbonate-copper(II) hydroxide (1:1)): 15.7%w/w pure substance, or 9%w/w expressed as copper. Propiconazole: 0.18%w/w pure substance Tebuconazole: 0.18%w/w pure substance 2-aminoethanol is a substance of concern in the formulation. For information on the full composition of the product, please refer to the confidential annex.
Formulation type:	SL (soluble concentrate)
Ready to use product (yes/no):	No
Is the product the very same (identity and content) to another product already authorised under the regime of Regulation 528/2012 (yes/no); If yes: authorisation no. and product name: or Has the product the same identity and composition like the product evaluated in connection with the approval of active substances for	No

Regulation 528/2012 (yes/no):	

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):*	Wood preservative for soft and hard wood in use classes 1, 2, 3 (3.1 & 3.2) & 4.
Target organisms:	Fungi and insects, including termites: • brown rot fungi • white rot fungi • soft rot fungi • wood boring beetles • termites (*Reticulitermes spp.*)
Category of users:	Industrial users (professional)
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:*	Preventive treatment through vacuum pressure treatment. Application rate: for use class 1 to 3: 1.30 - 4.17 % w/v for use class 4: 2.55 - 8.89 % w/v for use class 4 niche use (transmission poles): 8.89 % w/v Retention rate (in the analytical zone): for use class 1 to 3*: 7.6 - 16.67 kg/m^3 for use class 4: 15.3 - 27.8 kg/m^3 for use class 4 niche use (transmission poles): 44.44 kg/m^3 *For use in railway sleepers (UC3), UC4 retentions (up to 27.8 kg/m^3) are recommended
Potential for release into the environment (yes/no):	Yes.
Potential for contamination of food/feedingstuff (yes/no)	No, use of treated wood is excluded in the intended use instructions.
Proposed Label:	See SPC.
Use Restrictions:	See SPC.

1.5.3 Information on active substances

Active substance chemical name:	Basic copper carbonate copper (II) carbonate – copper (II) hydroxide (1:1)
CAS No:	12069-69-1
EC No:	235-113-6 (EINECS)
Purity (minimum, g/kg or g/l):	Dry weight specification: 957 g/kg (550g/kg as copper)
Inclusion directive:	2012/2/EU of 9 February 2012
Date of inclusion:	1 February 2014
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes

Manufacturer of active substance(s) used in the biocidal product:	Please refer to the SPC.

Active substance chemical name:	Propiconazole
CAS No:	60207-90-1
EC No:	262-104-4 (EINECS)
Purity (minimum, g/kg or g/l):	930 g/kg
Inclusion directive:	PT08: 2008/78/EC of 25 July 2008
Date of inclusion:	1 April 2010
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes
Manufacturer of active substance(s) used in the biocidal product:	Please refer to the SPC.

Active substance chemical name:	Tebuconazole
CAS No:	107534-96-3
EC No:	403-640-2 (ELINCS)
Purity (minimum, g/kg or g/l):	950 g/kg
Inclusion directive:	PT08: 2008/86/EC of 5 September 2008
Date of inclusion:	1 April 2010
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes
Manufacturer of active substance(s) used in the biocidal product:	Please refer to the SPC.

1.5.4 Information on the substance(s) of concern

Substance chemical name	2-aminoethanol
CAS No:	141-43-5
EC No :	205-483-3
Purity (minimum, g/kg or g/l):	~100%
Typical concentration (minimum and maximum, g/kg, or g/l):	30.3%
Relevant toxicological/ecotoxicological information:	Relevant H-statements: H302, H312, H314, H332, H335
Original ingredient (trade name):	Monoethanolamine

1.6 Documentation

1.6.1 Data submitted in relation to product application

New studies concerning the product Tanalith E 3462 have been submitted with respect to physical-chemical properties of the product, analytical methods, toxicity and efficacy. The studies are listed in Annex 1.

New studies concerning the product Tanalith E 3462 have been submitted with respect to the environmental aspect. The summaries of these studies are listed in Annex 8 and comprise two wood leaching studies for use classes 3 and 4 with the product Tanalith E 3462 and a chronic Daphnia study with the product Tanalith E 3485. As these were new data, the RMS NL briefly reviewed the environmental summaries produced by the applicant and compared it with the conclusions of the study reports. The results from the new Daphnia study were not included in the risk assessment from the applicant for Tanalith E 3462 but are included in this PAR only for illustrative purposes.

1.6.2 Access to documentation

The applicant has provided letters of access from the owners of the dossiers on the active substances basic copper carbonate, propiconazole and tebuconazole.

2 Summary of the product assessment

2.1 Identity related issues

The product is a wood preservative, based on three active substances, basic copper carbonate (15.7% pure active, 9%w/w expressed as copper), propiconazole (0.18% pure active) and tebuconazole (0.18% pure active).

The applicant has access to the substance data by means of a Letter of Access. The manufacturing sites of the active substances are the same as included in the evaluation for inclusion of the active substances in Annex I of Directive 98/8/EC (now Regulation No. 528/2012/EU). For basic copper carbonate, additional substance data was evaluated by the RMS France, discussed at the BPC Working Group meeting in March 2014.

The product applied for, Tanalith E 3462, was not included in the evaluation of the three active substances.

2-aminoethanol is a substance of concern in the formulation.

2.2 Classification, labelling and packaging

2.2.1 Classification and labelling

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
2-aminoethanol, copper(II) carbonate-copper(II) hydroxide, ethoxylated tallow alkyl amines, propiconazole, tebuconazole			
Pictogram:	GHS05 GHS07 GHS09	Signal word:	Danger
H-statements:	H302	Harmful if swallowed.	
	H318	Causes serious eye damage.	
	H332	Harmful if inhaled	
	H335	May cause respiratory irritation	
	H410	Very toxic to aquatic life with long lasting effects.	
P-statements:	P261	Avoid breathing	

		dust/fume/gas/mist/vapours/spray.
	P273	Avoid release to the environment.
	P280	Wear protective gloves/protective clothing and eye/face protection.
	P301 + P312	IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell
	P304 + P340	IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
	P305+P351+P338+P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
Supplemental Hazard information:	EUH208	Contains propiconazole. May produce an allergic reaction.
Child-resistant fastening obligatory?		Not applicable
Tactile warning of danger obligatory?		Not applicable

Explanation:	
Pictogram:	-
H-statements:	-
P-statements:	P280 is highly recommended with the assigned H318. Based on the risk assessment gloves and coverall are prescribed. P305+P351+P338+P310 is highly recommended with the assigned H318. All other statements are proposed by the applicant.
Other:	-

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

2.2.2 Packaging of the biocidal product

Professional users:

Applied for	**Authorized**
1000L HDPE IBC containers	1000L HDPE IBC containers
30,000L stainless steel bulk container for transport by road	30,000L stainless steel bulk container for transport by road*

**not actual commercial packaging type – no shelf-life data is available, but these containers are for transport only and not for storage for long periods of time.*

2.3 Physico/chemical properties and analytical methods

The product Tanalith E 3462 is a wood preservative based on the active substances basic copper carbonate (copper (II) carbonate – copper (II) hydroxide (1:1)). It is a dark blue liquid with a very weak uncharacteristic odour. It does not need to be classified regarding physical and chemical hazards as it is not flammable, not oxidising or explosive and does not self-ignite. It has a pH of 10.8 and its technical characteristics are acceptable.

A shelf-life claim of 2 years can be provisionally authorised. A shelf-life study of 2 years in HDPE is required to confirm the provisional data and should be submitted within 2 years after authorisation.

2.3.1 Physico-chemical properties

For the active substance data, please refer to the Competent Authority reports and the published Assessment Reports of the active substances.

Table 1: Physico-chemical properties of the biocidal product:

	Method	Purity/Specification	Results	Reference
Physical state and nature	Visual GLP	Batch CM/1/66/28/3/12 Copper: 9% Propiconazole: 0.177% Tebuconazole: 0.183%	Liquid	Woolley, A.J., 2012a
Colour	Visual GLP	Batch CM/1/66/28/3/12 Copper: 9% Propiconazole: 0.177% Tebuconazole: 0.183%	Dark blue, opaque	Woolley, A.J., 2012a
Odour	Olfactory GLP	Batch CM/1/66/28/3/12 Copper: 9% Propiconazole: 0.177% Tebuconazole: 0.183%	Very weak, uncharacteristic	Woolley, A.J., 2012a
Explosive properties	EC A14 Theoretical assessment	Batch CM/1/66/28/3/12 Copper: 9% Propiconazole: 0.177% Tebuconazole: 0.183%	The structures of the active ingredients indicate the product will not be explosive	Woolley, A.J., 2012
	Theoretical assessment	-	None of the components of the product are explosive. Therefore, it is safe to assume the product itself will not be explosive.	-
Oxidizing properties	EC A21 Theoretical assessment	Batch CM/1/66/28/3/12 Copper: 9% Propiconazole: 0.177% Tebuconazole: 0.183%	The structures of the active ingredients indicate the product will not be oxidising	Woolley, A.J., 2012
	Theoretical assessment	-	None of the components of the product are oxidising. Therefore, it is safe to assume the product itself will not be oxidising.	-
Flash point	Theoretical assessment	-	None of the components of the product are classified as flammable.	-

	Method	Purity/Specification	Results	Reference
			Therefore, it is safe to assume the product itself will not be flammable.	
Autoflammability	Theoretical assessment	-	None of the components of the product are self-igniting. Therefore, it safe to assume the product itself will not be self-igniting.	-
Other indications of flammability		-	The product is water based, therefore it is not expected to undergo reactions with water, release flammable gas or have pyrophoric properties.	-
Acidity / Alkalinity	CIPAC MT75.3 GLP	Batch CM/1/66/28/3/12 Copper: 9% Propiconazole: 0.177% Tebuconazole: 0.183%	pH at 25°C: Neat: 10.83 1% aqueous dispersion: 9.71	Woolley, A.J., 2012a
	CIPAC MT31.1 GLP	Batch CM/1/66/28/3/12 Copper: 9% Propiconazole: 0.177% Tebuconazole: 0.183%	18.4% as NaOH	Woolley, A.J., 2012a
Relative density / bulk density	EC A3 (pycnometer) GLP	Batch CM/1/66/28/3/12 Copper: 9% Propiconazole: 0.177% Tebuconazole: 0.183%	Density at 20°C: 1.19 kg/L	Woolley, A.J., 2012
Storage stability – stability and shelf life				
Effects of temperature	CIPAC MT39.3 GLP	Batch CM/1/66/28/3/12 Copper: 9% Propiconazole: 0.177% Tebuconazole: 0.183%	No separation or precipitation after storage for 7 days at 0°C.	Woolley, A.J., 2012
	CIPAC MT46.3 GLP	Batch CM/1/66/28/3/12 Copper: 9% Propiconazole: 0.177% Tebuconazole: 0.183%	Stable for 2 weeks at 54°C in glass containing HDPE strips. Properties investigated: appearance,	Woolley, A.J., 2012a

	Method	Purity/Specification	Results	Reference
			HDPE stability, weight change, active substance content. See table 2.3.1-1 for more details.	
	Not to GLP*	Batch CM/1/66/28/3/12 Copper: 9% Propiconazole: 0.177% Tebuconazole: 0.183%	Stable for 2 years at ambient temperatures in glass containing HDPE strips. Properties investigated: appearance, HDPE stability, weight change, active substance content, alkalinity. See table 2.3.1-2 for more details.	Woolley, A.J., 2014*
Effects of light			Not applicable	
Reactivity towards container material			See above	
Technical characteristics in dependence of the formulation type				
	CIPAC MT47.2 GLP	Batch CM/1/66/28/3/12 Copper: 9% Propiconazole: 0.177% Tebuconazole: 0.183%	5%w/w in CIPAC D water: 41mL foam/froth after 1 minute.	Woolley, A.J., 2012
	CIPAC MT47.2 Not to GLP	Tanalith E 3475	8.89%w/w in CIPAC D water: No foam after 1 minute	Hughes, K., 2013
	CIPAC MT41 Not to GLP	Tanalith E 3475	8.89%w/v: no separation	Hughes, K, 2013a
	Centrifugation Not to GLP	Tanalith E 3475	To show that the product is not an SC, but an SL, the product was centrifuged (100%, 50% and 8.89%) and analysed for active substance content, showing it is a true solution of the actives.	Hughes, K, not dated
Compability with other products			Not relevant	
Surface tension			Not relevant	
Viscosity	OECD 114, Ubbelohde GLP	Batch CM/1/66/28/3/12 Copper: 9% Propiconazole:	Kinematic viscosity $14.3 mm^2/s$ at 20°C	Woolley, A.J., 2012

	Method	Purity/Specification	Results	Reference
		0.177% Tebuconazole: 0.183%	7.16mm^2/s at 40°C	
Particle size distribution			Not relevant	

** interim report received in June 2014. Since the report did not contain a date, nor signatures of the study director and QA unit, it cannot yet be considered GLP compliant.*

Table 2.3.1-1 Accelerated storage data (Woolley, A.J., 2012a)

	Initial	After 2 weeks of storage
Copper content	0.177%w/w	0.176%w/w
Propiconazole	0.175%w/w	0.172%w/w
Tebucanzole	8.91%w/w	8.97%w/w
Appearance	Dark blue opaque liquid with a very weak uncharacteristic odour	Dark blue opaque liquid with a very weak uncharacteristic odour
Container	1000mL amber transparent glass	No change
Plastic (HDPE) strip	White translucent plastic strip	No change
Weight change - container - plastic strip	 - -	 0.131%(loss) 0.176%(gain)
pH at 25°C - neat - 1%	 10.83 9.71	 10.89 9.76

Table 2.3.1-2 (Interim) Real-time storage data (Woolley, A.J., 2014)

	Initial	6 months	12 months	18 months	24 months
Copper content	8.91%w/w	No data	9.03%w/w	8.99%w/w	9.41%w/w
Propiconazole	0.175%w/w	0.172%w/w	0.173%w/w	0.175%w/w	0.168%w/w
Tebucanzole	0.177%w/w	0.171%w/w	0.177%w/w	0.172%w/w	0.168%w/w
Appearance	Dark blue opaque liquid with very weak uncharacteristic odour	Dark blue opaque liquid with very weak uncharacteristic odour	Dark blue opaque liquid with weak uncharacteristic odour	Dark blue opaque liquid with odour of ammonia.	Dark blue opaque liquid with weak characteristic odour of ammonia
Container	1000mL amber transparant glass jar with a black opaque screw on lid. No signs of corrosion or degradation.	No change	No change	No change	No change
Plastic (HDPE) strip	White translucent plastic strip. No signs of corrosion or degradation.	No change	No change	No change	No change
Weight change - container - plastic strip		 - 0.05% < 0.182%	 - 0.6% - 0.145%	 - 0.938% + 0.162%	 - 1.56% + 0.331%
pH at 25°C - neat - 1%	 10.83 9.71	 10.83 9.73	 10.74 9.48	 10.61 9.53	 10.79 9.61

Alkalinity (%NaOH)	18.4	18.4	17.9	18.2	17.8

The accelerated and provisional real-time storage tests were performed in glass containers, which contain actual material of the commercial IBC containers. Although direct interaction of the product can be assessed, permeation and possible deformation cannot.

The applicant indicates that it would not be possible to compare the use of a smaller HDPE bottle to an IBC. It is the opinion of the RMS that an HDPE bottle would have a higher surface to volume ratio than an IBC container, hence the packaging material would be thinner and less rigid. Therefore, a regular HDPE bottle is considered worst-case compared to an IBC container.

Based on the above, real-time data is required to confirm the claimed shelf-life of the product in HDPE bottles. The data provided can only be used for a provisional authorisation.

2.3.2 Analytical methods

	Principle of method
Technical active substance as manufactured:	Refer to the assessment report(s) of the active substance(s)
Impurities in technical active substance:	Refer to the assessment report(s) of the active substance(s)
active substance in the formulation:	Copper: ICP-AES or ICP-MS Tebuconazole, propiconazole: HPLC-UV

2.3.2.1 Validation of the analytical method for the biocidal product

RMS note

The analytical methods, based on ICP-AES / ICP-MS and HPLC-UV were not specifically validated for Tanalith E 3462. Read-across from the product Wolman E (CA-C) was requested, but the matrix of the product applied for is more complex.. Therefore, the applicant has submitted validation of the same method for two more products, Tanalith E 8000 and Tanalith E 9000. The validation reports combined show that for all three products, the method is suitable. Based on the compositions of the three products Wolman E (CA-C), Tanalith E 8000 and Tanalith 9000, all concerns of the RMS regarding the read-across are addressed. The method validations are summarised below.

For an overview of the compositions of the three products Wolman E, Tanalith E 8000 and Tanalith E 9000, please refer to the confidential annex of this document. The validation data on the substance DDA was not included in the summary as it is not formulated in the product applied for.

Analytical method for the determination of copper

An aliquot (0.5g) of the product is dissolved in concentrated HNO_3 and water and brought into the copper calibration range, matching the 2%v/v HNO_3 in reagent water of the calibration standards.

<u>Validation data for Wolman E (CA-C)</u>

A Perkin-Elmer Optima 3000 DV ICP-AES in radial view mode and Perkin-Elmer Pneumatic Nebulizer was used for analysis (CU wavelengths:324.752nm and 327.393nm).

Specificity

Representative chromatograms showed no interferences.

Accuracy and repeatability
Recoveries were determined at three fortification levels, with 5 samples each. In addition, a reagent blank and formulation blank were run.

Fortification level (%w/w copper)	Recoveries (mean)	RSD (n)
Blanks	0	- (2)
5	99.2 – 101.0 (100.3)	0.782 (5)
10	98.9 – 101.2 (99.8)	1.09 (5)
15	97.2 – 102.0 (99.3)	1.81 (5)

Linearity
r^2 = 0.9999, y = 10548x-44.564, range 0 – 20 mg Cu/L (6 concentrations)

<u>Validation for Tanalith E 8000 and Tanalith E 9000</u>

An Agilent Technologies 7500cx ICP-MS system was used. Cu was determined using the masses 63 and 65.

Specificity
Representative chromatograms showed no interferences for both Tanalith E 8000 and Tanalith E 9000.

Accuracy
Accuracy data was generated using a Tanalith E 8000 blank formulation.

Fortification level (%w/w copper)	Recoveries (%)
Level 1 (~4% Cu)	102, 99.6
Level 2 (~8% Cu)	101, 99.8
Level 3 (~12% Cu)	93, 102
Overall mean	101 and 1.07%RSD

System precision
The standard deviation of the five injected samples was 0.117, resulting in a RSD of 1.50%, which meets the required RSD_r of 1.97%.

Linearity
r^2 = 1.000, y = $1.76.10^7$ x + $1.09.10^6$, range 0 – 20 mg Cu/L (6 concentrations and duplicate injections at each concentration)

<u>Conclusion</u>
The ICP-AES method for the determination of copper was successfully validated for the product Wolman E (CA-C), Tanalith E 8000. Specificity for Tanalith E 9000 was also addressed. Considering the similarities with Tanalith E 3462, the method is considered acceptable.

Analytical method for the determination of propiconazole and tebuconazole
An aliquot of the product is diluted with acetonitrile:water (20:80 v:v) and analysis by HPLC-UV at 220 nm.

Gradient:
Solvent A: HPLC reagent water with 0.1% H_3PO_4
Solvent B: Acetonitrile

Time	Percent A	Percent B

0	80	20
1	80	20
8	20	80
10	20	80
13	80	20
16	80	20

Retention times: Approx. 9.7 minutes for tebuconazole
Approx. 10.2 minutes for propiconazole

Validation data for Wolman E (CA-C)
An Agilent Series 1100/1200 HPLC with an Agilent Series 1100 Variable Wavelength Detector (220nm), equipped with a YMC ODC AM (150mmx4.6mmx3μm particle size) column was used for analysis.

Specificity
Representative chromatograms showed that is no interference.

Accuracy and repeatability
Recoveries were determined at three fortification levels, with 5 samples each. In addition, a reagent blank and formulation blank were run.

Fortification level (mg a.i. / L)	Recoveries (mean)	RSD (n)	Recoveries (mean)	RSD(n)
	Propiconazole		Tebuconazole	
Blanks	0	- (2)	0	- (2)
1.0	100.7 – 101.1 (100.9)	0.145 (5)	99.8 – 100.7 (100.2)	0.334 (5)
2.0	100.4 – 102.2 (101.5)	0.756 (5)	99.7 – 101.7 (100.8)	0.808 (5)
3.0	100.6 – 101.2 (100.9)	0.239 (5)	100.1 – 101.6 (100.4)	0.170 (5)

Linearity
Propiconazole: r^2 = 1.000, y = -3.7783 x + 193.004, range 0 – 10 mg ai/L, n = 6 with duplicate injections.
Tebuconazole: r^2 = 1.000, y = -1.1646 x + 204.678, range 0 – 10 mg ai/L, n = 6 with duplicate injections.

Validation for Tanalith E 8000 and Tanalith E 9000
An Agilent Series 1100 HPLC with autosamples, equipped with a Fortis Universil C18 column (150mmx4.6mmx5μm particle size) column was used for analysis.

Specificity
Representative chromatograms showed there is no interference in both Tanalith E 8000 and Tanalith E 9000.

Accuracy

Fortification level (mg a.i. / L)	Recoveries (mean)	Fortification level (mg a.i. / L)	Recoveries (%)
Propiconazole		Tebuconazole	
15.4	103, 103	7.41	99.3, 99.5
23.1	103, 104	11.1	99.4, 99.9

30.7	102, 102	14.8	99.5, 99.5

System precision
Tebuconazole:
5 different samples were injected, resulting in an RSD of 0.184%, which is considered acceptable compared to the maximum allowed RSD_r of 3.54%.
10 replicate injections resulted in an RSD of 0.166%.
Propiconazole:
5 different samples were injected, resulting in an RSD of 0.221%, which is considered acceptable compared to the maximum allowed RSD_r of 3.50%.
10 replicate injections resulted in an RSD of 0.114%.

Linearity
Propiconazole: r^2 = 1.000, y = $3.13.10^6$ x + $4.64.10^5$, range 0 – 24 mg ai/L, n = 10.
Tebuconazole: r^2 = 1.000, y = $3.25.10^6$ x + $1.68.10^5$, range 0 – 12 mg ai/L, n = 10.

Conclusion
The HPLC-UV method for the determination of propiconazole and tebuconazole was successfully validated for the product Wolman E (CA-C), Tanalith E 8000 and Tanalith E 9000. Although a slightly different column was used for the two validation studies, the validation data suggest the method is sufficiently robust to allow reading-across to Tanalith E 3462.

2.4 Risk assessment for Physico-chemical properties

The product Tanalith E 3462 is a water based wood preservative with a dark blue colour and very weak uncharacteristic odour. Based on the data provided, it does not require classification based on its physical and chemical properties, although its pH of 10.83 (alkalinity 18.4% as NaOH) indicates that the product may be corrosive to metals.

Tanalith E 3462 is stable at lower temperatures and provisionally for 2 years in HDPE. To confirm the product is 2 years stable in HDPE, additional data is required.

The 30,000L bulk containers applied for were not tested. The product is not actually brought onto the market in road containers. In addition, these containers are also not intended for long term storage, but merely for transport by road. Therefore, the Dutch CA does not consider it to be necessary these containers are tested.

2.5 Effectiveness against target organisms

2.5.1 Function

Tanalith E 3462 is a wood preservative for the protection of wood against fungi and insects, including termites, based on copper(II) carbonate-copper(II) hydroxide (1:1), 9.0 % w/w as copper ion, propiconazole 0.18 % w/w, and tebuconazole 0.18 % w/w. It is used for preventive protection of wood and constructional timbers in Use Classes 1 to 4. Tanalith E 3462 is applied by vacuum pressure application. The biocidal product concentrate is diluted to a suitable working concentration with water. The degree of dilution will vary depending on the wood species, type of wood product and the intended use of the treated wood.

For a description of the intended use in the use categories and codes of the claimed matrix according to the TNsG on the evaluation of efficacy of wood preservative products (PT08) (CA-July 13 – Doc.6.2.c) , see Table 2.5.1.1 below.

Table 2.5.1.1: Use categories and codes

Categories	Matrix wording	Code for produc
User category	Industrial (professional)	A.20
Wood category	softwood and hardwood	B.10; B.20
Wood product	solid wood; reconstituted solid wood; panels	C.10; C.11; C.20
Application aim	preventive treatment	D.40
Field of use	use classes 1, 2, 3 (3.1 & 3.2) & 4	E.10; E.20; E.31; E.32; E.40
Method of applicatio and rate	Pressure process / vacuum impregnation Application rate: for use class 1 to 3: 1.30 - 4.17 % w/v for use class 4: 2.55 - 8.89 % w/v for use class 4 niche use (transmission poles): 8.89 % w/v Retention rate (in the analytical zone): for use class 1 to 3*: 7.6 - 16.67 kg/m^3 for use class 4: 15.3 - 27.8 kg/m^3 for use class 4 niche use (transmission poles): 44.44 kg/m^3 *For use in railway sleepers (UC3), UC4 retentions (up to 27.8 kg/m^3) are recommended.	F.31
Target organisms	brown rot fungi	G.10
	white rot fungi	G.11
	soft rot fungi	G.12
	wood boring beetles	G.30
	termites (*Reticulitermes spp.*)	G.50

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

Organisms to be controlled are fungi (brown rot, white rot and soft rot fungi) and insects (wood boring beetles and termites of the genus *Reticulitermes*). Objects to be protected are wood and constructional timbers (solid wood, reconstituted solid wood and panels) of both softwood and hardwood in Use Classes 1 to 4.

2.5.3 Effects on target organisms

As copper based wood preservatives are used in conjunction with other biocides, full efficacy data of Tanalith E 3462 has to be provided at product authorisation stage. Seven studies according to EN standards were provided to demonstrate the efficacy of Tanalith E 3462. A short summary of the efficacy studies is given in Table 2.5.3.1.

The tests were performed with the formulation X1185. This formulation very slightly deviates from Tanalith E 3462 as the level of the pH adjuster in X1185 is slightly lower than that found in Tanalith E 3462. CA NL is of the opinion that such a deviation will not affect the efficacy against fungi and insects.

Table 2.5.3.1 Summary of efficacy studies of Tanalith E 3462

<table>
<tr><th>Test method</th><th>Test organism</th><th>Test results</th><th>Ref.</th></tr>
<tr><td>EN47 +EN73</td><td>Larvae of Hylotrupes bajulus beetle</td><td>% mortality at 0 kg/m^3 copper (untreated): 3.4%
% mortality at upper toxic value 0.31 kg/m^3 copper: 100%
Biol. ref. value: 0.31 kg/m^3 copper (equivalent to 3.4 kg/m^3 Tanalith E 3462)</td><td>B5.10-1</td></tr>
<tr><td>EN47 +EN84</td><td>Larvae of Hylotrupes bajulus beetle</td><td>% mortality at 0 kg/m^3 copper (untreated): 14%
% mortality at upper toxic value 0.31 kg/m^3 copper: 100%
Biol. ref. value: 0.31 kg/m^3 copper (equivalent to 3.4 kg/m^3 Tanalith E 3462)</td><td>B5.10-2</td></tr>
<tr><td>EN117 + EN73</td><td>Termites Reticulitermes santonensis</td><td>Visual assessment at 0 kg/m^3 copper (untreated): 4 – 4 – 4
Visual assessment at upper toxic value 0.93 kg/m^3: 1 – 0 – 0
Biol. ref. value: 0.93 kg/m^3 copper (equivalent to 10.3 kg/m^3 Tanalith E 3462)</td><td>B5.10-3</td></tr>
<tr><td>EN117 + EN84</td><td>Termites Reticulitermes santonensis</td><td>Visual assessment at 0 kg/m^3 copper (untreated): 4 – 4 – 4
Visual assessment at upper toxic value 0.95 kg/m^3: 1 – 0 – 0
Biol. ref. value: 0.95 kg/m^3 copper (equivalent to 10.6 kg/m^3 Tanalith E 3462)</td><td>B5.10-4</td></tr>
<tr><td>EN113 + EN73</td><td>Brown rot fungi
- Coniophora puteana
- Gloeophyllum trabeum
- Poria placenta

White rot fungi
- Coriolus versicolor</td><td>Lower and upper toxic values (kg/m^3 as copper) for individual basidiomycete test fungi:
<table>
<tr><th></th><th>Lower toxic value kg/m^3 copper</th><th>Upper toxic value kg/m^3 copper</th><th>Mass loss at lower toxic threshold (%)</th></tr>
<tr><td>Coniophora puteana</td><td>0.40</td><td>0.57</td><td>2.5</td></tr>
<tr><td>Gloeophyllum trabeum</td><td>-</td><td>0.39</td><td>-</td></tr>
<tr><td>Poria placenta</td><td>0.57</td><td>0.79</td><td>4.2</td></tr>
<tr><td>Coriolus versicolor (pine)</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Coriolus versicolor (beech)</td><td>0.37</td><td>0.60</td><td>6.7</td></tr>
</table>
Biol. ref. value (incl white rot): 0.68 kg/m^3 copper, equivalent to 7.6 kg/m^3 Tanalith E 3462</td><td>B5.10-5</td></tr>
</table>

<table>
<tr>
<td>EN113 + EN84</td>
<td>Brown rot fungi
- Coniophora puteana
- Gloeophyllum trabeum
- Poria placenta

White rot fungi
- Coriolus versicolor</td>
<td>Lower and upper toxic values (kg/m^3 as copper) for individual basidiomycete test fungi:
<table>
<tr><th></th><th>Lower toxic value kg/m^3 copper</th><th>Upper toxic value kg/m^3 copper</th><th>Mass loss at lower toxic threshold (%)</th></tr>
<tr><td>Coniophora puteana</td><td>-</td><td>0.40</td><td>-</td></tr>
<tr><td>Gloeophyllum trabeum</td><td>0.40</td><td>0.57</td><td>4.2</td></tr>
<tr><td>Poria placenta</td><td>0.40</td><td>0.57</td><td>5.4</td></tr>
<tr><td>Coriolus versicolor (pine)</td><td>-</td><td>0.40</td><td>-</td></tr>
<tr><td>Coriolus versicolor (beech)</td><td>0.38</td><td>0.59</td><td>13.1</td></tr>
</table>
Biological reference values according to EN 599-1:
For brown rot (and white rot in softwood): 0.49 kg/m^3 copper, equivalent to 5.4 kg/m^3
Including white rot in hardwood: 0.59 kg/m^3 copper, equivalent to 6.6 kg/m^3</td>
<td>B5.10-6</td>
</tr>
<tr>
<td>ENV807 + EN84</td>
<td>Unsterile soil with soft rot fungi (species not specified)</td>
<td>Mean mass losses after 24 and 32 weeks for the nominal retention of the reference preservative and the corresponding required retentions of the test preservative (see ENV 807):
<table>
<tr><th rowspan="2">Test product</th><th rowspan="2">Product retention kg/m^3</th><th colspan="2">Mean loss in mass (%)</th></tr>
<tr><th>24 weeks</th><th>32 weeks</th></tr>
<tr><td>Copper/ chromium reference preservative</td><td>0.7</td><td>1.3</td><td>4.2</td></tr>
<tr><td rowspan="2">X1185</td><td>0.0*</td><td>10.6</td><td>14.3</td></tr>
<tr><td>0.13*</td><td>2.1</td><td>2.8</td></tr>
</table>
* as copper

Biol. ref. values according to EN 599-1 (equivalent to the nominal effective retention</td>
<td>B5.10-7</td>
</tr>
</table>

		calculated in accordance with ENV 807): 1.38 kg/m^3 copper, equivalent to 15.3 kg/m^3 Tanalith E 3462	

Note on efficacy requirements:
For determining the efficacy requirements, CA NL followed the PT8 efficacy guidance that was available at the moment of application (July 2013), which was the Technical Notes for Guidance endorsed during the 52nd CA meeting for release for a 6-month consultation period of stakeholders (CA-July13-Doc.6.2.c – Final). According to this guidance document, field tests, although desirable for use in UC 3, 4 and 5, were not always considered mandatory, except for use in the marine environment (UC5). After the 6 month consultation period and discussions during the efficacy workshop in December 2014 , the requirements were changed and in more cases field test are mandatory.
These new and stricter requirements were not foreseen by the time of application for Tanalith E 3462 and, according to the note of guidance on 'Relevance of new guidance becoming available during the process of authorisation and mutual recognition of authorisations of biocidal products' (CA-July12-Doc.6.2d – Final) the competent authorities should therefore accept data based on the latest available guidance published (or applicable) on the date when the applicant can reasonably be expected to start collecting data (with a default cut-off value two years before the date of submission of the application). The efficacy assessment of Tanalith E 3462 is therefore based on the required laboratory tests according to EN599-1 and not on field data.

Conclusion on efficacy:
For insecticidal efficacy the required test were provided (EN47 + EN73/EN84 and EN117 + EN73/ EN84). The results show that for efficacy against wood boring beetles a retention of 3.4 kg/m^3 TANALITH E 3462 is sufficient for UC 1-4. For the prevention of termites in UC 1 and 2 a retention of 10.3 kg/m^3 and in UC3 and 4 a retention of 10.6 kg/m^3 is needed. In table 2.5.3.2 the critical values derived from the tests provided are specified per use class.

For fungicidal efficacy the required tests were provided (EN113 + EN73/EN84 and ENV807 + EN84). In the EN113+EN73 test no results for *C. versicolor* (white rot) in Scotts pine could be calculated since the untreated control showed not enough damage. However, the EN113+EN73 test provided results for *C. versicolor* in beech, and the EN113+EN84 provided results for both Scotts pine and beech. EN 599-1:2009 subsection 5.2.19 states that EN113 tests with *C. versicolor* need not to be conducted in both types of wood, providing there is evidence that the active ingredients in the product are equally effective in both timbers. The EN113+EN84 test shows that the product is more effective in Scotts pine than in beech, therefore efficacy against white rot in pine is sufficiently demonstrated. Only *C. versicolor* (white rot) was tested in both soft wood (Scots pine) and hard wood (beech), all other test were done in soft wood. This is according to the requirements.
Since *C. versicolor* is not the worst case target organism the retentions in UC 1-3 are based on the critical values for efficacy against brown rot and in UC 4 on the critical value against soft rot.
The results show that a retention of 7.55 kg/m^3 TANALITH E 3462 is sufficient for the prevention of brown rot and white rot in UC 1-3 and that a retention of 15.3 kg/m^3 TANALITH E 3462 is sufficient for the prevention of soft rot, brown rot and white rot in UC 4. In table 2.5.3.2 the critical values derived from the tests provided are specified per use class.

Table 2.5.3.2 Critical values derived from the tests provided

	Use class 1 and 2	**Use class 3**	**Use class 4**
target organisms			
Wood boring beetles	3.4 kg/m^3	3.4 kg/m^3	3.4 kg/m^3
Termites (*Reticulitermes spp.*)	10.3 kg/m^3	10.6 kg/m^3	10.6 kg/m^3
Brown and white rot fungi	7.55 kg/m^3	7.55 kg/m^3	7.55 kg/m^3
Soft rot fungi	-	-	15.3 kg/m^3
Intended retention on label	7.6 – 16.67 kg/m^3	7.6 – 16.67 kg/m^3	normal use: 15.3 – 27.8 kg/m^3 transmission poles: 44.44 kg/m^3

Overall the efficacy has been demonstrated for all intended uses at the intended method of application and intended retention rates, except for the use against termites for which a higher retention rate is needed in UC1-3. Since termites of the genus *Reticulitermes* mainly occur in the

southern part of Europe, use against termites will not be needed in all member states. Therefore a distinction is made in the dosing for use in UC1-3 as either:
- use against fungi and insects, including termites, or
- use against fungi and insects, excluding termites.

It is up to each member state to decide whether use against termites is needed in those use classes and to mention the corresponding application and retention rates on the label, see also Table 2.5.4.1.1.

Please note that for use in railway sleepers (UC3), UC4 retentions (up to 27.8 kg/m^3) are recommended by the applicant.

In UC 4 a distinction is made between retention rates for 'normal use' and niche use in transmission poles, see also Table 2.5.4.1.1. For 'normal use' the critical value for soft rot fungi (15.3 kg/m^3) are the minimum retention rates for the product in this use class, but for use in transmission poles a higher retention rate is needed. This higher retention rate is necessary to warrant sufficient service life for this niche application in which exposure conditions are severe and consequences of failure are at their highest. Therefore the retention rate was adjusted by the applicant and set at 44.44.kg/m^3.

2.5.4 Dose / mode of action / known limitations / resistance

2.5.4.1 Dose

Table 2.5.4.1.1 Application and retention rates in the analytical zone (kg/m^3) for the claimed target organisms and use classes

Use class	Target organisms	Application rate (% w/v)	Retention rate in the analytical zone (kg/m^3)
1-2	fungi and insects, excluding termites	1.30 - 4.17	7.6 - 16.67
1-2	fungi and insects, including termites	1.72 - 4.17	10.3 - 16.67
3*	fungi and insects, excluding termites	1.30 - 4.17	7.6 - 16.67
3*	fungi and insects, including termites	1.77 – 4.17	10.6 - 16.67
4	fungi and insects, including termites	2.55 - 8.89	15.3 - 27.8
4 transmission poles	fungi and insects, including termites	8.89	44.44

*Please note that for use in railway sleepers (UC3), UC4 retentions (up to 27.8 kg/m^3) are recommended.

2.5.4.2 Mode of action

Copper

It is known that the biologically active ion derived from the use of copper oxide and copper carbonate is Cu^{2+} in solution.

In the case of fungi it inhibits and prevents the development of the fungal mycelium. Fungal extra-cellular enzymes secreted by the fungus release copper from the wood substrate and the copper penetrate the fungal mycelium. The Cu^{2+} ion interferes with the activity of the pyruvate dehydrogenase system inhibiting the conversion of pyruvate to acetyl CoA within mitochondria. Copper reacts with most essential elements in the cell. It also reacts with ligands on the cell surface and this can interfere with membrane function.

The fungus may cause mobilization of the copper and its solubilisation causes it to penetrate the cell and react with essential cell constituents. Copper may also act extra-cellularly, inhibiting the production of fungal extracellular enzymes.

For insects copper in toxic doses acts as a stomach poison. In the case of termites the copper acts on the gut symbionts killing the gut microflora and fauna, and depriving the termite of its ability to digest cellulose.

Propiconazole and tebuconazole
As other triazole fungicides, propiconazole and tebuconazole inhibit the C14 demethylation step in the ergosterol biosynthesis of fungi and thereby interfere with basic metabolism of the fungal cell wall and contents.

2.5.4.3 Known limitations including resistance

Copper
There are strains of some species of wood destroying fungi that exhibit tolerance to copper. This phenomenon has been known for many years and has been reviewed in Pohleven et al. 2002[1]. Generally speaking wood preservative products containing copper require additional biocides in order to control copper tolerant strains of fungi where there is the potential for copper tolerant strains of fungi to be encountered by the treated timber in service.

There is no evidence of insects being naturally tolerant of the levels of copper used for biocidal purposes in wood preservation. Copper has been used for decades in wood preservation. It was used in copper chrome products and then over the last 20 years or more in copper azole, copper quat, Cu HDO etc. formulations. There have been no reports of copper resistance in insects or the need to increase product retentions to control insects over the years.

Propiconazole
Resistance to fungicides is a normal phenomenon embodied in the natural process of the evolution of biological systems and all DMIs (**de**m**e**thylation **i**nhibitors) including propiconazole have a similar resistance risk but resistance factors may be different. There are no specific resistance cases to propiconazole reported and the activity of all four isomers of propiconazole may reduce the formation of resistance. Therefore, occurrence of resistance to propiconazole is not considered further.

Tebuconazole
For industrial wood preservation using tebuconazole resistance is not an issue. Resistance is usually associated with continued application and resistance is formed between applications such that subsequent applications are less efficacious. Industrial wood preservatives are usually applied only once and there is no evidence to suggest resistance. Also, for other kinds of wood preservation with tebuconazole-containing products, cases of resistances are not reported or known up to the time being.

Resistance management strategy
Tanalith E 3462 contains three active substances. Because of the combined action of the three active substances the development of resistance against Tanalith E 3462 is not very likely. Therefore, it is not necessary to add a resistance management strategy to the label.

Triazole cross-resistance in *Aspergillus fumigatus*
In NL there is an increasing discussion on the resistance of *Aspergillus fumigatus* to triazole based medicines. Resistance to triazoles in plant protection products or biocides is well documented and leads to increasing problems with (cross) resistance against mycobiotics used in hospitals to control *Aspergillus fumigatus*. The situation is so serious that yearly ca. 50 patients in NL die of *A. fumigatus* resistant to triazole-based medicines, as there are no acceptable alternative to these medicines. Most patients enter the hospital with resistant spores present and in case the immune response of a patient is severely repressed, the fungus becomes a problem. We cannot ignore this problem and recently questions have been asked in the Dutch parliament. Cross resistance has to be taken into account. It is not clear where the triazole resistant *A. fumigatus* originates from. Triazoles,

[1] Pohleven, F., Miha, H., Sam, A & Jaka, B., 2002. Tolerance of wood decay fungi to commercial copper based wood preservatives. IRG Document No. 02-30291.

such as tebuconazole and propiconazole are used widely in agriculture to control fungi in wheat and other crops but also in wood preservation and as preservatives. As long as the source of the resistant *A. fumigatus* is not known and the problem increases (6% of the spores are now resistant in NL and resistance has been reported from France and India) it is difficult to decide on action but resistance management strategies should be seriously contemplated. Perhaps preserved wood may not be the main source of triazol resistance but if black moulds (= *A. fumigatus)* develop on treated wood and grow resistant, this may be also a way for exposure of humans to resistant spores.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

Tanalith E 3462 is a wood preservative for the protection of wood against fungi and insects, including termites, based on copper(II) carbonate-copper(II) hydroxide (1:1), 9.0 % w/w as copper ion, propiconazole 0.18 % w/w, and tebuconazole 0.18 % w/w.

This product is intended for industrial use only, for application by pressure process / vacuum impregnation of solid wood, reconstituted solid wood and panels in use classes 1, 2, 3 (3.1 & 3.2) and 4 at the following application and retention rates:

Application rate:	
for use class 1 to 3:	1.30 - 4.17 % w/v
for use class 4:	2.55 - 8.89 % w/v
for use class 4 niche use (transmission poles):	8.89 % w/v

Retention rate (in the analytical zone):	
for use class 1 to 3:	7.6 - 16.67 kg/m^3
for use class 4:	15.3 - 27.8 kg/m^3
for use class 4 niche use (transmission poles):	44.44 kg/m^3

Please note that for use in railway sleepers (UC3), UC4 retentions (up to 27.8 kg/m^3) are recommended.

2.6.2 Assessment of exposure to humans and the environment

2.6.2.1 Human Health

The applicant has submitted an effect and exposure assessment for the product Tanalith E 3462. The human health exposure and risk assessment of Tanalith E3462 is examined by the Dutch CA appropriately according to standard requirements. New toxicological studies with Tanalith E3462 and comparable products have been provided.
No new studies have been provided concerning the three active substances and human health exposure. The product was not a reference product in the EU-review program for inclusion of the three active substances in Annex I of Directive 98/8/EC. The Dutch CA has revised the risk assessment performed by the applicant for the human health aspect. See for more detail section 2.7.

2.6.2.2 Environment

Tanalith E 3462 is to be applied by industrial scale vacuum pressure treatment to timber intended for use in use classes 1 to 4. Environmental exposure occurs when Tanalith E 3462 is released from application and storage of treated wood prior to shipment and from treated wood in service. The product was not a reference product in the EU-review program for inclusion of the active substances in Annex I of Directive 98/8/EC.

An exposure and risk assessment (Doc IIB and Doc IIC) is prepared by the applicant which is based on the leaching studies for the product. The RMS NL has revised this risk assessment for the environmental aspect. See for more detail section 2.8 below.

2.7 Risk assessment for human health

Tanalith E 3462 is a biocidal product concentrate containing 15.7% copper(II)carbonatehydroxide, 0.18% tebuconazole and 0.18% propiconazole, which should be diluted to a suitable working strength with water. The degree of dilution will vary depending on the wood species, type of wood product and the intended use of the treated wood. The typical dilution rate varies with a maximum of use of 6.92 % for normal use in use class 4. For the niche use of transmission poles for extended service life a dilution to give a maximum of 8.89% can be used. During the annex I active review stage no products with all three active substances has been evaluated.

For this authorisation application, no new studies were submitted with the three active substances or concerning human exposure that were not already evaluated during the Annex I active review stage. Detailed data on the toxicity of the active substance can be consulted in Doc IIA of the final Assessment Reports for copper(II)carbonatehydroxide, tebuconazole and propiconazole, PT8.

The product Tanalith E3462 was not a reference product in the EU-review program for inclusion of the three active substances in Annex I of Directive 98/8/EC or for inclusion in the Union list of approved substances of EU Regulation 528/2012 (copper(II)carbonatehydroxidehydroxide approved 1 February 2014 (2012/2/EU), propiconazole approved 1 April 2010 (2008/78/EC)) and tebuconazole approved 1 April 2010 (2008/86/EC)). An acute dermal toxicity study and skin irritation study performed with Tanalith E 3462 are submitted. Furthermore, an acute oral toxicity and an eye irritation study with a comparable product was submitted (see 2.7.1.3 for results). For dermal absorption of copper(II)carbonatehydroxide, tebuconazole and propiconazole, the applicant provided a statement with the following dermal absorption values:

1. copper(II)carbonatehydroxide: 5% for diluted solutions and 100% for the concentrated product.
2. propiconazole: 2.4% for 0.006% propiconazole solutions (to be used for the diluted product), 1.6% for 0.06% propiconazole solutions (to be used for to concentrated product) and 0.9% for 25% propiconazole solutions (based on series of studies conducted with a 250 EC formulation (solvent-based) designed for agricultural uses described in the ECCO Full Report on propiconazole; described in doc IIB of the final CAR propiconazole PT8).
3. tebuconazole: 75% for both diluted solutions and the concentrated product.

The Dutch CA agrees with the values as provided by the applicant, as these values are based on the dermal absorption values from the different CARs and taking into account the (various) concentrations of Tanalith E 3462.

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The toxicology of the three active substances was examined extensively according to standard requirements. The results of these toxicological assessments can be found in the CARs. The threshold limits and labelling regarding human health risks are listed in Annex 4 „Toxicology and metabolism" must be taken into consideration.

2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product contains the following substance of concern: 2-aminoethanol. The content of 2-aminoethanol in the formulation is 30.3%. A worker exposure limit of 2.5 mg/m^3 (1 ppm) 8h-TWA value and the 7.6 mg/m^3 (3 ppm) 15 min-TWA and a skin notation were set by the Scientific Committee for Occupational Exposure Limits (SCOEL/SUM/24; 1996).

The basis for health assessment of the substance of concern is laid out in Annex 5 “Toxicology – biocidal product”

2.7.1.3 Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The product was not a dummy or reference product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC or for inclusion in the Union list of approved substances of EU Regulation 528/2012.

An acute dermal toxicity study and skin irritation study performed with Tanalith E 3462 are submitted. These indicate low dermal toxicity and a lack of dermal irritation. Based on these studies no classification of the Tanalith E 3462 for acute dermal toxicity or skin irritation is warranted. The submitted oral toxicity study and an eye irritation study with a comparable product are used for read-across for classification and labelling of Tanalith E 3462. Based on these studies Tanalith E 3462 needs to be classified with ”Harmful if swallowed (H302) and with “Causes serious eye damage” (H318) according to the Regulation (EC) No. 1272/2008. The acute inhalation study and the skin sensibilisation study are waived. In the interests of animal welfare Arch Timber Protection considers that the remaining toxicological properties and classification can be deduced using the known properties of the product, active substances and the non-active components of the product. The Dutch CA agrees with the waiving and the classification and labelling for these endpoints will be based on the calculation rules according to CLP-Regulation (EC) 1272/2008.

- A GLP-compliant acute toxicity study following a single oral administration (LD_{50}) in the rat has been submitted (OECD 401 (1987)). The results of this study are presented below.

  A sample of a comparable product was administered once only at the dose levels of 429, 559, 754, 1001, and 1339 mg/kg by the oral route (gastric gavage) to 60 rats (30 male, 30 female in groups of five). The study was performed in comparison with a control group of 10 rats of both sexes treated with purified water.

  Examinations for mortality and abnormal clinical sins were performed 15 minutes after intubation, then at 1, 2 and 4 hours, and then daily for the 14 day study period.

  All the animals were weighted the day before treatment, immediately before administration of he material, on days 8 and 15, as well as at the time of death from day 2 onwards.

  A necropsy was performed for all the animals that died during the study and for all surviving animals after the 14 day study.

  The following LD_{50} oral (Bliss method) were observed:

Male	741 mg/kg
Female	650 mg/kg
Male and Female	745 mg/kg

  Body weight changes in the treated groups were similar to that of the control animals throughout the study period

The results obtained, under these experimental conditions, enable to conclude that Tanalith E3462 based on administration of a comparable product of Tanalith E 3462 by the oral route in the rat needs to be classified with “Harmful if swallowed” (H302) according to the Regulation (EC) No. 1272/2008.

- A GLP-complaint acute dermal toxicity study has been submitted. Healthy albino rats were tested according to OECD 402. Animals were prepared the day before dosing by clipping an area of skin not less than 10% of the total body surface area.

  On Day 0, animals were treated with undiluted Tanalith E3462 and the application area covered with surgical gauze and a flexible cohesive bandage.

  After 24 hours, the wrappings were removed and the area cleaned with water. Observations for mortality and signs of toxicity were made daily for 14 days, dermal irritation observations were made on days 4, 7, 11, 14, and body weights measure on days 7, 14.

  On day 14, surviving animals were euthanised and subjected to gross necropsy.

  The following results were obtained: The LD50 (♂) was greater than 5050 mg/kg bw and the LD50 (♀) was estimated between 4000 and 5050 mg/kg bw. Animals surviving to termination exhibited weekly weight gain, with the exception of two males that lost weight between Days 0 and 7, and one female that lost weight between Days 7 and 14. Prominent in-life observations included activity decrease, piloerection, ptosis and decreased defecation. Surviving animals were asymptomatic by Day 3. Signs of dermal irritation included very slight to severe erythema, very slight edema, atonia, desquamation, eschar, necrosis/ulceration, alopecia, sloughing and shallow fissuring throughout the study.
  Necroscopy findings: Gross necropsy in animals that died on test revealed stained back fur; staining or matter on abdominal/tail areas; discoloured liver and empty gastrointestinal tract. Gross necropsy on animals surviving to termination of the study revealed no observable abnormalities.

  The results obtained , under these experimental conditions, enable to conclude that Tanalith E3462 does not need to be classified for acute dermal toxicity according to the Regulation (EC) No. 1272/2008.

- A GLP-complaint skin irritation study as been submitted. Healthy albino New Zealand White rabbits were tested according to OECD 404. Animals were prepared by shaving an area of skin (at least 8 × 8 cm) on the dorsal area of the trunk.

  On Day 0, animals were treated with 0.5 ml of undiluted Tanalith 3462 and the application area covered with surgical gauze and a semi-permeable surgical dressing.

  After 4 hours, the wrappings were removed and the area cleaned with water. Observations for erythema and edema and any other dermal effects were made at 1, 24, 48, 72 hours.

  The following results were obtained: Very slight erythema (score 0.44) and edema (score 0.44) were observed at 24 and 48 hours, and blue staining was observed on the test area. No other dermal effects were observed.

  The results obtained , under these experimental conditions, enable to conclude that Tanalith E3462 does not need to be classified for skin irritation according to the Regulation (EC) No. 1272/2008.

- No eye irritation study has been conducted on Tanalith E 3462 as an irritant effect is expected. A comparable product with two corrosive substances was classified as corrosive.Furthermore, an eye irritation study to OECD 405 showed that a classification of H318 “causes serious eye damage” was applicable. Based on read across from this comparable product Tanalith E3462 needs to be be classified with “Causes serious eye damage” (H318) according to the Regulation (EC) No. 1272/2008.

The basis for the health assessment of the biocidal product is laid out in Annex 5 ”Toxicology – biocidal product”

2.7.2 Exposure

The biocidal product contains the following active substances: copper(II)carbonatehydroxide (pure 15.7% or 9% copper-ion), tebuconazole (pure 0.18%) and propiconazole (pure 0.18%); and the substance of concern: 2-aminoethanol (30.3%).

The product is a preventive wood preservative (PT08), which is industrially applied in industrial timber treatment plant installations via vacuum pressure practices. The treated timber can then be used either by professional or non-professional persons for a variety of end use applications.
The use of both the product by professionals to treat timbers and both professional and non-professional users of timber treated with the product have been considered using the following product data (see Table 2.7.2-1).

Table 2.7.2-1: Summary of Tanalith E 3462 product data
Note these are maximum levels and for most uses the actual retentions may be lower and therefore the corresponding solutions strengths will be lower.

Exposure data		Use Class 3 [UC3]	Use Class 4 [UC4]	
			Normal use*	Niche use II**
Solution strength % (w/v)		4.17	6.92	8.89
Product loading kg /m^3		16.67	27.77	44.44
Solution uptake (l/m^3)***		400	400	500
Concentration in solution % (w/v)	Copper	0.375	0.623	0.781
	Propiconazole	0.0075	0.0125	0.016
	Tebuconazole	0.0075	0.0125	0.016
Loading in wood (kg/m^3)	Copper	1.5	2.5	4
	Propiconazole	0.03	0.05	0.08
	Tebuconazole	0.03	0.05	0.08

* - Niche use I - railway sleepers will use the UC4 ‘normal use’ retention levels
** - Niche use II – transmission poles with 60 year life service
*** - Based on analytical zone, assumes 100 % sapwood and is therefore very much a worst-case value when used for whole wood value.

Tanalith E 3462 is a concentrate product used by professionals in industrial timber treatment only. Therefore, primary exposure of non-professionals and the general public is not expected. The secondary human exposure estimates consider the potential for the exposure of adults (workers and consumers), infants and children in which they may come into contact with Tanalith E 3462 treated timber.

Table 2.7.2-2: Exposure of humans to copper, propiconazole and tebuconazole resulting from use as a preservative for wood.

Exposure path	Production	Industrial/profe	General public	Via the

		ssional use	*Non-primary professional and non-professional use and consumers*	environment
Inhalation	Yes	Yes	Yes	No
Dermal	Yes	Yes	Yes	No
Oral	No	No	Yes	No

2.7.2.1 Exposure of professional users

In Annex 6 "Safety for professional operators", the results of the exposure calculations for the active substances and the substance of concern for the professional user are laid out. Every biocidal product will give rise to exposure during its manufacture, use and disposal. Human exposure during the manufacture of the biocide active substances as copper(II)carbonatehydroxide, propiconazole and tebuconazole of the biocidal product Tanalith E3462 containing the active substances copper(II)carbonatehydroxide, propiconazole and tebuconazole will not be considered in this part (such processes are subject to other worker protection and environmental legislation). So only human occupational exposure to copper(II)carbonatehydroxide, propiconazole and tebuconazole during the use of the biocidal product Tanalith E3462 will be assessed. Copper(II)carbonatehydroxide, propiconazole and tebuconazole are used for the formulation of the wood preservative product Tanalith E 3462 which is a preventive product for treating wood and constructional timbers in Hazard Classes 1 to 4. Tanalith E3462 is supplied as a concentrate for dilution before use. It is in a form of an aqueous solution containing copper(II)carbonatehydroxide (15.7% or 9% copper-ion), 0.18% propiconazole and 0.18% tebuconazole and other active or non-active ingredients (detailed composition is confidential).

It is intended for use in industrial wood preservation to protect wood against insects and fungal infestation. The process is carried out by specialised professionals. In the vacuum pressure impregnation an application solution containing of 0.12-0.8% w/v Copper, 0.0023-0.016% w/v propiconazole and 0.0023-0.016% w/v tebuconazole (1,3-8.89% w/v product in use solution) is used.

Exposure may occur during mixing and loading (to the concentrate) and during the (post) application phase to the in-use product.

Mixing and loading phase

Tanalith E 3462 is a concentrate product used by industrial users only. Tanalith E 3462 has to be diluted in water prior to use. For general use in UC4, the in-use dilutions contain at maximum 6.92 % w/v product. There is a niche use for transmission poles for 60 years' service life where a maximum of 8.89 % w/v could be used. The dilution of the product prior to use in a vacuum pressure treatment system will take place using automated dosing or enclosed systems and therefore the potential for exposure is expected to be very low. Only the concentrate product will be classified whilst the in-use application dilutions are not. Although the dilution uses enclosed systems, and exposure is expected to be very low under normal operating conditions Dutch CA calculated the exposure by using the mixing and loading model 7 for the three active substances.

The product can be added in the concentrate form prior to the addition to the mixing tank. Exposure during manual mixing and loading of the concentrate is considered to represent the worst case scenario. It is assumed that this takes place once daily with an estimated exposure of 10 minutes/day The calculation is based mixing & loading model 7 (HEEG 2008, for pouring and pumping liquids. The indicative inside glove exposure is 1.01 min (101 mg/min without protective gloves) and for inhalation an exposure of 0.94 mg/m^3. Because the vapour pressure of the three substances are < 0.01 Pa the inhalation exposure is considered negligible and therefore is not taken into account for the calculations. For the exposure calculations to the undiluted product, the following dermal absorption percentages are considered: 5% for copper(II)carbonatehydroxide, 2.4% for propiconazole and 75% for tebuconazole. Tanalith E 3462 contains copper(II)carbonatehydroxide (15.7% or 9% copper-ion), 0.18% propiconazole and 0.18% tebuconazole. Based on these data the calculated exposure would be:

Without gloves:
For copper: 0.09*101*10*0.05= 4.6 mg/day
For propiconazole: 0.0018*101*10*0.024 = 0.043 mg/day
For tebuconazole: 0.0018*101*10*0.75 = 1.35 mg/day

Taking into account the $AEL_{long\text{-}term}$ of 0.041mg/kg bw/day for copper, 0.08 mg/kg bw/day for propiconazole and 0.03 mg/kg bw/day for tebuconazole and a bodyweight of 60 kg, the following risk indices are calculated: 1.99 for copper, <0.01 mg/kg bw/day for propiconazole and 0.75 for tebuconazole

With gloves:
For copper: 0.09*1.01*10*0.05= 0.046 mg/day
For propiconazole: 0.0018*1.01*10*0.024 = 0.00043 mg/day
For tebuconazole: 0.0018*1.01*10*0.75 = 0.0135 mg/day

Taking into account the $AEL_{long\text{-}term}$ of 0.041mg/kg bw/day for copper, 0.08 mg/kg bw/day for propiconazole and 0.03 mg/kg bw/day for tebuconazole and a bodyweight of 60 kg, the following risk indices are calculated: 0.019 for copper, <0.01 mg/kg bw/day for propiconazole and <0.01 for tebuconazole

On the basis of the above considerations, it can be concluded that the risk when applying the formulation Tanalith E 3462 for the professional user wearing gloves is acceptable.

Application phase and post-application phase
The product (Tanalith E 3462) is applied to timber in its diluted ready to use concentration in closed system industrial timber impregnation plant using vacuum pressure treatment cycles. Vacuum pressure plants are operated on a cyclical basis. These plants are automatic in operation and the process begins once the door to the treatment vessel has been closed and locked. After the treatment process is complete the timber is held for a post-treatment conditioning period at the treatment plant before being moved into storage for stock or placed into the supply and distribution chains.

Application includes all stages in preservation, from loading the treatment vessel to stacking the treated wood to dry. The job entails a cycle of loading, waiting, unloading and removal of treated timber to storage. Fresh and treated wood is usually moved using lift trucks, however, the operators are closely involved with handling restraining straps and treatment machinery, in maintaining the door seals of treatment vessels, in removing fallen wood and sawdust sludge. The proposed default cycle time for vacuum pressure operations is 3 per day, with each cycle taking 3 hours as a default assumption. Some 'accelerated fixation' processes take longer, so indicating fewer treatments per day. The professionals involved, spend only a fraction of their working time using wood-preservatives.

The exposure modelling approach TNsG (part 2) Handling model 1 is available for vacuum pressure treatment of timber:

The exposure assessment of the application is performed according the following method and default information presented in table 2.7.2.1-1

Table 2.7.2.1-1: Summary of method with default data

PT	Exposure scenario	Aggregation state of the product (solid/liquid/aerosol	Proposed exposure model by NL	Default settings	Remarks on the proposed model
8	Professional vacuum pressure treatment of wood	Liquid	Handling model 1	3- Cycles "Water-based products: Hands: 1080 mg/cycle (inside gloves) Body: 8570 mg/cycle Inhalation: 1.9 mg/m3	Calculation of the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account: • *the vapour pressure of the substance (a volatile substance has vapour pressure > 1 x 10-2 Pa at 20 °C).* The number of cycles is under discussion in HEEG (still in March 2014)

During vacuum pressure treatment, timber is treated in an enclosed vessel and the process is largely automated. During a treatment cycle, the worker/operator is not continually exposed and in many cases workers are engaged in other tasks for most of the treatment cycle. Therefore, operator exposure from vacuum pressure treatment should be low except during loading and particularly unloading the vessel, where they may contact wet wood, wet straps etc and overall cycle time is largely irrelevant.

Timber treatment plant operators are required to have adequate knowledge and skill in handling hazardous chemicals. Protective measures such as instruction, training, exposure control and PPE are required to be in place by health and safety law. In order to present reasonable a worst-case (RWC) approach treatment of wood for UC4 (normal use) and UC4 (niche use) has been presented as these treatments represent the maximum normal and niche treatments proposed for Tanalith E 3462. The niche use is unlikely to take place as a matter of routine but in batches for specific orders. However, to ensure that the maximum exposures are predicted for risk assessment no adjustment to the default cycles or cycle times have been made.

Professional intermittently handling water-wet or solvent-damp wood and associated equipment is calculated. The models are derived from data relating to industrial timber treatment using vacuum pressure plants and water-based (WB) or solvent –based (SB) liquid formulations. Hand exposure is actual exposure inside gloves. Exposure is expressed as mg/cycle and mg/m^3 in-use product. The indicative Exposures (Water based) are: hands 1080 mg/cycle, body 8570 mg/cycle and inhalation 1.9 mg/m^3.
Primary exposure will be predominantly via the dermal route as a result of direct contact with the surface of treated timber and through contact with ancillary equipment and contaminated process plants.

The exposure outputs or calculations are given in table 1-3 in annex 6. A Summary of primary exposures (TNsG) and risk characterisations against worst-case industrial applications of vacuum pressure treatments using Tanalith E 3462 is presented in table 2.7.2.1-2

Table 2.7.2.1-2 Summary of primary exposures (TNsG) and risk characterisations against worst-case industrial applications of vacuum pressure treatments using Tanalith E 3462

Task : Handling of wood during vacuum-pressure impregnation					
Tier-PPE	**Hazard Class**	**Active substance**	**Total exposure** **Systemic dose mg as / kg bw**	**AEL**	**% AEL**
Tier 1 : gloves, minimal clothing, no RPE	**UC4 Normal use**	**Copper**	0.152	0.041	371
		Propiconazole	0.0015	0.08	1.88
		Tebuconazole	0.045	0.03	150
	UC4 Niche use	**Copper**	0.193	0.041	471
		Propiconazole	0.0018	0.08	2.25
		Tebuconazole	0.058	0.03	193
Tier 2 : gloves, protective	**UC4 Normal use**	**Copper**	0.032	0.041	78.0

clothing, no RPE		**Propiconazole**	0.003	0.08	3.75
		Tebuconazole	0.0092	0.03	30.7
	UC4 Niche use	**Copper**	0.0398	0.041	97.1
		Propiconazole	0.00037	0.08	4.63
		Tebuconazole	0.012	0.03	40

For the proposed use of Tanalith E 3462 as a vacuum pressure treatment of wood using the maximum 'normal use for UC4' retention of 2.5 kg Cu/m^3; the predicted worker exposure levels have been shown to be within the relevant AELs for copper, propiconazole and tebuconazole and authorisation is therefore sought under the use conditions 'using gloves and protective clothing'. Acceptable exposure levels have also been shown for the proposed 'niche use' of Tanalith E 3462 for UC4 in the vacuum pressure treatment of transmission poles at the higher retention rate of 4 kg Cu/m^3. Also for this 'nich use' the use conditions should be 'using gloves and protective clothing'. As also footwear is required in industrial/professional use the final use conditions should be "protective clothing, gloves and footwear".

2.7.2.2 Exposure of non-professional users and the general public

In Annex 7 "Safety for non-professional operators and the general public", the results of the exposure calculations for the active substance and the substance of concern for the non-professional user and the general public are laid out.

The secondary human exposure assessment considers the potential for the exposure of adults, children and infants in situations where they may come into contact with Tanalith E 3462 treated timber. The scenarios used in this assessment are those contained in the TNsG on Human Exposure parts 2 and 3 and detailed in the reference scenario sections of the User guidance (2002, from page 51). The following scenarios have been identified as being relevant for assessing the potential exposure of humans to Tanalith E 3462 treated timbers during and after their use:

<u>Acute exposure</u>

Adults (consumers) - Acute handling, cutting and sanding treated timbers

Infants - Acute chewing preserved timber off-cuts

<u>Chronic exposure</u>

Adults (workers) - Chronic handling, cutting and sanding treated timbers

Children - Chronic playing on preserved timber playground equipment

Infants - Chronic playing on preserved timber playground equipment and mouth contacts with the treated timber surface.

Some of the secondary exposure scenarios assume oral exposure. For all of the calculations of oral exposure, copper uptake has been adjusted to take account of the 36 % oral absorption value as agreed for copper in WPCTF.

Model calculations – acute phase

The description of the model calculations and the exposure outputs or calculations of the secondary acute exposure scenarios for adults (consumers) - acute handling, cutting and sanding treated timbers -is presented in table 1 in annex 7. A summary of the risk characterisations is presented in table 2.7.2.2-1

Table 2.7.2.2-1: Summary of the risk characterisations for acute secondary exposure

Active substance	**Systemic dose (mg/kg bw/d)**	**AEL (mg/kg bw/d)**	**% AEL**
Copper	0.0042	0.082	5.1
Propiconazole	0.0000466	0.3	0.016
Tebuconazole	0.00106	0.03	3.53

From table 2.7.2.2-1 it can be seen that the systemic doses do not exceed the AELs when Tanalith E 3462 product data are used and so this secondary exposure scenario is considered acceptable.

The description of the model calculations and the exposure outputs or calculations of the secondary acute exposure scenarios for Infants - Acute chewing preserved timber off-cuts - is presented in table 2 in annex 7. A summary of the risk characterisations is presented in table 2.7.2.2-2

Table 2.7.2.2-2: Summary of the risk characterisation for acute exposure of infants

Active substances	**Systemic dose (mg/kg bw/d)**	**AEL (mg/kg bw/d)**	**% AEL**
Copper	0.144	0.082	175.6
Propiconazole	0.008	0.3	2.67
Tebuconazole	0.008	0.03	26.67

From table 2.7.2.2-2 it can be seen that using the default calculations above the systemic dose for copper exceeds the AEL, therefore, a refined Tier 2 calculation is required:
As stated in the Annex I dossier for Basic copper carbonate the above model from the TNsG Human Exposure is considered unrealistic as it is unlikely that an infant could chew a piece of timber 4 cm x 4 cm x 1 cm and certainly would not be able to generate enough saliva to extract wood preservative from the inside the block of treated wood. Treated wood is very hard and is highly likely to be distasteful to the infant. The infant would probably also expel unpleasant tasting materials from its mouth. However, the dislodgeable residues of copper from the surface of the wood may be removed by the infant and ingest this material. Therefore, a dislodgeable copper concentration of 2 µg/cm^2 (as agreed for copper in the WPCTF dossier with a copper loading of 3.42 kg/m^3; worst case for the copper loading of 2.5 kg/m^3 in this PAR) was used in following calculations:

Surface of wood in off cut = (2 x 4 x 4) + (4 x 4 x 1) = 48 cm^2

Dislodgeable copper = 48 cm^2 x 0.002 mg/cm^2 = 0.096 mg ingested

10 kg infant and 36 % oral absorption

= 0.096 mg x 0.36/10

= 0.0035 mg / kg bw/ day

Table 2.7.2.2-3: Summary of the risk characterisation for acute exposure of infants

Active substances	Systemic dose (mg/kg bw/d)	AEL (mg/kg bw/d)	% AEL
Copper	0.0035	0.082	4.268

Based on table 2.7.2.2-3 using the refined dislodgeable value for copper sufficiently reduces the potential systemic dose below the AEL. Therefore, this acute secondary exposure scenario is considered acceptable.

Model calculations – chronic phase

The description of the model calculations and the exposure outputs or calculations of the secondary chronic exposure scenarios for adults (non-professional) sanding treated wooden posts
is presented in table 3 in annex 7. A summary of the risk characterisations is presented in table 2.7.2.2-4.

Table 2.7.2.2-4: Summary of the risk characterisations for chronic secondary exposure for an adult sanding

Active substance	UC4 retention	Systemic dose (mg/kg bw/d)	AEL (mg/kg bw/d)	% AEL
Copper (5 %)	Normal use	0.0074	0.041	18.05
Propiconazole		0.00011	0.08	0.14
Tebuconazole		0.0011	0.03	3.67
Copper (5 %)	Nich use	0.0118	0.041	28.78
Propiconazole		0.000178	0.08	0.22
Tebuconazole		0.00179	0.03	5.97

From table 2.7.2.2-4 it can be seen that systemic doses do not exceed the AELs and so this chronic secondary exposure scenario is considered acceptable.

The description of the model calculations and the exposure outputs or calculations of the secondary chronic exposure exposure of children - Chronic playing on preserved timber playground equipment is presented in table 4 in annex 7. A summary of the risk characterisations is presented in table 2.7.2.2-5.

Table 2.7.2.2-5: Summary of the risk characterisations for chronic secondary exposure for a child in contact with playground structure

Active substance	UC4 retention (kg Cu/m^3)	Systemic dose (mg/kg bw/d)	AEL (mg/kg bw/d)	% AEL
Copper (5 %)	2.5	0.0067	0.041	16.34
Propiconazole	0.05	0.000064	0.08	0.08
Tebuconazole	0.05	0.002	0.03	6.67

From table 2.7.2.2-5 it can be seen that systemic doses do not exceed the AELs and so this chronic secondary exposure scenario is considered acceptable.

The description of the model calculations and the exposure outputs or calculations of the secondary chronic exposure exposure of infants - playing on (weathered) playground structure and mouthing - dermal and ingestion exposure is presented in table 5 in annex 7. A summary of the risk characterisations is presented in table 2.7.2.2-6.

Table 2.7.2.2-6: Summary of the risk characterisations for chronic secondary exposure for an infant in contact with playground structure (dermal and oral routes of exposure)

Active substance	UC4 retention (kg Cu/m^3)	Systemic dose (mg/kg bw/d)	AEL (mg/kg bw/d)	% AEL
Copper (5 %)	2.5	0.0136	0.041	33.17
Propiconazole	0.05	0.0051	0.08	6.4
Tebuconazole	0.05	0.008	0.03	26.67

From table 2.7.2.2-6 it can be seen that systemic doses do not exceed the AELs and so this secondary exposure scenario is considered acceptable. In addition, it is unlikely that all infants will actually mouth the wood on playing structures and so the above scenario is considered very worst case.

2.7.2.3 Exposure to residues in food

In Annex 8 "Residue behaviour", the results of the residue assessment are laid out.

Contact to food and feedstuffs from impregnated wood should be avoided, because no information related to residues in food and feedstuffs was provided in the dossier. Furthermore, using the assumption of an intake of 1 kg food/person/day and the worst case assumption of 1 kg food to be packed in 600 cm^2,. 2.5 mg/cm^3 copper or 0.05 mg/cm^3 propiconazole or 0.05 kg.cm^3 tebuconazole in the outer 1 cm will lead to 1500 mg/person/day for copper and 30 mg/person/day for propiconazole and tebuconazole. As the ADI of copper is 0.15 mg/kg bw/day, for propiconazole 0.08 mg/kg bw/day and for tebuconazole 0.03 mg/kg bw/day, the risk indices are respectively (1500/(0.15x60)=) 167, (30/(0.08x60)=) 6.25 and (30/0.03x60)=) 17. So, also based on the risk assessment contact to food and feedstuffs from impregnated wood should be avoided. Therefore, the restriction is included in the SPC "Contact to food and feedstuffs from impregnated wood should be avoided".

Although the applicant for a wood preservative is not aware of all end products packaging made of wood (as in wooden pallets, wooden crates, wooden boxes, or any other packing material made of wood) can be used to contain the following food categories: fruit and vegetables, fishery, wine and liquors, oils, cheese and milk derivatives, meat and meat products, bread and bakery products, pulses, nuts and dried fruits, tea. The treatment appropriate for wood packaging material used in international commercial trade is regulated by FAO's standard ISPM No. 15. The use of wood packaging in contact with food/ feed for international commercial trade is included in this regulation.

By using wooden boxes for e.g fruit, the general public could be potentially exposed to residues of copper, propiconazole and tebuconazole in food via migration of residues from wood used as "food contact material". The main requirements for the use as "food contact material" is established in REGULATION (EC) No 1935/2004 of The European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.
The regulation shall apply for the intended use of the products in the wood industry.

The applicant submitted an exposure assessment and risk assessment for livestock.

Livestock

Materials are treated with biocidal products to protect them from decay. Treated materials can be formed into structures that livestock animals have access to (e.g. wooden fence rails around paddocks), and may become part of animal housing and transport vehicles. In addition, existing structures may be treated with biocides. By chewing on (e.g. horses, rabbits, goats), rubbing against (large slaughter animals) or licking (e.g. ruminants) the treated materials, animals can take up residues of the biocidal product. In addition, volatile substances being released from the treated material may be inhaled.

Exposure of animals to treated timber

Using the available 'DRAWG Draft Proposal Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products' endorsed by the 39th CA meeting (Dec 2010) an assessment of the impact of Tanalith E 3462 on various livestock and companion animals has been carried out.
According to the guidance, wood treated with biocidal products to protect them from decay can be used to construct structures that livestock animals have access to (e.g. wooden fence posts around paddocks), and may become part of animal housing and transport vehicles. The guidance states that animals can take up residues of the biocidal product by chewing on (e.g. horses, rabbits, goats), rubbing against (large slaughter animals) or licking (e.g. ruminants) the treated materials. In addition, volatile substances being released from the treated material may be inhaled, but this is not relevant for Tanalith E 3462 since the active substances have been shown to be non-volatile.
Regarding the route of exposure, the guidance suggests that possible routes are via chewing and licking (oral), rubbing against (dermal) or breathing in volatile products (inhalation). The latter, inhalation, has not been considered as the product is applied as a pre-treatment and is not considered volatile. The extent of the oral and dermal exposures will be depended on the animals' behaviour and husbandry practices; e.g. dermal exposure will result during from transport of slaughter animals, but oral exposure (chewing/licking) will be more likely to occur during routine stabling or grazing where access to treated timber is commonplace.

The guidance also states that '*Only a fraction of the application amount will be available to animals and can be quantified by the amount of material an animal comes into contact with and the amount of residue that can be extracted from the material'*. Therefore, the calculations rely on a reasonable estimate of a) the amount of product available on and in the treated wood and b) the route (dermal/oral/inhalation), frequency and extent of an animal's exposure. In order to produce a reasonable worst-case assessment the guidance recommends a default maximum product uptake of 50 l/m^3 biocidal product absorbed into the outer 1 cm layer of treated wood of, all of which is considered to be available through chewing or licking. However, the maximum product uptake is 400 l/m^3 for UC3, which assumes 100 % sapwood and is unrealistic, additional calculations have been carried out using a value of 200 l/m^3 assuming an average of 50% sapwood in the available treated wood. Therefore, both values have been used in a Tier 1 (Draft Proposed Guidance) and Tier 2 (Product application) assessment approach.
The available example in the guidance; Example 3.1: Treatment of Materials – Exposure of horses to treated wood determines both oral and dermal exposures for horses, which seems to be an over prediction with dermal exposure unlikely outside of the transport scenario. Therefore, the following assessment can be considered an absolute worst-case assessment using the default information in table 2.7.2.3-1.

Table 2.7.2.3-1: Summary of the default data

Animal	Body weight (kg)	Body surface area in contact with treated wood (m^2)	Wood consumption (m^3/d)	Tongue surface area (m^2)	Licks per day
Horse	400	1.62	0.0000186	-	-
Beef cattle	500	1.44	0.0000232	-	-
Dairy cattle	650	1.68	0.0000302	-	-
Calf	200	0.87	0.00000929	0.008	10
Fattening pig	100	0.45	0.00000464	0.008	10
Breeding pig	260	0.84	0.0000121	0.008	10
Sheep	75	0.45	0.00000348	-	-
Lamb	40	0.3	0.00000186	-	-
Slaughter goat	13	0.15	0.000000604	-	-
Lactating goat	70	0.45	0.00000325	-	-

No assessment of the inhalation route has been made due to the low volatility of the active substances and product.

Using this assumption, the concentrations (g a.s./m^3) of a.s in UC3 (worst-case value) wood treated with Tanalith E 3462 (at copper (0.375 % w/w), propiconazole (0.0075 % w/w) and tebuconazole (0.0075 % w/w)) would be calculated. The description of the model calculations and the exposure outputs or calculations are presented in table 1-3 in annex 8. A summary of the risk characterisations is presented in table 2.7.2.3-2.

The data presented in annex 8 show that the reasonable worst-case exposure predictions using the product uptake TNsG default of 50 l/m^3 do not trigger the arbitrary trigger value of 0.004 mg/kg bw/d for oral, dermal or combined daily exposures. However, whilst propiconazole remains acceptable when the product uptake of 200 l/m^3 is used, the trigger value is exceeded for copper (oral and combined) and tebuconazole (dermal and combined) exposures. However, if these values are compared to the AEL values for copper and tebuconazole these suggest that there is no risk to the animals (see Table). These predictions are all very conservative, as the guidance suggests both dermal and oral exposure routes is not applicable to each animal. Therefore, copper propiconazole and tebuconazole within wood treated with Tanalith E 3462 is not expected to pose an unacceptable risk to the livestock animals considered.

Table 2.7.2.3-2: Summary of the copper and tebuconazole risk characterisation of wood treated with a product uptake of 200 l/m^3 Tanalith E 3462

Animal	Active substances	Total dose (mg/kg bw/d)	AEL* (mg/kg bw/d)	% AEL
Horse [chew]	Copper	0.009	0.41	2.2
	Tebuconazole	-	-	-
Beef cattle [chew]	Copper	0.009	0.41	2.2
	Tebuconazole	-	-	-
Dairy cattle [chew]	Copper	0.009	0.41	2.2
	Tebuconazole	-	-	-
Calf [chew]	Copper	0.0095	0.41	2.3
	Tebuconazole	-	-	-
Calf [lick]	Copper	0.00455	0.41	1.1
	Tebuconazole	-	-	-
Fattening pig [chew]	Copper	0.0095	0.41	2.3
	Tebuconazole	-	-	-
Fattening pig [lick]	Copper	0.0085	0.41	2.1
	Tebuconazole	-	-	-
Breeding pig [chew]	Copper	0.0095	0.41	2.3
	Tebuconazole	-	-	-
Breeding pig [chew]	Copper	0.0035	0.41	0.85
	Tebuconazole	-	-	-
Breeding pig [lick]	Copper	0.00985	0.41	2.4
	Tebuconazole	-	-	-
Sheep [chew]	Copper	0.01	0.41	2.4
	Tebuconazole	0.0041	0.3	1.4
Lamb [chew]	Copper	0.011	0.41	2.7
	Tebuconazole	0.007	0.3	2.3
Slaughter goat [chew]	Copper	0.01	0.41	2.4
	Tebuconazole	0.0043	0.3	1.4

* adjusted by a factor of 10 as there is no *intra-species* (humans) variability to be taken into account.

Therefore, the Dutch CA considers that the above assessment should be considered protective of companion animals since farmers and livestock owners are advised to restrict animals that habitually lick or chew wood in order to limit their opportunity in the interest of good husbandry due to the harmful effects of ingesting wood. In addition a recent EFSA paper (EFSA, 2012) the conditions of use for copper in feeds stuffs was investigated using cupric sulphate pentahydrate, in final feed for all animal species/categories with a maximum total content for companion animals investigated in the above assessment given as;

- 170 mg Cu/kg complete feeding stuffs for piglets (up to 12 weeks) and 25 mg Cu/kg for other pigs;
- 15 mg Cu/kg complete feeding stuffs for bovine before the start of rumination (milk replacers and other complete feeding stuffs) and 35 mg Cu/kg for other bovine;
- 15 mg Cu/kg complete feeding stuffs for ovine;

Moreover, based on man, an additional internal exposure of 3.56 mg Cu/day (worst-case) will exceed the MTDI in human. Therefore the value of 3.56 mg Cu/day will be used as the AEL for copper in man. Corrected to 60 kg body weight, it corresponds to (3.56 / 60 =) 0.059 mg Cu/kg bw/day in human.

These values support the conclusion with respect to copper in that the arbitrary cut off of 0.004 mg/kg bw/d is too conservative and supports the conclusion that Tanalith E 3462 does not pose a concern for animals who lick, chew or rub against the treated timber.

Substance of concern
The biocidal product contains the following substances of concern: 2-aminoethanol. The content of 2-aminoethanol in the formulation is 30.3%. The tox classification of 2-aminoethanol is taken into account in the classification and labelling of Tanalith E 3462.

A worker exposure limit of 2.5 mg/m^3 (1 ppm) 8h-TWA value and the 7.6 mg/m^3 (3 ppm) 15 min-TWA and a skin notation were set by the Scientific Committee for Occupational Exposure Limits (SCOEL/SUM/24; 1996). An exposure assessment and a risk characterisation is performed for 2-aminoethanol based on mentioned SCOEL recommendations. The SCOEL recommendation to prevent exposure to irritating levels 2-aminoethanol has a skin notation, because of dermal absorption.

Based on the SCOEL recommendation (see annex 5) the inhalation route seems to be more toxic than the oral route. At repeated inhalation systemic effects are seen at 168 mg/m3 (= 0.168 mg/L). For a study in rats at 6h exposure time the LOAEL will be (0.168 mg/L x 45 L/kg bw/h (default) x 6h) = 45 mg/kg bw/d. The oral NOAEL is 320 mg/kg bw/d. Therefore, based on the SCOEL recommendation Dutch CA derived a systemic AEL of 192 mg/person based on the oral NOAEL of 320 mg/kg bw/day, a safety factor of 100 and a bodyweight of 60 kg in the risk assessment for dermal exposure.

<u>Mixing and loading</u>
As the dilution uses enclosed systems, exposure is expected to be very low under normal operating conditions. The worker exposure limit of 2.5 mg/m^3 (1 ppm) 8h-TWA value and the 7.6 mg/m^3 (3 ppm) 15 min-TWA value are above the indicative value of 0.94 mg/m3 according to mixing & loading model 7 (HEEG 2008, for pouring and pumping liquids) for the product indicating that the inhalatory exposure to 2-aminoethanol is expected to be very low (<SCOEL values). In addition, according to mixing & loading model 7 (HEEG 2008, for pouring and pumping liquids) the indicative inside glove exposure is 1.01 min (101 mg/min without protective gloves; gloves are already necessary for the active ingredients). Using the 30.3% 2-aminoethanol in the product and the worst case dermal absorption percentage of 75% based on the EFSA guidance on dermal absorption 2012 (see annex 5) the calculated exposure would be:

0.303*1.01*10*0.75= 2.3 mg/day

Based on the AEL of 192 mg/person (based on the NOAEL of 320 mg/kg bw/day in a repeated oral study in rats, a safety factor of 100 and a bodyweight of 60 kg) the risk indices for dermal exposure is calculated to be 2.3/192 = 0.01.

On the basis of the above considerations, it can be concluded that no adverse effects are expected for protected professional users from the exposure to the substance of concern 2-aminoethanol during mixing&loading. Gloves are prescribed based on the risk assessment for the active substances.

<u>Application phase and post-application phase</u>
The worker exposure limit of 2.5 mg/m^3 (1 ppm) 8h-TWA value and the 7.6 mg/m^3 (3 ppm) 15 min-TWA value are above the indicative value of 1.9 mg/m3 according to handling model 1 for the product indicating that the inhalatory exposure to 2-aminoethanol is expected to be very low (<SCOEL values).

The dermal exposure value of 5811 mg according to handling model 1 for the product during handling using gloves and protective equipement is used in a risk characterisation. The worst case in use dilution of 2-aminoethanol is 8.89% x 30.3% = 2.69% resulting in 5811 mg x 0.0269 x 0.75 = 117.24 mg 2-aminoethanol per person (based on 75% dermal absorption based on EFSA guidance 2012 (see annex 5) .

Based on the AEL of 192 mg/person (based on the NOAEL of 320 mg/kg bw/day in a repeated oral study in rats, a safety factor of 100 and a bodyweight of 60 kg) the risk indices for dermal exposure is calculated to be 117.24/192 = 0.61.

On the basis of the above considerations, it can be concluded that no adverse effects are expected for protected professional users from the exposure to the substance of concern 2-aminoethanol during the application and post-application phase. Gloves, protective clothing and footwear are prescribed based on the risk assessment for the active substances.

Furthermore, as based on the risk assessment performed for the professional users the exposure to copper can be assumed to represent the worst case exposure scenarios for the exposure of non-professional users, the general public and contact to food and feedstuffs, the exposure to 2-aminoethanol caused by exposure of non-professional users, the gereral public and contact to food and feedstuffs won't result in a risk.

Combined exposure
The formulation Tanalith E 3462 is a mixture of 3 active substances. The combined toxicological effect of these three active substances has not been investigated with regard to repeated dose toxicity.

Based on the proposal for the assessment of combined exposure proposed by the MS France and endorsed at the TM IV, 2012, as a first tier the systemic effects of both substances are considered to be additive by default. This implies that if the sum of risk indices (%AEL) per exposure scenario is below 1 (for %AEL>100%), no risk of adverse effects from combined exposure to both substances is expected.

The following sum of risk indices (%AEL) can be calculated for primary exposure:
The niche use in tier 2 (gloves, protective clothing and no RPE) the %AEL >100%.

As a second tier, the critical effects of the substances need to be considered. The critical systemic effects from exposure to copper are effects on liver and kidney, haematological effects and effects on blood biochemistry. Based on **kidney damages**, consisting in an increase of cytoplasmic protein droplets, a NOAEL of 1000 ppm (16.3 and 17.3 mgCu/kg bw/day in male and female rats respectively) rats and was determined. Other findings such as liver inflammation and lesions of the forestomach were also reported at 2000 ppm and above (corresponding to doses from 34 mgCu/kg bw/day).The NOAEL of 16.3 mg/kg bw/d was used for the risk characterisation.

In case of exposure to propiconazole the critical effects are reduced litter size, pup weight, viability and effects at dose levels causing parental toxicity. **Liver toxicity** (swelling of hepatocytes and clear-cell changes) was evident in parental animals in the two-generation study in rat at dose levels of 500 ppm (lowest average intake 41.8 mg/kg bw/day) and 2500 ppm (lowest average intake 192.2 mg/kg bw/day). Reproductive effects occurred at 2500 ppm and included reduced litter sizes and pup weights, and reductions in testes/epididymides weights. The overall NOAEL for the study is 100 ppm (lowest average intake 8 mg/kg bw/day), based on liver toxicity in parental animals..

For tebuconazole, the dog was found to be the most sensitive animal tested and the only species showing potential for opacities of the eye lenses. Other effects observed in both rats and dogs were minor effects in the liver in the form of slightly increased weights, enzyme induction and decreased plasma glyceride levels as well as vacuolisation of the *zona fasciculata* cells of the adrenals. The AEL was derived from the one-year study in dogs where unspecific effects like histopathological alterations in the **adrenal cortex** were found. The NOAEL for this effect was 3 mg/kg bw/day.

It can thus be concluded with a reasonable degree of certainty that the substances do not exhibit systemic toxicity by the same mode of action and do not have the same target organs. It is therefore not expected that combined exposure to (residues of) the 3 active substances in Tanalith E 3462 will result in an additional risk above the estimated risks based on the individual substances.

2.7.3 Risk Characterisation

With proper use in accordance with regulations harmful effects on the health of users and third parties are not expected. The estimated exposures for the intended use are compared to the respective systemic AEL.

2.7.3.1 Risk for Professional Users

Based on the risk assessment of the active substance, a risk for professional users resulting from the intended use is unlikely. Regarding occupational safety, there are no objections against the intended use, because the predicted worker exposure levels have been shown to be within the relevant AELs for copper, propiconazole and tebuconazole and authorisation under the use conditions 'using gloves and protective clothing'.

2.7.3.2 Risk for non-professional users and the general public

The direct exposure, exposure via the environment or to other residues resulting from the intended use is unlikely to cause any unacceptable acute or chronic risk to consumers (non-professionals, bystanders and residents). Regarding consumer health protection, there are no objections against the intended uses

2.7.3.3 Risk for consumers via residues

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers in case treated wood will not be used as food package material. Therefore, a restriction is included in the SPC "the wood is not suitable to be used for food contact purposes as package material (e.g. wood boxes)".
Regarding consumer health protection, there are no objections against the intended uses.

2.8 Risk assessment for the environment

2.8.1 Effect Assessment

No studies were submitted with the product authorisation application for the active substances that were not already evaluated during the Annex I active review stage or studies. Detailed data on the fate and distribution of in the environment and the effect of the active substances on environmental organisms can be consulted in Doc IIA of the final Assessment Report (PT8) for basic copper carbonate (September 2011), propiconazole (December 2007) and tebuconazole (May 2007).
Both propiconazole and tebuconazole produce the metabolite 1,2,4-triazole; propiconazole at a maximum occurrence of 43 % AR and tebuconazole at 9 % AR. Propiconazole additionally degraded to the metabolite CGA 118 245 which was formed at a maximum concentration of 22 % AR.
The propiconazole Assessment Report states that the two degradation products of propiconazole are degraded faster than propiconazole itself and therefore, the concentrations of the two compounds would not exceed those of parent propiconazole in soil. Since earthworm studies on the two compounds display lower toxicity for the metabolites than parent (see Annex I Assessment Report for full details of PNEC values) a more detailed risk assessment for the metabolites is considered not to be required.

However because of its additional formation from tebuconazole, an assessment of 1,2,4-triazole has been considered further for the proposed use.

The PNECs for the active substances and metabolite 1,2,4 –triazole are included in the table below.

Table 2.8.1-1 Summary of the PNECs derived for basic copper carbonate, propiconazole and tebuconazole in the different compartments.

Compartment	Organism	Endpoint	AF	PNEC
Basic copper carbonate				
Freshwater	Freshwater organisms	HC5-50 from SSD (chronic data)	1	7.8 µg/L
STP	Micro organisms in STP	NOEC = 0.23 mg/L	1	0.23 mg/L
Sediment	Freshwater sediment organisms	HC5-50 from SSD (chronic data)	1	87 mg/kg dwt 18.9 mg/kg wwt
Soil	Soil organisms	HC5-50 from SSD (chronic data)	1	45.6 mg/kg dwt 40.35 mg/kg wwt
Propiconazole				
Freshwater	Algae	NOEC = 0.016 mg/L	10	1.6 µg/L
STP**	Micro organisms in STP	EC50 > 100 mg/L Max sol. 100 mg/L	100 1	1 mg/L 100 mg/L***
Sediment	Chironomus	NOEC = 5.4 mg/kg wwt	100	0.054 mg/kg wwt
Soil*	Earthworm	NOEC = 0.998 mg/kg wwt	10	0.113 mg/kg dwt 0.1 mg/kg wwt
Tebuconazole				
Freshwater	Daphnia	NOEC = 0.01 mg/L	10	1 µg/L
STP**	Micro organisms in STP	EC50 > 10000 mg/L Max sol. = 32 mg/L	100 1	100 mg/L 32 mg/L***
Sediment	Chironomus	NOEC = 54.5 mg/kg	100	0.55 mg/kg wwt
Soil	Earthworm	NOEC = 5.7 mg/kg dwt	50	0.114 mg/kg dwt 0.1 mg kg wwt
1,2,4 –triazole (major soil metabolite of propiconazole and tebuconazole)				
Soil	Soil micro organisms	NOEC =0.82 mg/kg wwt	100	0.0082 mg/kg wwt

* revised post PT08 Annex I

** As no inhibition was observed up to the highest test concentration which was above the water solubility the water solubility is used as PNEC without any AF according to the Manual of Technical Agreements of the Biocides Technical Meeting (MOTA, version 4, 2010).

*** Used for risk assessment

2.8.2 Exposure Assessment

2.8.2.1 Background

Tanalith E 3462 is a water-based product containing copper (as basic copper carbonate), propiconazole, and tebuconazole. This product is a preventative treatment intended for use on use class 3 (Wood exposed to weather, but not directly in contact with water or soil) and 4 (Wood directly in contact with soil or water) timbers. Label recommendations indicate that the concentrated product should be diluted to maximum product concentrations as given below (see Table 2.8.2.1-1) depending on the end-use of the treated timber.

Table 2.8.2.1-1: Summary of Tanalith E 3462 product data

Exposure data	Use Class 3 [UC3]	Use Class 4 [UC4]	
		Normal use*	II**
Solution strength % (w/v)	4.17	8.89	8.89

Product loading kg /m^3		16.67	27.77	44.44
Solution uptake (l/m^3)***		400		500
Concentration in solution % (w/v)	Copper	0.375	0.621	0.8
	Tebuconazole	0.0075	0.0125	0.016
	Propiconazole	0.0075	0.0125	0.016
Loading in wood (kg/m^3)	Copper	1.5	2.5	4
	Tebuconazole	0.03	0.05	0.08
	Propiconazole	0.03	0.05	0.08

* - Niche use I – railway sleepers will use the UC4 'normal use' retention levels
** - Niche use II – transmission poles with 60 year life service
*** - Based on analytical zone, assumes 100 % sapwood and is therefore very much a worst-case value.

The risk assessment is carried out on the basis of total concentrations of copper in the environment taking background concentrations into account. It was stated that this approach may be more reliable. The PEC values, initially calculated as 'added values' were added to the natural/pristine or the regional copper background concentrations (as agreed under the Council Regulation (EEC) 793/93 on Existing Substances – EU-RAR).

Table 2.8.2.1-2: Summary of EU agreed background concentrations of copper

Compartment	Natural/pristine background concentration	Regional background concentration	Unit
Surface water (dissolved)	0.88	2.9	µg/L
Ground water (dissolved)	0.88	2.9	µg/L
Soil	10.6	21.6	mg/kg wwt
Sediment	4.56	14.7	mg/kg wwt

Studies to copper in aged contaminated soils demonstrated a decrease of toxicity towards plants and soil invertebrates after 18 months of ageing. For micro-organisms, NOECs increased also but is probably due to an adaptation to copper. Therefore, an ageing factor of 2 was applied on the total copper concentrations in soil for the values calculated in TIME 2, in order to consider the phenomenon of copper ageing in soil. This strategy was validated at TMIII08 and implemented in the CAR for basic copper carbonate (PT8). Aging in sediments was not considered as sedimentation is a continuous process and therefore sediment dwelling organisms are exposed to freshly deposits materials only.

2.8.2.2 Leaching from treated wood

Two different studies have been carried out to support the application of Tanalith E 3462 by vacuum pressure treatment to wood that will be available for use up to use class 4 (UC4). Both studies have been summarised in the IIIB7.3 associated document to this submission.

<u>Use class 3: Wood exposed to weather, but not directly in contact with water or soil</u>
An use class 3 (UC3) semi-field leaching study was carried out in order to quantify the emissions of active substances from Tanalith E 3462 treated timber mounted vertically over a leachate collection unit for 2 years and 4 months (Cantrell, 2012a). Exposed timber panels were treated with Tanalith E 3462 to a loading of 1.43 kg/m^3, which is higher than the maximum intended retention rate by a factor of 0.98 for copper and lower than the maximum intended retention rate by a factor of 1.07 for tebuconazole and propiconazole. After each significant rain event during the exposure period the leachate was collected and stored. Once sufficient quantity was collected (≥ 1L) the leachate was analysed for copper, tebuconazole and propiconazole content. This allows a determination of the flux rate of the active substances over the course of the test. A summary of the resulting leach rate is

given below in Table 2.8.2.2-1, which have been used to define the leaching rates for the exposure assessment of UC3 timbers after adjustment for the maximum intended retention rates (see Table 2.8.2.2-4).

Table 2.8.2.2-1: Leach rate data from UC3 semi-field study

Active substances	Retention rates (kg/m^3)		Cumulative leaching (mg/m^2)		Daily leach rate	
	Intended	Actual (test)	T1 – 30 d	T2 – 20 yrs	T1 – 30 d	T2 – 20 yrs
Copper	1.4	1.43	34.8	5840	1.16	0.8
Tebuconazole	0.03	0.028	0.48	22.63	0.016	0.0031
Propiconazole	0.03	0.028	0.54	21.17	0.018	0.0029

Use class 4: Wood directly in contact with soil or water

For UC4 timbers, which are intended for use outdoors in direct contact with soil or water, a study was carried out in accordance with the OECD protocol for hazard class 4 environments (Cantrell, 2012b). The test involved timber specimens pre-treated to a loading of 2.5 kg Cu/m^3 being fully and continuously immersed in water for 52 days, with periodic exchange and analysis of the leachate for the active substances. As the retention used for this study was the same as the maximum intended for normal use of UC4 timbers, no adjustment of the following leach rate data (in Table 2.8.2.2-2) has been necessary for the exposure assessment values given in Table 2.8.2.2-4.

Table 2.8.2.2-2: Leach rate data from UC4 laboratory continuous immersion study (Cantrell, 2012b)

Active substances	Retention rates (kg/m^3)		Cumulative leaching (mg/m^2)		Daily leach rate	
	Intended	Actual (test)	T1-31 days*	T2 – 20 yrs	T1-31 days*	T2 – 20 yrs
Copper	2.5	2.5	743.22	1765.14	23.97	0.2418
Tebuconazole	0.05	0.05	26.63	78.11	0.86	0.0107
Propiconazole	0.05	0.05	31.16	125.56	1.01	0.0172

*Data taken from actual measured data after 31 days as worst-case cumulative value, therefore, daily rate has been calculated by dividing cumulative rate by 31 not 30 (see Cantrell, 2012 b). For a discussion on the use of actual cumulative values over 31 days in the risk assessment please see below.

The UC4 leaching study uses a 31 day measured value rather than a 30 day value due to timetabling. It is recognised that the risk assessment based on cumulative values over 31 days instead of 30 days is worst case but the effect is very minor. These cumulative leaching values for T1 will be re-defined as T1-30 days for the purposes of the OECD standardised Emission Scenario Assessments detailed below.

Niche uses

Two niche uses of Tanalith E 3462 are being sought as part of this application for product authorisation:

a) UC3 timbers: Railway sleeper

Since the retention level proposed for UC3 timbers is considered too low for this specific use, it is proposed that a retention level of 2.5 kg Cu/m^3 is used but ONLY for railway sleeper UC3 use. Therefore, for the exposure and risk assessment scenarios associated with this use have used the leach rates derived for the UC4 timbers. This can be taken to represent an absolute worst-case assessment since timbers used for railway sleepers are not in direct contact with ground or water.

b) UC4 timbers: Transmission pole

Transmission poles have an associated in-service life of 60 years, which requires an increased retention level of 4 kg Cu/m^3 to ensure efficacy can be maintained. As this is less than a factor of 2 higher than the tested retention rate of 2.5 kg Cu/m^3, a linear relationship has been assumed. Therefore, for the short-term leach rate a factor 1.6 applied to the original data (Table 2.8.2.2-4). As the service life has been extended from 20 to 60 years the data in Cantrell (2012b) was extrapolated from 20 to 60 years (see Table 2.8.2.2-3) and the final value multiplying by 1.6 for use in the risk assessment (Table 2.8.2.2-4).

Table 2.8.2.2-3: Leach rate data from UC4 laboratory continuous immersion study (Cantrell, 2012b)

Active Substance	Average Daily Leaching rate (mg/m^2/day)	Cumulative Leaching rate (mg/m^2/day)
10 years exposure		
Copper	0.447	1631.55
Tebuconazole	0.0182	66.43
Propiconazole	0.0298	108.77
20 years exposure		
Copper	0.2418	1765.14
Tebuconazole	0.0107	78.11
Propiconazole	0.0172	125.56
20 – 60 years exposure		
Copper	0.0147	214.62
Tebuconazole	0.0014	20.44
Propiconazole	0.002	29.2
*60 years exposure**		
Copper	0.0904	1979.76
Tebuconazole	0.0045	98.55
Propiconazole	0.0071	154.76

* Data for a 60 year assessment has been calculated by using ∑[20 years exposure (mg m^{-2})] + [20 – 60 year exposure (mg m^{-2})] cumulative data, and then dividing this by 21900 days to derive a daily leaching rate.

Table 2.8.2.2-4: Leaching rates calculated from available Tanalith E 3462 data for use in the environmental exposure and risk assessment of UC3 and UC4 treated timber

Substance	Retention rates			Leached over time (mg/m²)		Daily leach rate (mg/m²/day)	
	Intended (kg/m²)	Intended (kg/m³)	Actual (test) (kg/m³)	T1 – 30 d	T2 – 20 yrs	T1 – 30 d	T2 – 7300 d
UC3 Timber: Semi-field data*							
Copper	0.00686	1.4	1.43	34.10	5723	1.14	0.78
Tebuconazole	0.00147	0.03	0.028	0.51	24.21	0.017	0.0033
Propiconazole	0.00147	0.03	0.028	0.58	22.65	0.019	0.0031
UC4 Timber: Laboratory immersion data							
Copper	0.0131	2.5	2.5	743.22	1765.14	23.97	0.24
Tebuconazole	0.000263	0.05	0.05	26.63	78.11	0.86	0.0107
Propiconazole	0.000263	0.05	0.05	31.16	125.56	1.01	0.017
UC4 Timber: Transmission pole (read across from laboratory immersion data) **							
Substance	**Retention rates**			**Leached over time (mg/m²)**		**Daily leach rate (mg/m²/day)**	
	Intended (kg/m²)	**Intended (kg/m³)**	**Actual(test) (kg/m³)**	**T1 – 30 d**	**T2 – 60 yrs**	**T1 – 30 d**	**T2 – 21900 d**
Copper	0.021	4	2.5	1189.152	3167.616	38.36	0.145
Tebuconazole	0.00042	0.08	0.05	42.608	157.68	1.37	0.0072
Propiconazole	0.00042	0.08	0.05	49.856	247.616	1.61	0.0113

* leach rate data adjusted for difference between tested and intended retention rates (factor of intended/actual retention rates = 0.98 [copper] and 1.07 [tebuconazole & propiconazole] applied) for use in prediction of environmental concentrations
** leach rate data adjusted for difference between tested and intended retention rates (factor of intended/actual retention rates = 1.6 applied) for use in prediction of environmental concentrations

The leach rates determined for Tanalith E 3462 (in Table 2.8.2.2-4) have also been compared to the available leach rates for the individual active substances used within the Annex I listing (see Table 2.8.2.2-5). With the exception of Time 1 for propiconazole, all of the leach rates used for the Annex I assessments are greater or equal to those determined for Tanalith 3462.

Table 2.8.2.2-5: Maximum acceptable leaching rates given in available CAR for Annex I listing of active substances; copper, tebuconazole and propiconazole

	Daily leach rate (mg/m²/day)	
Active substance	**T1**	**T2**
Copper	23.97	0.8
Tebuconazole	2.21	0.033
Propiconazole	0.175	0.0626

2.8.3 Emission scenarios and environmental pathways

The revised emission scenario document (ESD) for wood preservatives (dated September 2013) and additional methods and scenarios endorsed at TM/WG meetings (see Annexes 4 and 5) have been used to define and calculate the environmental concentrations resulting from the application and in-service life scenarios applicable to the proposed use of Tanalith E 3462.

The emission scenario estimates the emission of wood preservatives from two stages of their life cycle :
- application and storage of treated wood prior to shipment;
- treated wood in service.

Several relevant emission scenarios have been identified based on intended uses.
In the case of treatment and storage of treated wood prior to shipment, the emission scenario that is used covers industrial preventive processes – vacuum pressure from the application until storage (storage is the period when the treated timber is stored after the post-treatment conditioning phase while waiting for shipment). The storage conditions of the treated timber can vary considerably; it can be under cover and/or paved (as it is usually in the case of high value joinery products) or exposed to the weather. The storage scenario employed in this assessment assumes that the storage area is uncovered and unpaved. Calculations are made according to the ESD, but the flow rate of adjacent water was adjusted to 18000 m^3/d, which is in harmonisation with the TGD. Emission to the sewer was additionally added to the storage scenarios as a representative of storage above water tight floors. This additional scenario assumes 50% runoff as well.

In the case of treated wood in service, the following emission scenarios have been run for use classes 3 and 4:

- house as a representative for wood applied above soils (UC3);
- bridge over pond as a representative for wood applied above or adjacent to stagnant surface water (UC3);
- city as a representative for the STP for wood applied in an urban environment above pavements (UC3, see EU Manual of Technical Agreements (MOTA) version 6)
- railway sleeper for emission to groundwater (UC3);
- fence post as a representative for wood directly in contact with soil (UC4);
- transmission poles as a representative for wood directly in contact with soil for which a long service life is required (UC4);
- jetty in the lake as a representative for wood directly in contact with stagnant surface water (UC4);
- sheet pilling in waterway as a representative for wood directly in contact with flowing surface water (UC4).

For emission to surface water for wood treated for use in use classes 3 and 4 the ESD proposes the bridge over pond, jetty in the lake and sheet pilling in waterway as main scenarios. The bridge over pond scenario is assumed to represent the realistic worst case emission to surface water with respect to emitting wood area in m^2 and the volume of receiving water course.
Application of the product on railway sleepers and on transmission poles are requested niche uses of Tanalith E 3462 by the applicant, for these niche uses UC4 leaching rates are applied in the exposure and risk assessment (see section 2.8.2.2).

The following exposure routes were identified and assessed (see also Table 2.8.3-1):

- direct release to surface water;
- direct release to soils;
- direct release to a STP and indirect release to surface water.

Table 2.8.3-1: Overview of emision pathways for use classes 3, 4a and 4b

	Air (outdoors)	**Sewage treatment plant**	**Surface water and sediment**	**Soil**	**Ground Water**
Application Process	✓	✓	✓	No	No
Storage above unpaved soils	No	No	✓	✓	✓
Storage above liquid tight floors	No	✓	✓	No	No
Treated wood in service	No	✓[1]	✓[2]	✓[3]	✓[4]

[1] city scenario
[2] bridge over pond scenario (UC3), jetty in the lake and sheet pilling in waterway scenarios (UC4)
[3] house (UC3) and fence post scenarios (UC4)

[4] Indirect exposure via leaching of the substance in soil, house and railway sleeper scenarios

2.8.4 Predicted environmental concentrations

2.8.4.1 General

Predicted environmental concentrations (PECs) are calculated according to the Exposure Scenario Document (ESD) for wood preservatives (version 2013). PECs are calculated for the industrial ex-situ application phase, storage of preserved wood, and for wood in service. Because the product is not intended to apply in-situ, release to the environment by spillage during cladding is not addressed. Once applied the active substances are continuously released to the environment by leaching from surfaces direct and shortly after rainfall or due to continuous contact with (moist) soil or surface water. Because leaching rates from freshly applied treated wood are usually larger, the ESD distinguishes between an initial assessment period, which is the period up to 30 days after application and a longer assessment period which lasts from 30 days until the end of the service life of treated wood. The amounts of active substances that are released during service life are determined by leaching tests. The applied leaching rates are presented and discussed previously.

Removal of the active substance from exposed environmental compartments by leaching to groundwater and/or biodegradation is considered, but evaporation from soils was excluded as none of the active substances are volatile. PECs were calculated on basis of plateau concentrations (i.e. the concentration on day 30 and the last day of the preserved product's service life) for the following reasons:

- TWA-based concentrations (time weighted average concentrations over 30 days and over the preserved product's service life) as described in the ESD are only applicable when the PEC decrease in time. Because it may be expected that concentrations in water and soils gradually increase as initial leaching rates are usually higher than disappearance rates, TWA-based PECs underestimate actual risks, especially for the initial assessment period and substances that does not degrade and/or not mobile in soils;
- A TWA-approach does not necessarily protect the environment as concentrations may temporarily exceed the accompanying PNECs. Because TWA-based concentrations are usually averaged over 30 or 180 days (default values for industrial and agricultural soils, respectively, according to the TGD), an exceeding of the PNEC may therefore last 90 days maximal. However, preserved wood is in service for decades and in those cases a TWA-approach even may result in PECs that exceed the PNECs for several years, which is considered undesirable.

The concentrations on day 30 and at the last day of the preserved product's service life are therefore calculated as follows:

$$C(t) = \frac{E_{leach}}{X \cdot k} - \left[\frac{E_{leach}}{X \cdot k} - C_{ini} \right] \cdot e^{-t \cdot k}$$

where:

C(t)	the concentration in the concerning compartment at time t;
E_{leach}	daily entry into the environment due to leaching (mg/d);
X	volume or size of the receiving compartment (L or kg);
k	first order rate constant for removal from the concerning compartment (/d);
C_{ini}	initial concentration in compartment X. Note that the initial concentration is zero for the initial assessment period, but the concentration at day 30 for the longer assessment period;
t	time (d).

The exposure assessment of each of the previous presented emission routes is explained in more detail in the following sections. The PECs are calculated by using the default values listed in the ESD unless otherwise noted. The physical-chemical parameters applied in the assessment for the different compartments (STP, water, sediment, and soils) are given in Annex 3. The formulas applied are presented in Annex 4.

For copper that is released to the STP, the concentrations in the effluent were not based on SimpleTreat calculations, but on monitoring data taken from the EU-RAR (2008). The concentrations in the STP's effluent were derived by applying a removal factor of 0.8.

It should be noted that all copper concentrations for water and soil have been presented as three formats, namely added (that predicted to have resulted from the use of Tanalith E 3462), including pristine background concentration and including regional background concentrations (the latter two values are presented in Table 2.8.2.1-2).

2.8.4.2 Preserved wood applied in, above, or adjacent to stagnant surface water

PT08 offers worst-case scenarios for direct exposure to surface water by leaching during the preserved wood's service life. PEC resulting from wood applied above and adjacent of surface water were calculated according to the bridge over pond scenario which assumes a bridge of 10 m² above a pond of 1000 m³. For wood applied in stagnant surface water the jetty in a lake scenario was applied. Because leaching rates are available for both wood exposed to rain and wood directly exposed to water, the corresponding leaching rates were applied for submerged and above water line parts of the jetty. At least, the sheet pilling scenario was run for wood applied in flowing surface water.

Emission to stagnant surface water is calculated according to the scenarios for bridge over pond (wood applied above or adjacent of surface water) and jetty in a lake (wood applied in water). The ESD applies a three compartment model in which equilibrium between water and suspended matter, and water and sediment is assumed. The corresponding concentration in water, suspended matter, and sediment are calculated according to the active substances' organic carbon-water partitioning coefficients (K_{oc}). This however contradicts with the TGD where sediment is defined as freshly deposited suspended matter in flowing water and the concentration in sediment is based on the characteristics of and distribution constants for suspended matter. It is, however, still questionable if the ESD's model is realistic for the bridge over pond and jetty in a lake scenario.

Direct exchange of active substances between water and sediment may be only relevant for shallow water with sufficient resuspension as equilibrium is reached fast. However, due to slow kinetics and stagnant boundary layers, it is unrealistic that in deeper waters the concentration in sediment is in equilibrium with the concentration in the overlying water phase, especially for the initial assessment period. Moreover, the sediment layer is continuously buried under freshly deposited suspended matter. Sedimentation should be therefore taken into account, but the required models and parameters are not yet available. Nevertheless, the sediment compartment cannot be ignored as sorption to suspended matter only and subsequent PEC calculations for sediments according to the TGD result in unrealistic high concentrations when biocides are released to stagnant water day after day. To overcome this, the three compartment model for the ESD was still applied, but sediment was defined as deposited suspended matter. Therefore, the concentration in sediment was based on the partition coefficient and density of suspended matter instead the corresponding values for sediment.

Volume and mass of sediment is based on a thickness of 3 cm and a density of 1150 kg wwt/m³. Although the jetty is located in a lake with a diameter of 100 m, no dimensions except for the volume (1000 m³) are given for the bridge over pond scenario. Therefore, a pond of 4 by 250 m was considered, where 4 m corresponds to the bridge's length. These dimensions are considered as a realistic worst case as larger surfaces (i.e. more sediment) are advantageous for all PECs.

2.8.4.3 Preserved wood applied above soils

PECs for soil were calculated by applying the brushing house scenario according to PT08. This scenario assumes that the soil (13 m³) adjacent of the façade (125 m²) is polluted by spilling during application and leaching during service life. The spillage during application was not assumed due to the process of impregnation before placement of the wooden objects.

2.8.4.4 Preserved wood applied in an urban environment – emission to STP

The scenario applied calculates the daily emission to the sewer from 4000 wooden houses of 125 m² each (ESD default) in an urban environment. Because it is unlikely that all houses are preserved or build in a single day, the leaching rate is related to the age of the corresponding building. The number of houses for which the fast leaching rate (initial assessment period) was applied was corrected with a factor 30/7300 representing the ratio between assessment period and total service life. The leaching rate for the longer assessment period was applied for the remaining number of houses. It was furthermore assumed that 50% of the houses are made from wood. The scenario applied is explained in more detail elsewhere (MOTA 6).

2.8.4.5 Preserved wood directly in contact with soils

The PECs were calculating according to the 'Fence posts' and 'Transmission poles' scenarios presented in the ESD. These scenarios assume a wooden pole buried into the soil. In contradiction to the existing ESD, the PECs were based on plateau concentrations instead of time-weighed average concentrations as discussed previously.

2.8.4.6 Groundwater

Assessment of the drinking water criterion defines that the concentration of the active substances and the relevant metabolites in groundwater for the preparation of drinking water need to be < 0.1µg/L. The concentration in groundwater was estimated using FOCUS PEARL 4.4.4. The annual dose applied per hectare was based on the daily emission to soils as calculated according to the accompanying ESD (365 emission days), and multiplied by 35 houses per hectare. Because PEARL is not suitable for continuous emission to the soil surface by leaching from treated wood, the dose was divided in ten equal proportions which were subsequently added to the soil surface every first of each month except for July and August. Model estimations were made for the default Kremsmuenster scenario and grass was applied as a representative crop. Uptake by plants was not considered.

2.8.5 Risk Assessment

Tanalith E 3462 is to be applied by industrial scale vacuum pressure treatment to timber intended for use in use classes 3 and 4. The concentrations in STP, surface waters (including sediment) and soils resulting from the predicted emissions during the industrial application and storage of Tanalith E 3462 treated timber have been calculated using the available guidance within the revised ESD and the Technical Guidance Document on Risk Assessment (Part II, Chapter 3; ECB, 2003).

2.8.5.1 Industrial application

The emissions to water from the application stage are assumed to pass via internal drains and local STP, and the risks posed by this have been considered below in Table 2.8.4.1-1.

Table 2.8.4.1-1: Risk assessment for surface water and sediment exposed via the STP to copper, propiconazole and tebuconazole from vacuum treatments with Tanalith E 3462 at industrial treatment plants

Compound	STP		fresh water		sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/L)	PEC/PNEC	PEC (mg/kg wwt)	PEC/PNEC
Copper (added)	8.76E-02	0.381	8.67E-03	**1.1**	5.70E+01	**3.0**
Copper (+Pristine background	n/a	n/a	9.55E-03	**1.2**	6.16E+01	**3.3**
Copper (+Regional background)	n/a	n/a	1.16E-02	**1.5**	7.17E+01	**3.8**
Propiconazole	6.04E-03	<0.001	6.03E-04	0.377	1.29E-02	0.238
Tebuconazole	1.20E-03	<0.001	1.20E-04	0.12	2.68E-03	0.005
Combined (maximum risk)	9.48E-02	0.381	1.23E-02	**2.0**	7.17E+01	**4.0**

n/a not applicable

The application of Tanalith E 3462 by vacuum pressure treatment of UC3 and UC4 timbers is not acceptable for the aquatic environment for copper. The sum of the PEC/PNEC values for the individual substances also exceeds 1 for the application phase. The risk can be reduced to acceptable levels if residues are collected and discharged as hazardous waste. Therefore, a risk mitigation is proposed stating that spills and residual fluids have to be collected and discharged as hazardous waste.

2.8.5.2 Storage

The impact of the storage of treated timbers to surrounding surface water and sediment and on bare soil prior to shipment off-site has been considered. In addition, risks were assessed for the STP, surface water and sediment when wood is stored above water tight floors with connection to the sewer. The results of this storage scenario are presented in Tables 2.8.4.2-1 to 2.8.4.2-3. For soil, the risks are presented in Table 2.8.2.2-3 for both 30 days and 10 year leaching from stored wood treated with Tanalith E 3462.

Table 2.8.4.2-1: Risk assessment for surface water and sediment exposed via the STP to copper, propiconazole and tebuconazole from storage above watertight floors where rainwater is collected and discharged to industrial treatment plants

Compound	STP		fresh water		sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/L)	PEC/PNEC	PEC (mg/kg wwt)	PEC/PNEC
Copper (added)	2.28E-04	<0.001	2.26E-05	0.003	1.48E-01	0.008
Copper (+Pristine background	n/a	n/a	9.03E-04	0.116	4.71E+00	0.25
Copper (+Regional background)	n/a	n/a	2.92E-03	0.37	1.48E+01	0.790
Propiconazole	2.50E-05	<0.001	2.50E-06	0.002	5.32E-05	<0.001
Tebuconazole	2.19E-05	<0.001	2.18E-06	0.002	4.88E-05	<0.001
Combined (maximum risk)	2.75E-04	<0.001	2.92E-03	0.37	1.48E+01	0.790

Table 2.8.4.2-2: Risk assessment for surface water and sediment exposed to copper, propiconazole and tebuconazole from storage at industrial treatment plants due to run-off from storage sites

Compound	fresh water		sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/kg wwt)	PEC/PNEC
Copper (added)	1.25E-04	0.016	8.25E-01	0.044
Copper (+Pristine background	1.01E-03	0.129	5.38E+00	0.285
Copper (+Regional background)	3.03E-03	0.388	1.55E+01	0.821

Compound	fresh water		sediment	
	PEC (mg/L)	**PEC/PNEC**	**PEC (mg/kg wwt)**	**PEC/PNEC**
Propiconazole	3.10E-06	0.002	6.60E-05	0.001
Tebuconazole	2.72E-06	0.003	6.09E-05	<0.001
Combined (maximum risk)	3.04E-03	3.93E-01	1.55E+01	0.822

No risks for the aquatic compartment are expected when wood is stored outdoors next to surface water or above a water tight floor where rainwater is collected and discharged to the STP. The standards for the aquatic environment are met. No mitigation measures regarding the aquatic environment are required.

Table 2.8.4.2-3: Risk assessment for the soil compartment exposed to copper, propiconazole, tebuconazole and soil metabolite 1,2,4-triazole after 10 years of leaching from wood stored at industrial treatment plants

Compound	PEC (mg/kg wwt)	PEC/PNEC
Copper (added)	2.68E+01	0.665
Copper (+Pristine background	3.74E+01	0.928
Copper (+Regional background)	4.84E+01	**1.2**
Propiconazole	4.57E-01	**4.6**
Tebuconazole	4.02E-01	**4.0**
1,2,4- triazole from propiconazole	1.96E-01	**23.9**
1,2,4- triazole from tebuconazole	3.61E-02	**4.4**
Combined (maximum risk)	4.95E+01	**38.1**

The storage of UC3 and UC4 timbers treated with Tanalith E 3462 by vacuum pressure is not acceptable for the soil compartment for copper (including regional background concentrations), propiconazole, tebuconazole and soil metabolite 1,2,4-triazole. The sum of the PEC/PNEC values for the individual substances also exceeds 1 for the storage phase, even after 10 years of leaching from stored wood.
Therefore, wood has to be shielded off from rain during storage, stored under a protective roof or above water tight floors that are connected to the STP. Therefore, a risk mitigation is proposed stating that storage of treated wood is restricted to under a protective roof or above a water tight floor that is connected to the STP.

Conclusion

The following restrictions should be included on the product label to mitigate direct losses to soil and groundwater from industrial application and storage:

- Storage of treated wood is restricted to under a protective roof or above a water tight floor that is connected to the STP.
- Discharge of spills and residual fluids to the sewer system during treatment is not permitted. Spills and residues containing the product need to be recycled or need to be removed as chemical waste .

2.8.5.3 IN-SERVICE USE

2.8.5.3.1 Soil compartment

<u>Metabolite 1,2,4-triazole</u>
Both propiconazole and tebuconazole produce the metabolite 1,2,4-triazole; propiconazole at a maximum occurrence of 43 % AR and tebuconazole at 9 % AR. Propiconazole

additionally degraded to the metabolite CGA 118 245 which was formed at a maximum concentration of 22 % AR.
The propiconazole Assessment Report states that the two degradation products of propiconazole are degraded faster than propiconazole itself and therefore, the concentrations of the two compounds would not exceed those of parent propiconazole in soil. Since1,2,4-triazole displays a higher toxicity than the parents (see section 2.8.1 for PNEC values) a more detailed risk assessment for the metabolite is required.
Concentrations of 1,2,4-triazole formed as a result of degradation of propiconazole and tebuconazole in soil were calculated from the maximum undegraded concentration of the parent compounds, with correction for maximum formation (43 % AR from propiconazole and 9 % AR from tebuconazole observed in laboratory studies) and relative molecular masses (propiconazole 342.2 g/mol; tebuconazole 307.8 g/mol; 1,2,4-triazole 69.1 g/mol).

The primary receiving environmental compartment is considered to be soil via rain run-off from timber cladded houses. It is assumed that the emission from the treated wood of transmission poles and fence posts to soil is a result of:
1. rainfall for the above soil part of the pole, and;
2. permanent contact with the soil water phase for the below soil part.

On the basis of the test results, the emissions from the above and below soil parts are calculated and summed up to a total emission. UC 3 and UC4 leaching rates are applied for these parts respectively.
The risks are presented in Tables 2.8.4.3.1-1 to 2.8.4.3.1-3, degradation is included in the calculations.

Timber cladded houses:

Table 2.8.4.3.1-1: Risk assessment for the soil compartment for the active substances copper, propiconazole and tebuconazole and soil metabolite 1,2,4-triazole for the in-service use of timber pre-treated with Tanalith E 3462 using the timber cladded house scenario and UC3 leaching data (worst-case)

Compound	PEC (mg/kg wwt)	PEC/PNEC
Copper (added)		
after 30 days	1.93E-01	0.005
after 365 days	1.82E+00	0.045
after 7300 days*	1.62E+01	0.402
Copper (+Pristine background)		
after 30 days	1.08E+01	0.267
after 365 days	1.24E+01	0.308
after 7300 days*	2.15E+01	0.533
Copper (+Regional background)		
after 30 days	2.18E+01	0.540
after 365 days	2.34E+01	0.580
after 7300 days*	2.70E+01	0.670
Propiconazole		
after 30 days	3.03E-03	0.030
after 365 days	3.23E-03	0.032
after 7300 days	3.27E-03	0.033
Tebuconazole		
after 30 days	2.53E-03	0.025
after 365 days	2.06E-03	0.021
after 7300 days	2.04E-03	0.020
1,2,4-triazole from propiconazole		
after 30 days	8.23E-04	0.100
after 365 days	1.86E-04	0.023

after 7300 days	1.86E-04	0.023
1,2,4-triazole from tebuconazole		
after 30 days	1.52E-04	0.018
after 365 days	4.17E-05	0.005
after 7300 days	4.17E-05	0.005
Combined (maximum risk)		
after 30 days	2.18E+01	0.595
after 365 days	2.34E+01	0.633
after 7300 days	2.70E+01	0.723

*Copper PEC values adjusted by a factor of 2 in accordance with agreement within WPCTF dossier for aged copper

Direct emissions to soil from timber cladded houses are presenting an acceptable long-term risk for soil compartment. The standards for the terrestrial environment are therefore met.

Fence post:

Table 2.8.4.3.1-2: Calculated emissions, PECsoil values and risk assessment for the active substances copper, propiconazole and tebuconazole and soil metabolite 1,2,4-triazole for the in-service use of timber pre-treated with Tanalith E 3462 using the fence post scenario with UC3 and UC4 leaching data (worst-case)

Compound	PEC (mg/kg wwt)	PEC/PNEC
Copper (added)		
after 30 days	8.55E-02	0.002
after 365 days	1.91E-01	0.005
after 7300 days*	1.24E+00	0.031
Copper (+Pristine background)		
after 30 days	1.07E+01	0.265
after 365 days	1.08E+01	0.267
after 7300 days*	6.54E+00	0.162
Copper (+Regional background)		
after 30 days	2.17E+01	0.537
after 365 days	2.18E+01	0.540
after 7300 days*	1.20E+01	0.298
Propiconazole		
after 30 days	3.00E-03	0.03
after 365 days	7.84E-04	0.008
after 7300 days	5.35E-04	0.005
Tebuconazole		
after 30 days	2.44E-03	0.024
after 365 days	3.00E-04	0.003
after 7300 days	2.59E-04	0.003
1,2,4-triazole from propiconazole		
after 30 days	8.17E-04	0.1
after 365 days	2.05E-05	0.002
after 7300 days	3.12E-05	0.004
1,2,4-triazole from tebuconazole		
after 30 days	1.46E-04	0.018
after 365 days	3.89E-06	<0.001
after 7300 days	5.29E-06	<0.001
Combined (maximum risk)		
after 30 days	2.17E+01	0.709
after 365 days	2.18E+01	0.553

Compound	PEC (mg/kg wwt)	PEC/PNEC
after 7300 days	1.20E+01	0.310

*Copper PEC values adjusted by a factor of 2 in accordance with agreement within WPCTF dossier for aged copper

There is no unacceptable risk to the terrestrial environment when preserved wood is in direct contact with soils. The standards for the terrestrial environment are therefore met.

Transmission pole:
For the UC4 treated wood in ground contact the scenario for transmission poles can be considered to be the worst-case scenario as this results in the highest predicted soil concentrations. This scenario has been carried out using the UC3 retention rate of 1.43 Cu/m^3 for the above soil part of the pole and the UC4 retention rate of 2.5 kg Cu/m^3 for the below soil part over 20 years assessment as a normal use assessment (see Table 2.8.4.2.1-3). The intended UC4 retention rate of 4.0 kg Cu/m^3 is a factor 1.6 higher than the actual retention rate of 2.5 kg Cu/m^3 for UC4 and a factor 2.8 higher than the actual retention rate of 1.43 kg Cu/m^3 for UC3. Although the UC3 actual retention rate is more than a factor 2 lower than the intended retention rate, it was considered justified to extrapole the UC3 leaching rates with a factor 2.8 as the UC3 leaching rates were obtained from a semi-field study.
The leaching rates for 60 years' service-life are extrapolated using the factors 1.6 and 2.8 for UC3 and UC4 respectively (see Table 2.8.4.2.1-4).

Table 2.8.4.3.1-3: Calculated emissions, PECsoil values and risk assessment for the active substances copper, propiconazole and tebuconazole and soil metabolite 1,2,4-triazole for the in-service use of timber pre-treated with Tanalith E 3462 using the transmission pole scenario with UC3 and UC4 leaching data (worst-case) and retention 2.5 kg Cu/m^3 for 20 years service life

Compound	PEC (mg/kg wwt)	PEC/PNEC
Copper (added)		
after 30 days	2.73E-01	0.007
after 365 days	5.86E-01	0.015
after 7300 days*	3.52E+00	0.087
Copper (+Pristine background)		
after 30 days	1.09E+01	0.269
after 365 days	1.12E+01	0.277
after 7300 days*	8.82E+00	0.219
Copper (+Regional background)		
after 30 days	2.19E+01	0.542
after 365 days	2.22E+01	0.550
after 7300 days*	1.43E+01	0.355
Propiconazole		
after 30 days	9.70E-03	0.097
after 365 days	2.96E-03	0.03
after 7300 days	1.64E-03	0.016
Tebuconazole		
after 30 days	7.88E-03	0.079
after 365 days	1.12E-03	0.011
after 7300 days	7.78E-04	0.008
1,2,4-triazole from propiconazole		
after 30 days	2.64E-03	0.322
after 365 days	9.58E-05	0.012
after 7300 days	9.58E-05	0.012
1,2,4-triazole from tebuconazole		
after 30 days	4.73E-04	0.058

Compound	PEC (mg/kg wwt)	PEC/PNEC
after 365 days	1.59E-05	0.002
after 7300 days	1.59E-05	0.002
Combined (maximum risk)		
after 30 days	2.19E+01	**1.1**
after 365 days	2.22E+01	6.05E-01
after 7300 days	1.43E+01	3.93E-01

*Copper PEC values adjusted by a factor of 2 in accordance with agreement within WPCTF dossier for aged copper

There is an unacceptable risk to the terrestrial environment from wood in service in the transmission scenario (20 years service life) which can mainly be attributed to the leaching of copper after TIME 1 (30 days). However, after one year the risk has decreased to an acceptable level (PEC/PNEC < 1) and the standards for the terrestrial environment are therefore met.

Table 2.8.4.3.1-4: Calculated emissions, PECsoil values and risk assessment for the active substances copper, propiconazole and tebuconazole and soil metabolite 1,2,4-triazole for the in-service use of timber pre-treated with Tanalith E 3462 using the transmission pole scenario with UC3 and UC4 leaching data (worst-case) and retention 4 kg Cu/m^3 for 60 years service life

Compound	PEC (mg/kg wwt)	PEC/PNEC
Copper (added)		
after 30 days	4.81E-01	0.012
after 365 days	7.63E-01	0.019
after 7300 days*	9.37E+00	0.232
Copper (+Pristine background)		
after 30 days	1.11E+01	0.275
after 365 days	1.14E+01	0.282
after 7300 days*	1.47E+01	0.363
Copper (+Regional background)		
after 30 days	2.21E+01	0.547
after 365 days	2.24E+01	0.554
after 7300 days*	2.02E+01	0.500
Propiconazole		
after 30 days	1.62E-02	0.162
after 365 days	3.69E-03	0.037
after 7300 days	1.25E-03	0.012
Tebuconazole		
after 30 days	1.32E-02	0.132
after 365 days	1.24E-03	0.012
after 7300 days	6.27E-04	0.006
1,2,4-triazole from propiconazole		
after 30 days	4.41E-03	0.538
after 365 days	7.29E-05	0.009
after 7300 days	7.29E-05	0.009
1,2,4-triazole from tebuconazole		
after 30 days	7.91E-04	0.096
after 365 days	1.28E-05	0.002
after 7300 days	1.28E-05	0.002
Combined (maximum risk)		
after 30 days	2.21E+01	**1.5**
after 365 days	2.24E+01	0.614
after 7300 days	2.02E+01	0.529

*Copper PEC values adjusted by a factor of 2 in accordance with agreement within WPCTF dossier for aged copper

There is an unacceptable risk to the terrestrial environment from wood in service in the transmission scenario (60 years service life) which can mainly be attributed to the leaching of copper after TIME 1 (30 days). However, after one year the risk has decreased to an acceptable level (PEC/PNEC < 1) and the standards for the terrestrial environment are therefore met.

2.8.5.3.2 Groundwater compartment

Copper

The added concentrations in soils predicted for copper in the house, railway sleeper and transmission pole scenario TIME 2 (worst cases) have been used to calculate a worst-case concentration in groundwater (soil porewater) acording to the TGD (equilibrium partitioning). The results are presented below.

Scenario (TIME 2)	Copper	PEC_{soil}	$PEClocal_{soil\ porewater}$
		[mg kg^{-1} wwt]	[mg l^{-1}]
House	Added	32.4	0.02
Fence post	Added	1.2	0.001
Transmission pole 20 years service life	Added	3.5	0.002
Transmission pole 60 years service life	Added	9.4	0.01
Railway sleeper*	Added	0.9	0.0005

*Soil concentration calculated from amount leached to a hectare (7.27 kg/ha in 8500000 kg wet soil)

The drinking water limit for copper is appropriate and not the pesticides limit of 0.1 µg/L as copper is naturally occurring in the environment.
When the predicted values for copper are compared to the drinking water limit of 2 mg/L for copper, the above assessments show that the use of Tanalith E 3462 would not pose an unacceptable risk to the groundwater compartment.

Propiconazole
The in-service use wood leaching to groundwater potential was evaluated in the Annex I CAR assessment using the leaching model FOCUS PEARL 3.3.3 for the house scenario (35 houses were assumed per hectare). All scenarios indicated an acceptable risk to groundwater with a significant margin of safety since all PECgw values were < 0.001 µg/L. On the basis that the Annex I assessment leaching rate is greater than would be assumed for this product (an equivalent conservative assumption would be 0.021 g propiconazole/ m^2 lost in a 5 year period of 1 g propiconazole/ m^2 lost in the Annex I listing assessment) no additional groundwater assessment has been carried out for this active substance.

Tebuconazole
The assessment report for tebuconazole indicates that the fate and behaviour for tebuconazole suggest that it is not expected to reach groundwater since this compound has been shown to have a low mobility in soil. Also, as for propiconazole an in-service assessment was carried out as part of the CAR using the leaching model FOCUS PEARL 3.3.3 for the house scenario (35 houses were assumed per hectare). That assessment was based upon an application rate of 1 g tebuconazole/m^2 treated wood which is significantly greater than the 0.023 g tebuconazole/m^2 that has been shown to leach out from UC3

timbers exposed for > 2 years. Therefore, it can be considered that the current application does not pose any additional risks of tebuconazole to groundwater.

Metabolite – 1, 2, 4-triazole
In order to address the concerns for the major metabolite 1,2,4-triazole, which is formed in soil from the degradation of both propiconazole and tebuconazole a detailed FOCUS PEARL model was run against this metabolite in accordance with ESD guidance and the PPP guidance for the implementation of bi-phasic kinetics in leaching models.

Parameter/variable	Symbol	Value		Unit
INPUT		**Propiconazole**	**Tebuconazole**	
Leachable wood area of one house	AREAhouse	125	125	m^2
Number of houses in a rectangular field of 1 hectare	Nhouse	35	35	/ha
Duration of the initial assessment period	TIME1	30	30	d
Duration of the long-term assessment period	TIME2	7300	7300	d
Cumulative quantity of a.s. leached out of 1 m^2 of treated wood over an initial assessment	Qleach*,time1	5.79E-07	5.14E-07	kg/m^2
Cumulative quantity of a.s. leached out of 1 m^2 of treated wood over a longer assessment	Qleach*,time2	2.27E-05	2.42E-05	kg/m^2
Cumulative quantity of a.s. leached over the initial assessment period on one hectare	Qleach,time1	2.53E-03	2.25E-03	kg/ha
Cumulative quantity of a.s. leached over the longer assessment period on one hectare	Qleach,time2	0.099	1.06E-01	kg/ha
Model calculations Qleach,time1 = AREAhouse x Nhouses x Q*leach,time1 Qleach,time2 = AREAhouse x Nhouses x Q*leach,time2				
PEARL applications per year $(Q_{leach,time1}/TIME1)*365]$	$PEARL_{Annum,time1}$	0.03082	0.02736	kg/ha/year
PEARL applications per year $(Q_{leach,time2}/TIME2)$	$PEARL_{Annum,time2}$	0.00497	0.00529	kg/ha/year
PEARL applications per application [$PEARL_{Annum,time}$ 1/10]	$PEARL_{Applic,time1}$	0.00308	0.00274	kg/ha/appl.
PEARL applications per application [$PEARL_{Annum,time}$ 2/10]	$PEARL_{Applic,time2}$	0.00050	0.00053	kg/ha/appl.

The concentrations of propiconazole, tebuconazole and metabolite 1,2,4-triazole or a combination of these substances were for all recommended EU scenarios (Chateaudun, Hamburg, Jokoinen, Kremsmuenster, Okehampton, Piacenza, Porto, Sevilla and Thiva) < 0.1 µg/L.

Railway sleeper
The Standard approach for groundwater is to consider the use of UC3 timbers on houses as wooden cladding. In addition, the revised OECD ESD also recommends a scenario to consider the use of UC3 treated timber as railway sleepers. The railway sleeper scenario is defined as:

- Service life of industrially pre-treated wooden railway sleepers (UC3)
- Soil beneath ballast is considered to be part of the techno sphere, the receiving environmental compartment covered by the scenario is therefore groundwater
- Two railway lines crossing a field of one hectare
- Models under discussion for the exposure assessment: FOCUS –PEARL (including a dilution factor) or HARDspec

Any preservative leaching out from the wood will first end up in the ballast layer where it will be prone to abiotic degradation or other removal processes.

The lower width of the ballast is estimated to be 9 m (see Figure 2.8.4.3.2-1) for a track with two lines, based on information provided on www. Gleisbau-welt.de and by Deutsche Bahn (2010):

- The width of the sleepers is 2 x 2.60 m = 5.20 m.
- The distance between the centres of lines according to the German EBO, § 10 is 4 m, resulting in a distance between the sleepers of 1.40 m = 4 m – (2 * 2.6 m * 0.5).
- The distance between the sleepers and the edges of the railway line is assumed to be about 1 m in the case of levelled railway tracks with no railway embankment.

A schematic cross section through a railway line including ballast layers is provided in the following:

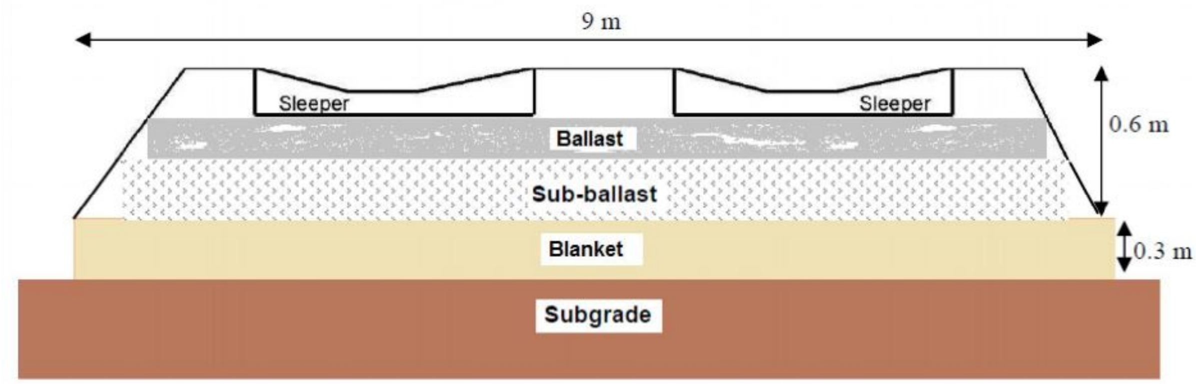


Figure 2.8.4.3.2-1: Cross section through a railway line (adapted from Hollis *et al.*, 2004)

Blanket: Permeable layer of fine, granular material placed directly on subgrade. A blanket is only necessary if the subgrade is cohesive.
Subgrade: Natural stratum (soil or rock) or embankment (from trimming natural stratum) on which the track bed (ballast, sub-ballast and blanket) is constructed.

This scenario is intended for UC3 timber, for which the maximum UC3 treatment level of Tanalith E 3462 results in 1.5 kg copper /m3. However, sleepers are considered a special case and are treated up to 2.5 kg/m3 copper, which is the same as the UC4 timbers. Therefore, the leach rate for UC4 is used, which can be considered as an absolute worst-case as taken from an immersion test to simulate direct contact with soil or water.

The emission scenario for railway sleepers is as given in the revised ESD for PT08 (EC, 2013):

Parameter/variable	**Symbol**	**Value**			**Unit**
INPUT		**Copper**	**Propiconazole**	**Tebuconazole**	
Leachable wood area of one railway sleeper (surface and sides)	AREAsleeper	1.59	1.59	1.59	m^2

Number of sleepers in a rectangular field of 1 hectare	Nsleepers	2583	2583	2583	/ha
Duration of the initial assessment	TIME1	30	30	30	d
Duration of the long-term assessment period A)	TIME2	7300	7300	7300	d
Cumulative quantity of a.s. leached out of 1 m^2 of treated wood over an initial assessment	Q*leach,time1	7.43E-04	3.12E-05	2.66E-05	kg/m^2
Cumulative quantity of a.s. leached out of 1 m^2 of treated wood over a longer assessment	Q*leach,time2	1.77E-03	1.26E-04	7.81E-05	kg/m^2
Cumulative quantity of a.s. leached over the initial	Qleach,timel	3.05	0.128	0.109	kg/ha
Cumulative quantity of a.s. leached over the longer assessment period on one hectare	Qleach,time2	7.27	0.516	0.321	kg/ha
Model calculations					
Qleach, time1 = AREAsleeper X Nsleepers X Q*leach,time1 Qleach, time2 = AREAsleeper X Nsleepers X Q*leach,time2					

The model PEARL (FOCUS model designed for Plant Protection Product assessments) has been used to determine if there is a risk to groundwater from propiconazole, tebuconazole and major soil metabolite (1,2,4-triazole) as a result of wood preservative leaching from railway sleepers. However, this model is not thought to be suitable for metals, therefore, the copper data was not assessed any further. Also, copper is known to adsorb strongly to soils and is unlikely to present a problem for groundwater as agreed in the WPCTF Annex I dossier. However, the specific concerns of the Netherlands have been addressed in the beginning of this section.

The PEARL model calculates the resulting concentrations of substances in groundwater after simulating an application to crops, grass or soil. For the railway sleeper scenario, a long-term assessment is considered more applicable (Time 2). Therefore, an annual leach rate per hectare was calculated from the Qleach, time 2 (kg/ha), which was then divided into 10 equal applications for use in the PEARL model.

Parameter/variable	Value		Unit
	Propiconazole	Tebuconazole	
PEARL applications per year (time 1)	1.557	1.331	kg/ha/year
PEARL applications per year (time 2)	0.026	0.016	kg/ha/year
PEARL applications per application (time 1)	0.156	0.133	kg/ha/application
PEARL applications per application (time 2)	0.0026	0.0016	kg/ha/application

The outcomes for TIME 1 (worst-case dosages) are presented in Table 2.8.4.2.2-1 below.

Table 2.8.4.3.2-1: Calculated emissions to groundwater for TIME 1 (worst-case dosages) as a result of railway sleepers treated with Tanalith E 3462

EU location	Concentration of active substance/metabolite in groundwater (closest to the 80th percentile (µg/L)		
	Propiconazole	Tebuconazole	1,2,4-triazole (total)
Chateaudun	<0.001	<0.001	5.8
Hamburg	<0.001	<0.001	18.6

Jokioinen	<0.001	<0.001	14.0
Kremsmuenster	<0.001	<0.001	11.3
Okehampton	<0.001	<0.001	14.4
Piacenza	<0.001	<0.001	9.5
Porto	<0.001	<0.001	10.9
Sevilla	<0.001	<0.001	< 0.001
Thiva	<0.001	<0.001	3.0

The concentrations of a combination of propiconazole, tebuconazole and metabolite 1,2,4-triazole were > 0.1 µg/L for the recommended EU scenarios Chateaudun, Hamburg, Jokoinen, Kremsmuenster, Okehampton, Piacenza, Porto and Thiva in case when emission was based on the leaching rate from freshly impregnated wood (Qleach1) (except for Sevilla) and therefore the risk for groundwater from the service life of railway sleepers treated withTanalith E 3462 is not acceptable. However, the expected concentrations are unrealistic considering that emission to groundwater was based on the fast leaching rate during the whole railway sleepers' service life, while leaching is only expected to be rapid up to a few months after construction of the railway or the railway yard. Because the concentrations in groundwater are < 0.1 µg/L when based the on slow leaching rate (Qleach2), unacceptable emission to groundwater is not considered realistic. Therefore, the standards for groundwater are met.

No groundwater assessment is recommended for wood preservatives for use of UC4 treated timbers like fence posts and transmissions poles, however, the assessment of timber cladded houses and railway sleepers show that there are no concerns for groundwater.

2.8.5.3.3 STP

For the city scenario it is assumed that the leachate resulting from rainfall is collected on the pavement and discharged to the sewer, and finally enters a municipal sewage treatment plant (STP). The expected risks are presented in Table 2.8.4.3.3-1.

Table 2.8.4.3.3-1: Risk assessment for the STP for the active substances copper, propiconazole and tebuconazole for the in-service use of timber pre-treated with Tanalith E 3462 using the city scenario with UC3 leaching data (worst-case)

Compound	**STP**	
	PEC (mg/L)	**PEC/PNEC**
Copper (added)	9.86E-02	0.429
Propiconazole	3.57E-04	<0.001
Tebuconazole	3.69E-04	<0.001
Combined (maximum risk)	9.93E-02	0.431

No unacceptable risks are expected when leachate is collected on the pavement and discharged to the STP as the summarised PEC/PNECs are <1. The standards for micro-organisms in the STP are therefore met.

2.8.5.3.4 Surface water and sediment

Indirect emission to surface water and sediment

For the city scenario, discharge of STP effluent results in exposure of surface water and sediment. The risks for the scenario are presented in Table 2.8.4.3.4-1, degradation is included in the calculations.

Table 2.8.4.3.4-1: Risk assessment for surface water and sediment exposed via the STP for the active substances copper, propiconazole and tebuconazole for the in-service use of timber pre-treated with Tanalith E 3462 using the city scenario with UC3 leaching data (worst-case)

Compound	fresh water		sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/kg wwt)	PEC/PNEC
Copper (added)	1.36E-03	0.174	8.92E+00	0.472
Copper (+Pristine background	2.24E-03	0.287	1.35E+01	0.713
Copper (+Regional background)	4.26E-03	0.546	2.36E+01	**1.25**
Propiconazole	3.56E-05	0.022	7.59E-04	0.014
Tebuconazole	3.68E-05	0.036	8.23E-04	0.001
Combined (maximum risk)	4.33E-03	0.604	2.36E+01	**1.27**

There is an unacceptable risk to the sediment environment exposed via the STP when preserved wood is applied in an urban environment where rain water is collected on the pavement and discharged to the sewer. These risks are however based on 2000 wooden houses in a city, which is very unlikely in The Netherlands. Considering that preserved wood is predominantly applied in windows frames and doors for which the surface exposed to weather is significantly lower (5.57 m²/house), and in fences which are normally surrounded by bare soils, the above presented risk ratios are overpredictive. An exceeding of 1.3 is therefore considered acceptable.

Direct emission to surface water and sediment

For the bridge over pond, jetty in the lake and sheet pilling in waterway scenarios direct exposure of surface water and sediment to the active substances leaching from the treated wood is assumed. The risks for the scenarios are presented in Tables 2.8.4.3.4-2 to 2.8.4.3.4-4 respectively, degradation is included in the calculations.

Bridge over pond

Table 2.8.4.3.4-2: Risk assessment for surface water and sediment directly exposed to the active substances copper, propiconazole and tebuconazole for the in-service use of timber pre-treated with Tanalith E 3462 using the bridge over pond scenario with UC3 leaching data (worst-case)

Compound	fresh water		sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/kg wwt)	PEC/PNEC
Copper (added)				
after 30 days	1.03E-06	<0.001	6.77E-03	<0.001
after 365 days	9.70E-06	0.001	6.38E-02	0.003
after 7300 days	1.73E-04	0.022	1.14E+00	0.060
Copper (+Pristine background)				
after 30 days	8.81E-04	0.113	4.57E+00	0.242
after 365 days	8.90E-04	0.114	4.62E+00	0.245
after 7300 days	1.05E-03	0.135	5.70E+00	0.302
Copper (+Regional background)				
after 30 days	2.90E-03	0.372	1.47E+01	0.778
after 365 days	2.91E-03	0.373	1.48E+01	0.781
after 7300 days	3.07E-03	0.394	1.58E+01	0.838
Propiconazole				
after 30 days	1.59E-06	<0.001	3.40E-05	<0.001

after 365 days	3.14E-07	<0.001	6.68E-06	<0.001
after 7300 days	3.14E-07	<0.001	6.68E-06	<0.001
Tebuconazole				
after 30 days	2.31E-06	0.002	5.17E-05	<0.001
after 365 days	1.22E-06	0.001	2.73E-05	<0.001
after 7300 days	1.22E-06	0.001	2.72E-05	<0.001
Combined (maximum risk)				
after 30 days	2.90E-03	0.375	1.47E+01	0.779
after 365 days	2.91E-03	0.375	1.48E+01	0.782
after 7300 days	3.07E-03	0.396	1.58E+01	0.839

Application of preserved wood above or adjacent of surface water will not result in unacceptable risks for the aquatic environment as the summarised PEC:PNEC ratios are below one. The standards for the aquatic environment are therefore met. No additional risk mitigations are required.

<u>Jetty in the lake and sheet piling in the waterway</u>

Table 2.8.4.3.4-3: Risk assessment for surface water and sediment directly exposed to the active substances copper, propiconazole and tebuconazole for the in-service use of timber pre-treated with Tanalith E 3462 using the jetty in the lake and sheet piling in the waterway scenarios with UC4 leaching data (worst-case)

Compound	fresh water		sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/kg wwt)	PEC/PNEC
Jetty in the lake				
Copper (added)				
after 30 days	3.06E-06	<0.001	2.01E-02	0.001
after 365 days	5.17E-06	<0.001	3.40E-02	0.002
after 7300 days	4.52E-05	0.006	2.97E-01	0.016
Copper (+Pristine background)				
after 30 days	8.80E-04	0.113	4.58E+00	0.242
after 365 days	8.80E-04	0.113	4.59E+00	0.243
after 7300 days	8.80E-04	0.113	4.86E+00	0.260
Copper (+Regional background)				
after 30 days	2.90E-03	0.372	1.47E+01	0.779
after 365 days	2.91E-03	0.372	1.47E+01	0.780
after 7300 days	2.95E-03	0.378	1.50E+01	0.790
Propiconazole				
after 30 days	7.03E-06	0.004	1.50E-04	0.003
after 365 days	1.79E-07	<0.001	3.81E-06	<0.001
after 7300 days	1.79E-07	<0.001	3.81E-06	<0.001
Tebuconazole				
after 30 days	1.00E-05	0.01	2.23E-04	<0.001
after 365 days	5.24E-07	<0.001	1.17E-05	<0.001
after 7300 days	4.85E-07	<0.001	1.08E-05	<0.001
Combined (maximum risk)				
after 30 days	2.92E-03	0.386	1.47E+01	0.783
after 365 days	2.91E-03	0.374	1.47E+01	0.782
after 7300 days	2.95E-03	0.380	1.50E+01	0.792
Sheet piling in the waterway				
Copper (added)				
recently installed	2.14E-01	**27.4**	1.41E+03	**74.5**
>30 d after installation	2.10E-03	0.269	1.38E+01	0.730

Compound	fresh water		sediment	
	PEC (mg/L)	PEC/PNEC	PEC (mg/kg wwt)	PEC/PNEC
Copper (+Pristine background)				
recently installed	2.15E-01	**27.6**	1.41E+03	**74.7**
>30 d after installation	2.98E-03	0.382	1.84E+01	0.971
Copper (+Regional background)				
recently installed	2.17E-01	**27.8**	1.42E+03	**75.3**
>30 d after installation	5.00E-03	0.641	2.85E+01	**1.51**
Propiconazole				
recently installed	7.75E-03	**4.85**	1.65E-01	**3.06**
>30 d after installation	1.29E-04	0.081	2.75E-03	0.051
Tebuconazole				
recently installed	9.61E-03	**9.61**	2.15E-01	0.391
>30 d after installation	1.16E-04	0.116	2.60E-03	0.005
Combined (maximum risk)				
recently installed	2.34E-01	**42.3**	1.42E+03	**78.8**
>30 d after installation	5.25E-03	0.838	2.85E+01	**1.57**

The emission of copper from preserved wood applied in stagnant surface water as represented by a jetty in a lake will not increase the background concentration significantly. An exceeding of the PNEC is therefore not expected. Considering that propiconazole and tebuconazol contribute only minimally, the summarised PEC:PNEC ratios are below one even when background concentrations are considered.

The emission of copper of wood applied as sheet pilling in a streaming water way, however, results in unacceptable risks for water and sediments. The highest risks are related to sheet pilings that are recently installed as leaching rates are high. However, the scenario assumes an unrealistic instalment of 2 km of sheet pilings (two sides of a 1 km long waterway) within one day. Moreover, installation of sheet pilings may disturb the aquatic environment anyway due to the heavy machinery that is required, noise, etc. However, considering that PEC:PNEC ratios are still above one for a recovered aquatic ecosystem, insufficient recovery is expected as copper is not removed from the aquatic environment.

The conclusions from the ESD sheet piling scenario are supported by additional calculations performed with TOXSWA 1.0 representing small ditches in the Netherlands. The sheet piling scenario presented in the ESD represent a waterway that measures 5 m width and 1.5 m depth, and a water flow of 50 m/d, whereas sheet pilings in The Netherlands are often installed in small ditches with lower water exchange rates.

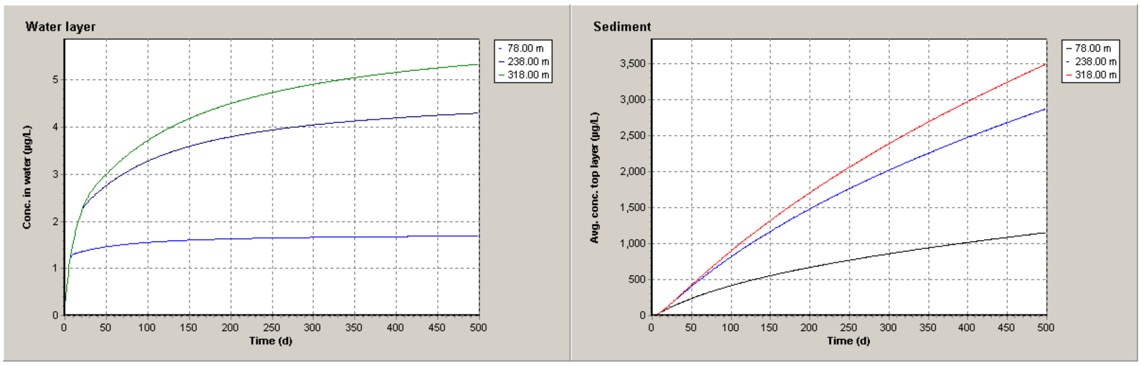
The TOXSWA 1.0 model represents emission to a standard Dutch ditch of one meter width, 30 cm deep, and 320 m long where water flows with 10 m/d. To simulate sheet pilings on both sides, the ditch's dimensions were adjusted as follows:

- side slope (horizontal/vertical) was decreased from one to 1E-5;
- bottom width was increased from 0.4 to one meter.

The daily emission was based on the leaching rate obtained for the longer assessment period. Considering a piling's height of 30 cm that are installed on both sides and the leaching rate of the longer assessment period, the corresponding dose is 0.146 mg $Cu/m^2/d$ which is applied to the water surface for 500 successive days (maximum number of events). The organic matter-water partition coefficient (K_{om}, 175440 L/kg) was derived from the measured partition coefficient between water and suspended matter (K_p) assuming 10% organic carbon in suspended matter (TGD default) and a conversion factor of 1.724. No corrections were made for concentration-depended sorption (Freundlich exponent is 1).

After one year the concentrations in water and sediment at the end of the ditch were 0.534E-02 mg/L and 3.50 g/m³, respectively. Considering a density of deposited suspended matter of 1150 kg/m³), the corresponding concentration in sediment is 4.03 mg/kg dwt. Although these concentrations are lower than presented in Table 2.8.4.3.4.3 and below the PNECs, one should realise that steady state was not reached. Although water was close to equilibrium the concentrations in sediment will increase remarkably during the preserved products service life as presented below.

Figure 2.8.4.3.4-1: Concentrations in water and sediment in a default Dutch Ditch modelled with TOXSWA 1.0.



As the PEC:PNEC ratio including the regional background concentration is 0.991 after 500 days, an exceeding of the PNEC is likely during the service life of the sheet piling due to accumulation of copper in sediments. Consequently, unacceptable risks for the aquatic environment are expected due to accumulation of copper in sediments when preserved wood is applied large scale in water (e.g. sheet pilings).

Metabolites

None relevant for the aquatic environment.

2.8.5.3.5 Non compartment specific effects relevant to the food chain (secondary poisoning)

Copper

Copper is an essential micronutrient, needed for optimal growth and development of micro-organisms, plants, animals and humans. Copper acts as an active cofactor in over 20 enzymes and proteins (Ralph & McArdle, 2001). To ensure appropriate copper tissue levels without causing toxicity from copper excess, internal copper levels are homeostatically regulated by all living organisms. Homeostatic regulation of copper allows organisms, within certain limits, to maintain their total body copper level and to maintain physiologically required levels of copper in their various tissues, both at low and high copper intakes.

In the aquatic environment, homeostatic regulation of invertebrates and fish resulted in an inverse relationship between copper BCFs and concentrations in the water (Mc Geer *et al.*, 2003). The importance of such homeostasis regulation was recognised in the regulatory framework of aquatic hazard classification (OECD, 2001). Similarly, in terrestrial plants, copper BCFs were inversely related to copper levels in soils (Ginocchio *et al.*, 2002).

The molecular mechanism of copper homeostasis, is related to 2 key elements: P-type ATPases that can pump copper across biological membranes in either direction and copper chaperones, important for the intracellular copper homeostasis (Odermatt *et al.,* 1992). This cellular copper homeostasis mechanism is considered as being universal as the sequences of copper chaperones are highly conserved between species (Wunderli *et al.*, 1999).

Besides these active regulation mechanisms, some groups of organisms have developed additional internal regulation mechanism (molecular binding and sequestration) as a strategy to cope against copper excess (Rainbow, 1998).

In higher organisms, dietary copper exposure studies in mammals and humans have shown that the intestinal adsorption/ biliary excretion of copper is regulated with varying dietary intakes (WHO, 1998). Research (Turnlund *et al.*, 1989 & 1998) indeed demonstrated that copper adsorption in humans can vary between 11 and 75 %, depending on the dietary intake. Similarly, mammals and birds, can rely on intestinal adsorption and biliary excretion to maintain internal copper levels with large variation in dietary intakes.
Based on the above information, bioaccumulation and biomagnification of copper are considered as not applicable for copper.

Propiconazole
According to TGD, part II (2003) an assessment of secondary poisoning is performed if a substance shows bioaccumulation potential and is classified with very toxic (T+), toxic (T) or harmful (Xn) with at least one of the risk phrases R48 "Danger of serious damage to health by prolonged exposure", R60 "May impair fertility", R61 "May cause harm to the unborn child", R62 " Possible risk of impaired fertility", R63 "Possible risk of harm to the unborn child", R64 "May cause harm to breastfed babies" or if there are other indications (e.g.) endocrine disruption. Based on this there is no need to perform an assessment of secondary poisoning for propiconazole.

Tebuconazole
A secondary exposure of tebuconazole to man via the food chain can be excluded due to the minimum amount which reaches the soil, which mostly is not used for agricultural purposes.

2.9 Measures to protect man, animals and the environment

The following restrictions should be included on the product label to mitigate direct losses to STP, water, sediment, soil and groundwater from industrial application and storage:

- Storage of treated wood is restricted to under a protective roof or above a water tight floor that is connected to the STP;
- Discharge of spills and residual fluids to the sewer system during treatment is not permitted. Spills and residues containing the product need to be recycled or need to be removed as chemical waste.

Risks were identified when Tanalith E 3462 is applied as a preservative for wood directly contacted to water (Use Class 4b). Based on the available information no risk mitigation measures can be proposed.
No risks were identified for wood applied in Use Classes 1, 2, 3, and 4a. No risk mitigation measures are required.

3 Decision

It is concluded that the application of Tanalith E 3462 according to the use instructions as stated in the SPC, will be effective and that there will be no harm for the health of humans and for the environment.

Tanalith E 3462 has been applied for and evaluated as a fungicide, and insecticide. The authorisation is granted for preventive protection of wood and constructional timbers in Hazard Classes 1, 2, 3 and 4a by vacuum pressure application.

Based on the assessment, the Dutch CA concludes that the product can be safely used by professional user, taking into account the risk mitigation measures as indicated under 2.9.

The assessment presented in this report has shown that Tanalith E 3462 may be authorised for use as a wood preservative (product type 8) on timbers:

- under cover, fully protected from the weather and not exposed to wetting (Use Class 1);
- under cover, fully protected from the weather and occasionally but not persistently exposed to wetting (Use Class 2);
- outdoors directly contacted to weather (Use Class 3);
- in direct contact with soils (Use Class 4a).

Tanalith E 3462 cannot be authorised for the requested applications in Use Classe 4b in direct contact with water as risks were identified for the aquatic environment.

The authorisation is subject to the following condition:
Appropriate risk mitigation measures must be taken to protect the soil and aquatic compartments as indicated in section 2.9 of this report and in the Summary of Product Characteristics (SPC).

The authorisation is subject to the following provision:
A shelf-life study of 2 years in HDPE is required to confirm the provisional data The study should be submitted when available, but not later than 30th of June 2017.

4 Annexes

1. **List of studies reviewed**
2. **Analytical methods residues – active substance**
3. **Toxicology and metabolism –active substance**
4. **Toxicology – biocidal product**
5. **Safety for professional operators**
6. **Safety for non-professional operators and the general public**
7. **Residue behaviour**
8. **Annex environment**

Annex 1 List of studies reviewed

List of <u>new data</u> submitted in support of the evaluation of the biocidal product

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
IVB3_1	1	Woolley, A.J.	2012	Tanalith E 3462: : Determination of physico-chemical properties. Harlan Laboratories Limited. Project number 41201556. GLP. Unpublished	Arch Timber Protection (A LONZA Company)		N	Y	
IVB3_1	2	Woolley, A.J.	2012	Tanalith E 3462: : Determination of Accelerated Storage Stability. Harlan Laboratories Limited. Project number 41201557. GLP. Unpublished	Arch Timber Protection (A LONZA Company)		N	Y	
IVB3_7	1	Woolley, A.J.	2014	Tanalith E 3462: : Determination of Long-Term Storage Stability. Harlan Laboratories Limited. Project number 41201558 (interim report). GLP. Unpublished	Arch Timber Protection (A LONZA Company)		N	Y	

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IVB4_1	1	Nixon, Willard B and Van Hoven, R.L	2007	Tanalith E 3462: Analytical method validation for the determination of Copper and Basic Copper Carbonate in Wolman E (CA-C) and µCu formulations. Wildlife International. Project number 581C-110 . GLP. Unpublished	Arch Timber Protection (A LONZA Company)		N	Y	
IVB4_1	2	Chafey, K.W and Nixon, W. B.	2007	Tanalith E 3462: Analytical method validation for the determination of Tebuconazole and Propiconazole in Wolman E (CA-C). Wildlife International. Project number 581C-109 . GLP. Unpublished	Arch Timber Protection (A LONZA Company)		N	Y	
IVB4_1	3	Wu, M.	2007	Read Across Statement from Wolman to Tanalith E	Arch Timber Protection (A LONZA Company)		N	Y	
IVB4_1	4	Woolley, A.J.	2013	Tanalith E 8000, also known as 8001, 8002, 8003: Analytical Method Validation Harlan Study no. 41205536 GLP Unpublished	Arch Timber Protection (A LONZA Company)		N	Y	
5	B5.10-1	Brunet C. and Paulmier I.	2008	Determination of the toxic values against Hylotrupes bajulus (L.) larvae (EN 47 with EN 73), FCBA, 401/033/07F/1/c-e (unpublished)	Arch Timber Protection (A LONZA Company)		N	Y	

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access	Data protection claimed
5	B5.10-2	Brunet C. and Paulmier I.	2008	Determination of the toxic values against Hylotrupes bajulus (L.) larvae (EN 47 with EN 84), FCBA, 401/033/07F/1/b-e (unpublished)	Arch Timber Protection (A LONZA Company)	N	Y
5	B5.10-3/ B5.10.4	Howard N. J. and Suttie E.	2010	Determination of the toxic values of product X1185 against Reticulitermes species (European termites) – (laboratory method) EN 117: 2005, BRE, 254-426 (unpublished)	Arch Timber Protection (A LONZA Company)	N	Y
5	B5.10.5/ B5.10.6	Howard N. J. and Suttie E.	2010	Determination of protective effectiveness of product X1185 against basidiomycetes according to EN 113: 1997, BRE, 254-427 (unpublished)	Arch Timber Protection (A LONZA Company)	N	Y
5	B5.10.7	Howard N. J.; Lea, R.G. and Suttie E.	2012	Determination of the effectiveness of product X1185 against soft rotting micro-fungi and other soil inhabiting micro-organisms - DD ENV 807: 2001, BRE, 274-352 (unpublished	Arch Timber Protection (A LONZA Company)	N	Y
IVB6_1_ 1	IVB6_1_1	Lheritier, M .	1992	Test to Evaluate the acute toxicity following a single oral administration (LD50) in the rat, Hazleton France, Report Number 202353, 11 March 1992.	Arch Timber Protection (A LONZA Company)	N	Y

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IVB6_1_2	IVB6_1_2	Kuhn, J.O	2012	Tanalith E 3462: Acute Dermal Toxicity in Rats; Stillmeadow Inc.; Laboratory Study ID 16176-12; 6 September 2012; GLP; Unpublished	Arch Timber Protection (A LONZA Company)		N	Y	
IVB6_1_3	IVB6_1_3	Kuhn, J.O	2012	Tanalith E 3462: Acute Dermal Irritation in Rabbits; Stillmeadow Inc.; Laboratory Study ID 16177-12; 15 May 2012; GLP; Unpublished	Arch Timber Protection (A LONZA Company)		N	Y	
IVB7_1_1	IVB7_1_1	Sims, I.	1993	The Toxicity of Tanalith 3485 wood preservative to Daphnia Magna in a 21-day reproduction test (OECD 202b), Report Number: CO 3297, GLP. Unpublished.	Arch Timber Protection (A LONZA Company)		N	Y	
IVB7_1_2	IVB7_1_2	Cantrell, D.	2012b	Determination of the emissions of biocides from BPD formulation Tanalith E-3462treated timber (2.5 kg m-3copper) using the OECD protocol for hazard class 4 environments. Arch Timber Protection Technical Centre. Report No W20/58 ; Not GLP; Not published.	Arch Timber Protection (A LONZA Company)		N	Y	

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access	Data protection claimed
IVB7_1_3	IVB7_1_3	Cantrell, D.	2012a	Semi-field test to monitor emission of active substances from Tanalith E (3462) treated timber. Arch Timber Protection Technical Centre. Report No W20/59 ; Not GLP; Not published.	Arch Timber Protection (A LONZA Company)	N	Y

Annex 2 Analytical methods residues – active substance

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	Purity is not directly determined but calculated from total copper content. This is possible because other copper forms (i.e. metallic and cuprous) are not expected to be present in the technical materials. Total copper content can be determined by various well-known methods such as volumetric thiosulphate method (CIPAC E Copper 44/TC/M/3.2), electrogravimetric method (CIPAC E Copper 44/TC/M/3.1). A validation study is required.
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	Trace metals, including those of toxicological significance (arsenic, cadmium) can be determined by AAS. Before analysis, the sample is dissolved in an acid mixture and placed on a hotplate until digestion is complete. The AAS methods used to obtain five batch analysis data of impurities in copper oxide are variations on internationally accepted guidelines such as ASTM E53-98 and US EPA methods 206.2, 213.1 and 239.1 for arsenic, cadmium and lead, respectively. Other suitable methods include Inductively Coupled plasma – Atomic Absorption Spectroscopy (ICP-AES) (e.g. US EPA method 200.7), which is applicable to the determination of µg/l concentrations of a large number of elements in a variety of matrices. Prior to analysis, samples must be solublised or digested using an appropriate method. Samples are nebulised and the resulting aerosol is transported to the plasma torch. Element-specific emission spectra are produced by a fadio-frequency inductively coupled plasma. The spectra are dispersed by a grating spectrometer, and the intensities of the emission lines are monitored by photosensitive devices. Method for ~~or~~ one impurity > 0.1% and for nickel must be provided

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA,	ICP-AES methods (e.g. AOAC official method

point 4.2)	990.8). The estimated instrumental limit of detection (LOD) is 6 µg Cu/l (LOQ not determined). Another suitable method is AAS (e.g. US EPA method 7210), with an LOD of 20 µg Cu/l and a LOQ of 200 µg Cu/l. For both methods of analysis, the sample must first be digested.
Air (principle of method and LOQ) (Annex IIA, point 4.2)	Residues of copper may be determined in air using Flame-AAS or ICP-AES methods (e.g. NIOSH methods 7029 or 7300 respectively). The estimated instrumental limits of determination (LOD) are 0.05 and 0.07 µg Cu/filter (LOQ not determined
Water (principle of method and LOQ) (Annex IIA, point 4.2)	In water, trace elements may be determined by Inductively Coupled Plasma – Mass Spectroscopy (ICP-MS) (e.g. US EPA method 200.7). The estimated LOQ for this method is 20 µg Cu/l. Other suitable methods include AAS with direct aspiration (LOQ 0.2 mg/l) (e.g. US EPA method 220.1) and AAS with graphite furnace (LOQ 5.0 µg/l) (e.g. US EPA method 220.2). For all three methods of analysis, the sample must first be digested.
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	ICP-AES may also be used for analysing elements in body fluids and tissues following acid digestion of the sample. LOQs are 10 µg/100 g blood, 2 µg/g tissue (e.g. NIOSH method 8005) and 0.25 µ/sample of urine (NIOSH method 8310).
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not applicable
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not applicable

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	GC-FID packed column, internal standardization
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	Refer to Confidential Annex

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	GLC-NPD; LOQ : 0.02 mg/kg (parent compound) GLC-ECD; LOQ : 0.05 mg/kg (total; 2,4-DCBA) HPLC-UV; LOQ : 0.01 mg/kg as 1,2,4-triazole (total; 1,2,4-triazole) LC-LC-ESI/MS/MS; LOQ : 0.005 mg/kg (CGA 118 244) HPLC-LC/MS/MS; LOQ: 0.005 mg/kg as parent compound and its degradation products CGA 21795, CGA 91305, CGA 118244, CGA 118245, CGA 136735 and CGA 71019 (1,2,4-triazole)
Air (principle of method and LOQ) (Annex IIA, point 4.2)	GLC-NPD; LOQ : 10 µg/m^3 (parent compound) GC-MS; LOQ : 10 µg/m^3 (parent compound)
Water (principle of method and LOQ) (Annex IIA, point 4.2)	GLC-ECD; LOQ : 0.05 µg/l (parent compound in potable water) GC-MS : 0.05 µg/l (parent compound in potable water and surface water) *Sediment* HPLC-LC/MS/MS: 0.010 mg/kg (parent compound and its degradation products CGA 217495, CGA 91305 and CGA 136735)
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	Not applicable (not toxic or very toxic substance)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not applicable
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not applicable

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	The method to determine the assay of Folicur (tebuconazole) in industrial active component is based on capillary gas chromatography using flame ionisation detector. The quantitative evaluation is carried out according to the method of the internal standard (Di-(2-ethylhexyl)phthalate (DIOP))
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	The method to determine the assay of the by-products in technical active substance (Folicur, techn., tebuconazole) in the range 0.05 to 5% is based on capillary gas chromatography using flame ionisation detector. The quantitative evaluation is carried out according to the method of the internal standard (Dimethylphthalate)

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	The DFG Method S 19 describes the analytical procedures for the determination of tebuconazole in soil. The extraction from soil is performed with acetone followed by the clean-up procedures of gel permeation chromatography (GPC) on Bio Beads S-X3 polystyrene gel. Tebuconazole is analysed by gas chromatography on fused silica gel with a nitrogen/phosphorus detector or mass specific detector. Evaluation is carried out with external standard. Limit of quantification (LOQ): 0.01mg/kg
Air (principle of method and LOQ) (Annex IIA, point 4.2)	Air is sucked through Tenax or XAD-2 adsorption tubes at a rate of 2 l/min during a period of 6 hours. The adsorbed active ingredient is extracted with ethyl acetate and determined after gas chromatographic separation by means of a nitrogen and phosphorous selective detector (GC-NPD). A confirmatory procedure is based on gas chromatography using mass selective detection (GC-MSD). No deviation from the described Tenax sampling and extraction technique is necessary. The same crude extracts could be investigated by both different GC methods. Evaluation is carried out with external standard. Limit of quantification (LOQ): 0.001 mg a.i./ m3 air

Analytical methods for residues (continued)

Water (principle of method and LOQ) (Annex IIA, point 4.2)	Determination for tebuconazole in surfacewater is performed according to DFG Method W 5. Water samples are analysed by means of gas chromatography on fused silica gel after extraction with dichloromethane and clean up by gel

	permeation chromatography on Bio Beads S-X3 polystyrene gel. For detection a mass selective detector (MSD) is used. Evaluation is carried out with external standard. Limit of quantification (LOQ): 0.05 µg/l
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	Relevant only for toxic substances.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not relevant
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not relevant

Annex 3 Toxicology and metabolism –active substance

Copper(II)carbonatehydroxide

Threshold Limits and other Values for Human Health Risk Assessment

Date: 21.11.2012

Summary			
	Value	Study	SF
AEL long-term	0.041 mg/kg bw/d	90d in rats	MOE ref = 100
AEL short and medium-term	0.082 mg/kg bw/d	90d in rats	MOE ref = 50
ADI (if residues in food or feed)	0.15 mgCu/kg bw/day	EFSA (2008)	Not applicable.

Inhalative absorption	No data
Oral absorption	It was agreed during the TMIII09 that an oral absorption of 36% for humans and 25% for animals have to be used.
Dermal absorption	It was agreed during the TMIII09 that a dermal absorption of 5% has to be used for diluted solutions and 100% for the concentrated product.

Classification	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	Xn, Harmful R20, Harmful by inhalation R22, Harmful if swallowed
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Acute Tox. 4 /H332 – Harmful if inhaled Acute Tox. 4/H302 – Harmful if swallowed

propiconazole

Threshold Limits and other Values for Human Health Risk Assessment

Date: 12.2007

Summary

	Value	Study	SF
AEL	0.08 mg/kg bw/day	2-generation rat study	100
AEL acute	0.3 mg/kg bw/day	Developmental study in rat	100

Inhalative absorption	No data
Oral absorption	86% within 48 h
Dermal absorption	Based on the latest in vivo dermal absorption study in rat and the in vitro comparison of dermal penetration in rat and human skin, the predicted dermal absorption figures in humans are 0.9 %, 1.6 % and 2.4 % for dilutions containing 25 %, 0.06 % or 0.006 % propiconazole, respectively (based on studies in the CAR with the product Tilt 250 EC).

Classification

with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	Xn R22 R43;
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	H302, H317

tebuconazole

Threshold Limits and other Values for Human Health Risk Assessment

Date: 05.2007

Summary			
	Value	Study	SF
AEL	0.03 mg/kg bw/day	1 year / dog	100

Inhalative absorption	No data
Oral absorption	> 98% (based on urinary (7.4%) and biliary (90.9%) excretion within 48 hours) Peak plasma levels approximately 1 to 2 hours after administration
Dermal absorption	The value of 75% for tebuconazole has to be used for diluted solutions and for the concentrated product

Classification	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	Xn; Repr. Cat.3 R63: Possible risk of harm to the unborn child R22: Harmful if swallowed
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	H361d H302

Annex 4 Toxicology – biocidal product

Tanalith E3462

Date: 03-10-2014

General information

Formulation Type	concentrate
Active substance(s) (incl. content)	15.7% copper(II)carbonatehydroxide, 0.18% tebuconazole and 0.18% propiconazole,
Category	PT8

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD50 oral (OECD 420)	H302 (harmful if swallowed) based on comparison with comparable product
Rat LD50 dermal (OECD 402)	LD50>4000 mg/kg bw/day, no classification
Rat LC50 inhalation (OECD 403)	Waived based on vapour pressure
Skin irritation (OECD 404)	No skin irritation, no classification
Eye irritation (OECD 405)	H318 (causes serious eye damage) based on read across to comparable product
Skin sensitisation (OECD 429; LLNA)	Waived, applicant proposes EUH208 based on propiconazole

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	No study submitted
Toxicological data on active substance(s) (not tested with the preparation)	No study submitted
Toxicological data on non-active substance(s) (not tested with the preparation)	No study submitted
Further toxicological information	Dermal absorption study submitted for 2-aminoethanol (not acceptable, see beneath)

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Regulation 1272/2008/EC	H302, H318, H332, H335, EUH208

The basis for health assessment of the substance of concern 2-aminoethanol is based on the SCOEL recommendation SCOEL/SUM/24 1996:

Ethanolamine is absorbed through the skin, lungs and gastrointestinal tract (Klain *et al*, 1985;

Weeks *et al*, 1960; Weissbach and Sprinson, 1953). It is a normal constituent of the body, and following condensation to phosphatidyl ethanolamine or transformation into phosphatidyl choline 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 (Smyth *et al*, 1951). Repeated inhalation exposure at concentrations above 66 ppm (168 mg/m3) caused behavioural changes and pathological lesions to the lung, liver, kidneys, spleen and testes in a number of species (Weeks *et al*, 1960). A NOAEL was not found in this study.
Exposure of rats, dogs and guinea pigs to ethanolamine vapour was reported to produce skin irritation at levels as low as 5 ppm (13 mg/m3), although this may have been potentiated by direct skin contact with ethanolamine liquid that had condensed on the surface of the inhalation chamber (Weeks *et al*, 1960). Rats exposed to 5 ppm (13 mg/m3) ethanolamine also exhibited lethargy after 2-3 weeks exposure. Behavioural changes are therefore concluded to be the critical effect of ethanolamine.Ethanolamine has not been found to be mutagenic in bacteria (Dean *et al*, 1985; Hedenstedt and Frascati, 1978; Mortelmans *et al*, 1986) and did not induce cell transformation (Inuoe *et al*, 1982). There is evidence for reproductive toxicity at exposure levels much higher than those inducing skin irritation and behavioural effects (Mankes, 1986; Weeks *et al*, 1960). Ethanolamine has not been tested for immunotoxicity in animals or for carcinogenicity. Very little information is available on the effects of exposure to ethanolamine vapour in humans, although the liquid has been reported to be a skin irritant and sensitizer (Cosmetic Ingredient Review Expert Panel, 1983; Tsyrkunov, 1975). Some studies, which are mostly poorly documented, suggest that ethanolamine may give rise to occupational asthma (Gelfand, 1963).

The study of Weeks *et al* (1960), establishing a LOAEL of 5 ppm (13 mg/m3) for behavioural effects in rats, was considered to be the best available basis for proposing occupational exposure limits. An uncertainty factor of 5 was applied because of the extrapolation from animal studies.
The lack of a NOAEL did not justify a higher factor in this instance because the effects seen were minimal. The recommended 8-hour TWA is 1 ppm (2.5 mg/m3). A STEL (15 mins) of 3 ppm (7.6 mg/m3) was recommended to prevent exposure to irritating levels. A "skin" notation was recommended as dermal absorption could contribute substantially to the total body burden.

Key bibliography:

Criteria document for an occupational exposure limit for ethanolamine. Prepared by Industrial Toxicology Unit, Institute of Occupational Health, Birmingham. (EUR 14240)

Cosmetic Ingredient Review Expert Panel (1983). Final report on the safety assessment of triethanolamine, diethanolamine and monoethanolamine. J. Am. Coll. Toxicol. 2, 183-235.

Dean, B.J., Brooks, T.M., Hodson-Walker, G. and Hutson, D.H. (1985). Genetic toxicology testing of 41 industrial chemicals. Mutat. Res. 153, 57-77.

Gelfand, H.H. (1963). Respiratory allergy due to chemical compounds encountered in the rubber,lacquer, shellac and beauty culture industries. J. Allergy 34, 374-381.

Hedenstedt, A. and Frascati, L. (1978). Mutagenicity screening of industrial chemicals: seven aliphatic amine and one amide tested in the Salmonella/microsomal assay. Mutat. Res. 53, 198-199.

Inoue, K., Sunakawa, T., Okamoto, K. and Tanaka, Y. (1982). Mutagenicity tests and in vitro transformation assays on triethanolamine. Mutat. Res. 101, 305-313.

Klain, G.J., Reifenrath, W.G. and Blacj, K.E. (1985). Distribution and metabolism of topically applied ethanolamine. Fund. Appl. Toxicol. 5, 127-133.

Mankes, R.F. (1986). Studies on the embryopathic effects of ethanolamine in Long-Evans rats: preferential embryopathy in pups contiguous with male siblings in utero. Teratogenisis, Carcinogenesis and Mutagenesis 6, 403-417.

Mortelmans, K. Haworth, S., Lawlor, T., Speck, W., Trainer, B. and Ziegler, E. (1986). Salmonella mutagenicity tests:2. Results from testing of 270 chemicals. Environ. Mutagen. 8, 1-119.

Smyth, H.F., Carpenter C.P. and Weil, C.S. (1951). Range finding toxicity data: List IV. Arch. Ind. Hyg. Occup. Med. 4, 119-122.

Tsyrkunov, L.P. (1975). Skin diseases in workers in contact with inhibitors of atmospheric corrosion of metals. Vestnik Dermatologii Venerologii 3, 62-65.

Weeks, M.H., Downing, T.O., Musselman, N.P., Carson, T.R. and Groff, W.A. (1960). The effect of continuous exposure of animals to ethanolamine vapour. Am. Ind. Hyg. Ass. J. 21, 374-381.

Weissbach, A. and Sprinson, D.B. (1953). The metabolism of 2-carbon compounds related to
glycine. II. Ethanolamine. J. Biol. Chem. 203, 1031-1037.

Dermal absorption 2-aminoethanol

The applicant submitted a dermal absorption study, an “In vitro method with full thickness skin preparations from mice, rats, humans and rabbits” (Sun J D *et al.,* 1996, J Toxicol. – Cut. and Ocular Toxicol. 15 (2), 131). The Dutch CA does not accept the study, because of the low recovery (<60%) and the fact that it isnot evident that the 6 human skin samples are derived from 1 or more persons. Furthermore, the absorption in human skin has a long lag time, and starts very slowly. It will be first absorbed in the skin. Therefore, at least the absorbed dose in the skin should also be taken into account.

Because the study submitted is not acceptable Dutch CA used the dermal percentage of 75% based on the EFSA guidance 2012 in the risk assessment for 2-aminoethanol.

Annex 5: Safety for professional operators

Tanalith E 3462

Date: 3-6-2014

Exposure assessment

Exposure scenarios for intended uses (Annex IIIB, point 6.6)

Tables 1-3 are the exposure outputs or calculations of the primary exposure scenarios of professionals for the application and post-application phase by using handling model 1.

Table 1: Exposure outputs using Handling Model 1 with gloves

TNsG Part 2, p 160 (includes application and post- application exposures);

Descriptor	Units	UC4 – Normal use	UC4 – Niche use
Active substance			
Copper	%w/v	0.623	0.781
Propiconazole	%w/v	0.0125	0.016
Tebuconazole	%w/v	0.0125	0.016
Potential body exposure			
Indicative value (75^{th} % value)	mg/cycle	8570	
Duration	cycles/day	3	
Potential dermal deposit	mg	25710	
Actual dermal deposit [*product*]	mg	25710	
Hand exposure			
Indicative value inside gloves	mg/cycle	1080	
Duration	cycles/day	3	
Actual hand deposit [*product*]	mg	3240	
Total dermal exposure on skin			
Product	mg	28950	
Copper	mg	180.36	226.1
Propiconazole	mg	3.62	4.63
Tebuconazole	mg	3.62	4.63
Total systemic exposure through skin			
Copper (5% dermal absorption)	mg	9.02	11.31
Propiconazole (2.4% dermal absorption)	mg	0.087	0.11
Tebuconazole (75% dermal absorption)	mg	2.71	3.47
Exposure by inhalation			
Indicative value	mg/m^3	1.9	
Duration	min	540	
Inhalation rate	m^3/min	0.021	
Inhaled volume	m^3	11.34	
Mitigation by RPE	-	none	
Inhaled [*product*]	mg	21.546	
Copper (100% absorption)	mg	0.134	0.168
Propiconazole (100% absorption)	mg	0.00269	0.00345
Tebuconazole (100% absorption)	mg	0.00269	0.00345

Table 2: Exposure outputs using Handling Model 1 with gloves and protective clothing *TNsG Part 2, p 160 (includes application and post- application exposures);*

Descriptor	**Units**	**UC4 – Normal use**	**UC4 – Niche use**
Active substance			
Copper	%w/v	0.623	0.781
Propiconazole	%w/v	0.0125	0.016
Tebuconazole	%w/v	0.0125	0.016
Potential body exposure			
Indicative value (75^{th} % value)	mg/cycle	8570	
Duration	cycles/day	3	
Potential dermal deposit	mg	25710	
Protective clothing (10% penetration)	mg	2571	
Actual dermal deposit [*product*]	mg	2571	
Hand exposure			
Indicative value inside gloves	mg/cycle	1080	
Duration	cycles/day	3	
Actual hand deposit [*product*]	mg	3240	
Total dermal exposure on skin			
Product	mg	5811	
Copper	mg	36.20	45.38
Propiconazole	mg	0.73	0.93
Tebuconazole	mg	0.73	0.93
Total systemic exposure through skin			
Copper (5% dermal absorption)	mg	1.81	2.23
Propiconazole (2.4% dermal absorption)	mg	0.018	0.022
Tebuconazole (75% dermal absorption)	mg	0.55	0.70
Exposure by inhalation			
Indicative value	mg/m^3	1.9	
Duration	min	540	
Inhalation rate	m^3/min	0.021	
Inhaled volume	m^3	11.34	
Mitigation by RPE	-	none	
Inhaled [*product*]	mg	21.546	
Copper (100% absorption)	mg	0.134	0.168
Propiconazole (100% absorption)	mg	0.00269	0.00345
Tebuconazole (100% absorption)	mg	0.00269	0.00345

Table 3: Summary of exposure estimates: direct exposure to industrial professionals

Task : Handling of wood during vacuum-pressure impregnation					
Tier-PPE	**Hazard Class**	**Active substance**	**Dermal exposure** **Systemic dose mg as / kg bw**	**Inhalation exposure** **Systemic dose mg as / kg bw**	**Total exposure** **Systemic dose mg as / kg bw**
Tier 1 : gloves, minimal clothing, no RPE	**UC4 Normal use**	**Copper**	0.15	0.0022	0.152
		Propiconazole	0.0015	0.000045	0.0015
		Tebuconazole	0.045	0.000045	0.045
	UC4 Niche use	**Copper**	0.19	0.0028	0.193
		Propiconazole	0.0018	0.000058	0.0018
		Tebuconazole	0.058	0.000058	0.058
Tier 2 : gloves, protective clothing, no RPE	**UC4 Normal use**	**Copper**	0.03	0.0022	0.032
		Propiconazole	0.0003	0.000045	0.003
		Tebuconazole	0.0092	0.000045	0.0092
	UC4 Niche use	**Copper**	0.037	0.0028	0.0398
		Propiconazole	0.00037	0.000058	0.00037
		Tebuconazole	0.012	0.000058	0.012

Annex 6: Safety for non-professional operators and the general public

Tanalith E 3462

Date:03-10-2014

Acute exposure

Adults (consumers) - Acute handling, cutting and sanding treated timbers

Infants - Acute chewing preserved timber off-cuts

The description of the model calculations and the exposure outputs or calculations of the following secondary acute exposure scenarios are presented in tables 1 and 2:

Table 1: Description of the model calculation and the exposure outputs or calculations of the secondary acute exposure of adults (consumers) - acute handling, cutting and sanding treated timbers -

a) Adult (non-professional) sanding treated wooden posts for one hour
TNsG assumptions (TNsG 2002, Part 3, p. 50):

Wood preservative in outer 1 cm outer layer
Posts 4 cm x 4 cm x 2.5 m treated posts (0.004 m^3 wood, area 40032 cm^2)
Task = hand-held power sanding surface of posts for outdoor play area
Exposure = 5 mg/m^3 dust for 60 minutes
Inhalation rate 1.25 m^3/hour, 60 kg adult

The TNsG example has been modified to allow for a more realistic assessment by using the Tanalith E 3462 highest retention rates and not 50 litres of product in outer 1 cm. Therefore, as the highest proposed retention of the product proposed is 27.77 kg/m^3 for treatment of UC4 timber (or 2.5 kg/m^3 copper, 0.05 kg/m^3 propiconazole and 0.05 kg/m^3 tebuconazole in the outer 1 cm), the following worst-case levels of active substance are available for the secondary exposure;
= 2.5 mg copper / cm^3
= 0.05 mg propiconazole cm^3
= 0.05 mg tebuconazole / cm^3

This assumes that all the active substance in the outer 1cm is available on the surface of the wood which is a gross over estimation.

<u>Inhalation exposure</u>
TNsG Assumptions

Exposure = 5 mg/m^3 dust for 60 minutes
Inhalation rate 1.25 m^3/hour, 60 kg adult
Wood dust density of 0.8 g/cm^3 replaced by 0.4 g/cm^3 in Manual of Technical Agreements (see MOTA, decided at TMIII08)

Amount of wood dust inhaled in 1 hour:
Exposure x *Inhalation rate*
= 5 x 1.25
= 6.25 mg wood dust,
which is equivalent to 6.25/1000 ÷ 0.4 = 0.0156 cm^3 treated wood giving;
- 0.0156 cm^3 wood contain (2.5 mg a.s./cm^3 × 0.0156 cm^3) = **0.039 mg copper by inhalation**
- 0.0156 cm^3 wood contain (0.05 mg a.s./cm^3 × 0.0156 cm^3) = **0.00078 mg propiconazole by inhalation**
- 0.0156 cm^3 wood contain (0.05 mg a.s./cm^3 × 0.0156 cm^3) = **0.00078 mg tebuconazole by inhalation**

Based on the absorption via inhalation of 100% for the three substances and a body weight of 60 kg the systemic doses are: 0.00065 mg copper by inhalation, 0.000013 mg propiconazole by inhalation and = 0.000013 mg tebuconazole by inhalation

<u>Dermal exposure</u> (via hands no gloves worn) handling treated timber

Tanalith E 3462 contains three active substances and the proposed dermal uptake has been assumed to be 5% for copper, 2.4 % for propiconazole and 75 % for tebuconazole;
The combined surface area of both palms of hands is 420 cm^2 (TNsG default value) and during prolonged and repeated contact 20 % of the hand is contaminated (TNsG, User Guidance, p. 52).
Retention = 2.5 mg Cu/cm^3, 0.05 mg propiconazole/cm^3, 0.05 mg tebuconazole/cm^3 which as a worst case can be translated to

2.5 mg Cu/cm^2 0.05 mg propiconazole/cm^2 0.05 mg tebuconazole/cm^2 The transfer efficiency from sawn timber has been assumed to be 2 % as given by the TNsG (and used by WPCTF in finall CAR). *Copper* 2.5 × 420 cm² × 0.2 × 0.02 = 4.2 mg copper on hands Systemic Exposure = 4.2 mg x 0.05 (dermal uptake) = 0.21 mg copper (0.0035 mg kg bw/day) *Propiconazole* 0.05 mg/cm^2 × 420 cm² × 0.2 × 0.02 = 0.084 mg propiconazole on hands Systemic Exposure = 0.084 mg x 0.024 (dermal uptake) = 0.002016 mg propiconazole (0.0000336 mg/kg bw/day) *Tebuconazole* 0.05 × 420 cm² × 0.2 × 0.02 = 0.084 mg tebuconazole on hands Systemic Exposure = 0.084 mg x 0.75 (dermal uptake) = 0.063 mg tebuconazole (0.00105 mg/kg bw/day)   Total systemic dose (= Inhalation dose + Dermal dose) *Copper [5 %]* = 0.039 + 0.21 = 0.249 mg a.s = 0.0042 mg a.s./kg bw per event *Propiconazole* = 0.00078 + 0.002016 = 0.002796 mg a.s = 0.0000466 mg a.s./kg bw/day *Tebuconazole* = 0.00078+ 0.063 = 0.06378 mg a.s = 0.00106 mg a.s./kg bw/day

Table 2: Description of the model calculation and the exposure outputs or calculations of the secondary acute exposure Infants - chewing wood off-cut - ingestion route -

b) Infants chewing wood off-cut - ingestion route For infants (10 kg body weight) who are chewing wood it is assumed that the active substance in the treated timber is located in the outer 1 cm layer. It is assumed that the infant is chewing a 4 cm x 4 cm x 1 cm chip and in doing so extracts 10 % of the active substance. The following calculation should be considered to be very much a worst-case approach since it uses the highest UC4 retentions, which is unlikely to be available to the general public. volume of off-cut from treated post = 4 x 4 x 1 = 16 cm^3 - concentration of the active substance in the treated wood = 2.5 mg copper/cm^3, 0.05 mg propiconazole/cm^3, 0.05 mg tebuconazole/cm$^{3.}$ - 16 cm^3 wood contains 16 x 2.5 mg copper/cm^3 = 40 mg copper, 16 x 0.05 mg propiconazole/cm^3 = 0.8 mg propiconazole and 16 x 0.05 mg tebuconazole/cm^3 = 0.8 mg tebuconazole.

- 10 % extraction from wood = 4 mg copper, 0.08 mg propiconazole and 0.08 mg tebuconazole - Systemic exposure (ingestion) = 0.144 mg/kg bw copper (adjusted for 36 % dietary absorption, see annex 4), 0.008 mg/kg bw propiconazole and 0.008 mg/kg bw tebuconazole; per event.

Chronic exposure

Adults (workers)	- Chronic handling, cutting and sanding treated timbers
Children	- Chronic playing on preserved timber playground equipment
Infants	- Chronic playing on preserved timber playground equipment and mouth contacts with the treated timber surface.

The description of the model calculations and the exposure outputs or calculations of the following secondary chronic exposure scenarios are presented in tables 3-5:

Table 3: Description of the model calculation and the exposure outputs or calculations of the secondary acute exposure of adults (workers) - Chronic handling, cutting and sanding treated timbers

a)Adult sanding treated wooden posts

a1)Inhalation of volatilised residues indoors - inhalation route

The product may be used on joinery elements that are used indoors and so inhalation of volatilized residues has been considered.

Chronic inhalation exposure can occur from the treated wood installed indoors. According to Curry et al (1995), as a general rule, a substance should only be considered volatile if it has a vapour pressure > 10mPa at 20^{o}C. The vapour pressure of copper is not measurable, propiconazole is 5.6 x 10^{-5} Pa @25 ^{o}C and tebuconazole is 1.7 x 10^{-3} mPa @ 20ºC. Therefore, the active substances within this product are unlikely to present a significant risk and no further evaluation is considered necessary.

a2)Adult – professional sanding of treated wood

The exposure of workers using UC3 and UC4 treated wood in the construction industry is likely to involve sawing and sanding, which need to be considered as part of the risk assessment for Tanalith E 3462. In addition to the maximum 'normal use' UC4 retention rate of 2.5 kg Cu/m^3, the 'niche use' retention rate of 4 kg Cu/m^3 has been used as part of this assessment in order to estimate the potential exposure to professionals installing transmission poles. This is likely to involve drilling of the transmission poles for the attachment of kingbolts, or mounting brackets. However, it should be noted that the transmission pole will not be sanded under normal use and so the following exposure estimations should be taken to represent an unrealistic and worst-case scenario.

The refined short-term non-professional sanding scenario Tier 2 approach has been extrapolated to the long-term situation by assuming that the exposure time is 6 hours per day. The model exposure data used in these calculations are derived from exposure studies on non-professionals where no gloves were worn. Therefore, the following calculated dermal exposure levels for professionals are an over estimate, as professionals would usually wear gloves.

Inhalation route

Wood dust per day inhaled will be 5 mg/m^3 x 1.25 m^3/h x 6 hours = 37.5 mg

Volume of wood in 37.5 mg wood dust (i.e. 0.0375 g) (with density 0.4 g/cm^3: MOTA decided at TMIII08) is equivalent to 0.0375 ÷ 0.4 = 0.0938 cm³.

Active substance available in wood dust for both the normal use as the nich use for UC4 is calculated for professional sanding;

UC4 - normal use

- 0.0938 cm³ wood contain (2.5 mg a.s./cm³ × 0.0938 cm³) = **0.2345 mg copper**
- 0.0938 cm³ wood contain (0.05 mg a.s./cm³ × 0.0938 cm³) = **0.0047 mg propiconazole**
- 0.0938 cm³ wood contain (0.05 mg a.s./cm³ × 0.0938 cm³) = **0.0047 mg tebuconazole**

UC4 - niche use

- 0.0938 cm³ wood contain (4 mg a.s./cm^3 × 0.0938 cm³) = **0.375 mg copper**
- 0.0938 cm³ wood contain (0.08 mg a.s./cm³× 0.0938 cm³) = **0.0075 mg propiconazole**
- 0.0938 cm³ wood contain (0.08 mg a.s./cm³ × 0.0938 cm³) = **0.0075 mg tebuconazole**

Dermal exposure (hands – no gloves worn)

The surface area of both palms of hands is 420 cm² and during prolonged and repeated contact 20 % of the hand is contaminated (see acute scenario and User Guidance, p. 52). The dermal uptake is 5 % for copper, 2.4 % for propiconazole and 75 % for tebuconazole. As for the acute scenario, the transfer efficiency from sawn timber has been assumed to be 2 % as given by the TNsG.

UC4 - normal use
The copper, propiconazole and tebuconazole concentration on the surface of timber has been taken to be 2.5, 0.05 and 0.05 mg a.s./cm^2

Copper
2.5 mg a.s./cm^2 × 420 cm^2 × 0.2 × 0.02 = 4.2 mg copper on hands
Systemic Exposure = 4.2 mg x 0.05 (dermal uptake) = 0.21 mg copper (0.0035 mg kg bw/day)

Propiconazole
0.05 mg a.s./cm^2 × 420 cm^2 × 0.2 × 0.02 = 0.084 mg propiconazole on hands
Systemic Exposure = 0.084 mg x 0.024 (dermal uptake) = 0.002016 mg propiconazole (0.0000336 mg/kg bw/day)

Tebuconazole
0.05 mg a.s./cm^2 × 420 cm^2× 0.2 × 0.02 = 0.084 mg tebuconazole on hands
Systemic Exposure = 0.084 mg x 0.75 (dermal uptake) = 0.063 mg tebuconazole (0.00105 mg/kg bw/day)

UC4 - niche use
The copper, propiconazole and tebuconazole concentration on the surface of timber has been taken to be 4, 0.08 and 0.08 mg a.s./cm^2 respectively.

Copper
4 mg a.s./cm^2 × 420 cm^2× 0.2 × 0.02 = 6.72 mg copper on hands
Systemic Exposure = 6.72 mg x 0.05 (dermal uptake) = 0.336 mg copper (0.0056 mg/kg bw/day)

Propiconazole
0.08 mg a.s./cm^2 × 420 cm^2× 0.2 × 0.02 = 0.1344 mg propiconazole on hands
Systemic Exposure = 0.1344 mg x 0.024 (dermal uptake) = 0.0032 mg propiconazole (0.000053 mg/kg bw/day)

Tebuconazole
0.08 mg a.s./cm^2 × 420 cm^2× 0.2 × 0.02 = 0.1334 mg tebuconazole on hands
Systemic Exposure = 0.1334 mg x 0.75 (dermal uptake) = 0.100 mg tebuconazole (0.0017 mg/kg bw/day)

Total systemic dose (= Inhalation dose + Dermal dose)

UC4 - normal use
Copper [5 %]
= 0.2345 + 0.21 = 0.4444 mg a.s
= 0.0074 mg a.s./kg bw per day

Propiconazole
= 0.0047 + 0.002016 = 0.0067 mg a.s
= 0.00011 mg a.s./kg bw per day

Tebuconazole
= 0.0047 + 0.063 = 0.068 mg a.s
= 0.0011 mg a.s./kg bw per day

UC4 - niche use
Copper [5 %]
= 0.375 + 0.336 = 0.711 mg a.s
= 0.0118 mg a.s./kg bw per day

Propiconazole
= 0.0075 + 0.0032 = 0.0107 mg a.s
= 0.000178 mg a.s./kg bw per day

Tebuconazole
= 0.0075 + 0.100 = 0.1075 mg a.s
= 0.00179 mg a.s./kg bw per day

Table 4: Description of the model calculation and the exposure outputs or calculations of the secondary chronic exposure of children - Chronic playing on preserved timber playground equipment

b) Child - playing on playground structure outdoors with prolonged and repeated contact of wood with hands (no oral exposure is predicted).
TNsG assumption (reference scenarios User Guidance, p. 53):
Active substance residue on surface
UC4 product data = 2.5 mg Cu/cm^2, 0.05 mg propiconazole/cm^2 and 0.05 mg tebuconazole/cm^2
Hand surface area = 200 cm^2
Assume 20 % of hand (40 cm^2) has been contaminated and 2 % dislodgeable transfer efficiency has been taken from the TNsG (part 2, page 204).
Body weight 15 kg
The dermal uptake is 5 % for copper, 2.4 % for propiconazole and 75 % for tebuconazole.

Dermal exposure
Copper
2.5 mg a.s./cm^2 × 200 cm^2 × 0.2 × 0.02 = 2 mg copper on hands
Systemic Exposure = 2 mg × 0.05 (dermal uptake) = 0.1 mg copper
Systemic dose = 0.0067 mg/kg bw/d (15 kg child)

Propiconazole
0.05 mg a.s./cm^2 × 200 cm^2 × 0.2 × 0.02 = 0.04 mg propiconazole on hands
Systemic Exposure = 0.04 mg × 0.024 (dermal uptake) = 0.00096 mg propiconazole
Systemic dose = 0.000064 mg/kg bw/d (15 kg child)

Tebuconazole
0.05 mg a.s./cm^2 × 200 cm^2× 0.2 × 0.02 = 0.04 mg tebuconazole on hands
Systemic Exposure = 0.04 mg × 0.75 (dermal uptake) = 0.03 mg tebuconazole
Systemic dose = 0.002 mg/kg bw/d (15 kg child)

Table 5: Description of the model calculation and the exposure outputs or calculations of the secondary acute exposure of infants - Chronic playing on preserved timber playground equipment and mouth contacts with the treated timber surface

c) Infants - playing on (weathered) playground structure and mouthing - dermal and ingestion exposure

TNsG assumption (reference scenarios User Guidance, p. 53):

<u>Active substance residue on surface</u>

UC4 product data = 2.5 mg Cu/cm^2, 0.05 mg propiconazole/cm^2 and 0.05 mg tebuconazole/cm^2

Body weight = 10 kg

Hand surface area = 200 cm^2

Assume 20 % of hand (40 cm^2) has been contaminated and 2 % using the dislodgeable transfer efficiency has been taken from the TNsG (part 2, page 204).

The dermal uptake has been assumed to be 5 % for copper, 2.4 % for propiconazole and 75 % for tebuconazole.

<u>Dermal exposure</u>

Copper

2.5 mg/cm^2 × 200 cm^2× 0.2 × 0.02 = 2 mg copper on hands

Systemic Exposure = 2 mg x 0.05 (dermal uptake) = 0.1 mg copper

Propiconazole

0.05 mg/cm^2 × 200 cm^2 × 0.2 × 0.02 = 0.04 mg propiconazole on hands

Systemic Exposure = 0.04 mg x 0.024 (dermal uptake) = 0.00096 mg propiconazole

Tebuconazole

0.05 mg/cm^2 × 200 cm^2 × 0.2 × 0.02 = 0.04 mg tebuconazole on hands

Systemic Exposure = 0.04 mg x 0.75 (dermal uptake) = 0.03 mg tebuconazole

<u>Oral routes</u>

According to the TNsG, the expected route of oral exposure is as a direct result of the infant mouthing the wood. Ingestion of surface deposit on 5 x 10 cm^2 of wood has been considered in line with TNGs reference scenario in User Guidance.

Product data: Assumes a dislodgeable transfer rate of 2 % except for copper where a dislodgeable copper concentration of 2 µg/cm^2 (as agreed for copper in the WPCTF dossier and used for acute ingestion by infant) has been applied

The oral absorption has been assumed to be 36 % for copper and 100 % for both propiconazole and tebuconazole.

Active substance ingested = Surface retention × area of wood × % dislodgeable transfer rate

Copper

0.002 mg/cm^2 × 50 cm^2 × 1 = 0.1 mg copper ingested

Systemic Exposure = 0.1 × 0.36 (oral absorption) = 0.036 mg copper

Propiconazole

0.05 mg/cm^2 × 50 cm^2 × 0.02 = 0.05 mg propiconazole ingested

Systemic Exposure = 0.05 mg × 1 = 0.05 mg propiconazole

Tebuconazole

0.05 mg/cm^2 × 50 cm^2 × 0.02 = 0.05 mg tebuconazole ingested

Systemic Exposure = 0.05 mg × 1 = 0.05 mg tebuconazole

<u>Total systemic dose</u> (= Dermal dose + ingestion / 10 kg)

Copper (5 %)
= 0.1 + 0.036 = 0.136 mg a.s
= 0.0136 mg a.s./kg bw per event

Copper (0.5 %)
= 0.01 + 0.036 = 0.046 mg a.s
= 0.0046 mg a.s./kg bw per event

Propiconazole
= 0.00096 + 0.05 = 0.051 mg a.s
= 0.0051 mg a.s./kg bw per event

Tebuconazole
= 0.03 + 0.05 = 0.08 mg a.s
= 0.008 mg a.s./kg bw per event

Conclusion:
Exposure of (non-)professionals and the general public to the biocidal product containing copper (II)carbonatehydroxide, propiconazole and tebuconazole as active substances is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

Annex 7: Residue behaviour

Active Substances: copper(II)carbonatehydroxide, propiconazole and tebuconazole

Date: 23.06-2014

Table 1: Description of the model calculation and the exposure outputs or calculations

Tier 1: Product uptake of 50 l/m^3 [Guidance]
(50 l/m^3) x (% w/w) x 1000 gives;
Copper - 187.50 g/m^3
Propiconazole - 3.75 g/m^3
Tebuconazole - 3.75 g/m^3
Thichness of surface layer of the wooden wall representing the amount of substance per square meter = 0.05 mm.

The amounts of a.s. in the outer 1 cm layer of wood (mg a.s./m^2) are then calculated from;
(g/m^3) x (5 x 10^{-5} m depth) x 1000 gives;
Copper - 9.38 mg/m^2
Propiconazole - 0.188 mg/m^2
Tebuconazole - 0.188 mg/m^2

Tier 2: Product uptake of 200 l/m^3 [Tanalith E 3462 actual value]
(200 l/m^3) x (% w/w) x 1000 gives;
Copper – 750 g/m^3
Propiconazole – 15 g/m^3
Tebuconazole – 15 g/m^3

The amounts of a.s. in the outer 1 cm layer of wood (mg a.s./m^2) are then calculated from;
(g/m^3) x (5 x 10^{-5} m depth) x 1000 gives;
Copper – 37.5 mg/m^2
Propiconazole – 0.75 mg/m^2
Tebuconazole – 0.75 mg/m^2

Total exposure
Oral exposure (mg a.s./kg bw)
Calculated from;
Chewing = (Conc. of a.s. per m^3) x (daily wood consumption in m^3)/body weight
Licking = (Conc. of a.s. per m^2) x (tongue surface area m^2 x licks per day)/body weight
See Table2 and 3.
These values are very much worst-case as they assume that wood is ingested and 100 % is removed from the wood. For copper the absorption has been assumed to be 25 % (copper oral absorption in animals), whereas 100 % has been assumed for both propiconazole and tebuconazole.

Dermal exposure (mg a.s./kg bw)
See table 2 and 3.
Calculated from;
(amount of a.s. per m^2) x (body surface area in contact)/body weight
In the guidance, no consideration of % adsorption has been given with 100 % absorption assumed as a worst-case. However, since animals have fur/wool/hair this can be considered unrealistic. Therefore, in the absence of specific data the absorption levels previously used for humans have been introduced (copper 0.5 %, propiconazole 2.4 % and

tebuconazole 75 %).
Currently there is no agreed approach for reading across from the available mammalian studies to companion or livestock animals, therefore a trigger value of 0.004 mg/kg bw has been agreed. Where exposures are shown to exceed this additional data may be required. The resulting predicted data for oral, dermal and total exposures predicted resulting from animals chewing or licking wood have been summarised in tables below. Where the trigger value is exceeded the data are shown in bold.

Table 2: Summary of the exposure data resulting from dermal exposure in addition to chewing or licking treated wood (mg a.s./kg bw) @ product uptake of 50 l/m^3 [Tier 1]

Animal	Oral exposure	Dermal	Total
Copper			
Horse [chew]	0.0022	0.00019	0.0024
Beef cattle [chew]	0.0022	0.00014	0.0023
Dairy cattle [chew]	0.0022	0.00012	0.0023
Calf [chew]	0.0022	0.0002	0.0024
Calf [lick]	0.0009	0.0002	0.001
Fattening pig [chew]	0.0022	0.00021	0.0024
Fattening pig [lick]	0.0019	0.00021	0.0021
Breeding pig [chew]	0.0022	0.00015	0.0023
Breeding pig [lick]	0.0007	0.00015	0.0009
Sheep [chew]	0.0022	0.00028	0.0025
Lamb [chew]	0.0022	0.00035	0.0025
Slaughter goat [chew]	0.0022	0.00054	0.0027
Lactating goat [chew]	0.0022	0.0003	0.0025
Propiconazole			
Horse [chew]	0.00017	0.00002	0.0002
Beef cattle [chew]	0.00017	0.00001	0.0002
Dairy cattle [chew]	0.00017	0.00001	0.0002
Calf [chew]	0.00017	0.00002	0.0002
Calf [lick]	0.00008	0.00002	0.0001
Fattening pig [chew]	0.00017	0.00002	0.0002
Fattening pig [lick]	0.00015	0.00002	0.0002
Breeding pig [chew]	0.00017	0.00001	0.0002
Breeding pig [lick]	0.00006	0.00001	0.00007
Sheep [chew]	0.00017	0.00003	0.0002
Lamb [chew]	0.00017	0.00003	0.0002
Slaughter goat [chew]	0.00017	0.00005	0.0002
Lactating goat [chew]	0.00017	0.00003	0.0002
Tebuconazole			
Horse [chew]	0.00017	0.00057	0.0007
Beef cattle [chew]	0.00017	0.00041	0.0006
Dairy cattle [chew]	0.00017	0.00036	0.0005
Calf [chew]	0.00017	0.00061	0.0008
Calf [lick]	0.00008	0.00061	0.0007
Fattening pig [chew]	0.00017	0.00063	0.0008
Fattening pig [lick]	0.00015	0.00063	0.0008
Breeding pig [chew]	0.00017	0.00045	0.0006
Breeding pig [lick]	0.00006	0.00045	0.0005
Sheep [chew]	0.00017	0.00084	0.001

Animal	Oral exposure	Dermal	Total
Lamb [chew]	0.00017	0.0011	0.001
Slaughter goat [chew]	0.00017	0.0016	0.002
Lactating goat [chew]	0.00017	0.0009	0.001

Table 3: Summary of the exposure data resulting from dermal exposure in addition to chewing or licking treated wood (mg a.s./kg bw) @ product uptake of 200 l/m^3 [Tier 2]

Animal	Oral exposure	Dermal	Total
Copper			
Horse [chew]	**0.0085**	0.00075	**0.00925**
Beef cattle [chew]	**0.0085**	0.00055	**0.00905**
Dairy cattle [chew]	**0.0085**	0.0005	**0.009**
Calf [chew]	**0.0085**	0.0008	**0.0093**
Calf [lick]	0.00375	0.0008	**0.00455**
Fattening pig [chew]	**0.0085**	0.00085	**0.00935**
Fattening pig [lick]	**0.0075**	0.00085	**0.00835**
Breeding pig [chew]	**0.0085**	0.0006	**0.0091**
Breeding pig [lick]	0.0029	0.0006	0.0035
Sheep [chew]	**0.0085**	0.00115	**0.00965**
Lamb [chew]	**0.0085**	0.00115	**0.00965**
Slaughter goat [chew]	**0.0085**	0.00215	**0.01065**
Lactating goat [chew]	**0.0085**	0.0012	**0.0097**
Propiconazole			
Horse [chew]	0.0007	0.000075	0.000775
Beef cattle [chew]	0.0007	0.00005	0.00075
Dairy cattle [chew]	0.0007	0.000045	0.000745
Calf [chew]	0.0007	0.00008	0.00078
Calf [lick]	0.0003	0.00008	0.00038
Fattening pig [chew]	0.0007	0.00008	0.00078
Fattening pig [lick]	0.0006	0.00008	0.00068
Breeding pig [chew]	0.0007	0.00006	0.00076
Breeding pig [lick]	0.00025	0.00006	0.00031
Sheep [chew]	0.0007	0.00011	0.00081
Lamb [chew]	0.0007	0.000135	0.000835
Slaughter goat [chew]	0.0007	0.00021	0.00091
Lactating goat [chew]	0.0007	0.000115	0.000815
Tebuconazole			
Horse [chew]	0.0007	0.0023	0.003
Beef cattle [chew]	0.0007	0.0016	0.0023
Dairy cattle [chew]	0.0007	0.00145	0.00215
Calf [chew]	0.0007	0.00245	0.00315
Calf [lick]	0.0003	0.00245	0.00275
Fattening pig [chew]	0.0007	0.00255	0.00325
Fattening pig [lick]	0.0006	0.00255	0.00315
Breeding pig [chew]	0.0007	0.0018	0.0025
Breeding pig [lick]	0.00023	0.0018	0.00203
Sheep [chew]	0.0007	0.0034	**0.0041**
Lamb [chew]	0.0007	0.0042	**0.0049**
Slaughter goat [chew]	0.0007	0.0065	**0.0072**
Lactating goat [chew]	0.0007	0.0036	**0.0043**

SECTION B7 – ECOTOXICOLOGICAL DATA FOR THE BIOCIDAL PRODUCT

Section B7.1: Foreseeable routes of entry into the environment on the basis of the use envisaged

Section B7.1-1 Annex Point IIB, IVB7.1	Foreseeable routes of entry into the environment on the basis of the use envisaged	
		Official use only
	1 Reference	
1.1 Reference	IVB7_1_3	
1.2 Data protection	Yes	
1.2.1 Data owner	Arch Timber Protection (part of Lonza)	
1.2.2		
1.2.3 Criteria for data protection	Data on new b.p. for authorisation	
	2 Guidelines and Quality Assurance	
2.1 Guideline study	Yes The overall design of the test was derived from the NT Method NT Build 509.	
2.2 GLP	No	
2.3 Deviations	Yes The test was designed following the principles of NT Method NT Build 509. However, the method was not followed in full details it deviated from the method in the following respects: 40 Duplicate and not triplicate replicas of the panels were used. Previous work by Arch had found that there was good agreement between pairs of panels and it was judged sufficient to set up two panels for each test. (ii) The wood boards were cut oversize, end-sealed and then treated. The boards were then cut to size and the cut end was not re-end-sealed. NT Build 509 specifies wood is treated with one end free of end-seal. The effect of this is expected to be minor, as there is still a cut end wood end open to leaching on each board when exposed. (iii) The wood boards were commercially sourced to be representative of commercially used timber. Boards were chosen to maximise sapwood and minimise knots. It was not possible to source full sapwood boards. Each board had three faces comprised of sapwood, this ensure that the faces open to leaching were full sapwood. NT 509 specifies all sapwood boards. The effect of this is expected to be minor as any heartwood portions face away from the weather and are completely shielded by the panel mounting apparatus. (iv) The density of the wood boards varied more than specified in the NT Method. This was due to sourcing the boards commercially. This variation is not expected to be significant as the dominating factor in leaching will be the retention of the	

preservative.

The effect of (iii) and (iv) is to make the leaching from the wood more reflective of the actual leaching from commercially sourced pine sapwood.

(v) The leachates were chemically analysed each time a sufficient amount for analysis had accrued. NT 509 specifies that a planned time schedule is adopted. There will be no effect on the overall results due to this change. The method followed here obviates the need for longer term storage of leachates and ensure they are analysed in as fresh as state as possible.

(vi) The untreated wood panels were not set up to run concurrently with the test as specified in NT 509. Two untreated wood horizontal panels were set up in apparatus made of the same material as the vertical apparatus and monitored prior to this test starting. These panels confirmed that over an extended period there were no appreciable concentrations of biocides in the leachates.

(vii) The design of the collection apparatus was optimised compared to NT509. Detailed drawings of the panels are shown in Appendix 1; the leachate is collected in a 'funnel' design rather than from the end of collection gutter 'run'. This removes potential dead space at the end of the gutter run.

3 Materials and Methods

3.1 Test material Tanalith E 3462

3.1.1 Lot/Batch number Not reported

3.1.2 Specification Not reported

3.1.3 Purity Not reported

3.1.4 Stability Not reported

3.1.5. Composition of Product

Active substance	Concentration %	
	Concentrate	Treatment Solution
Copper	9.01	0.244
Tebuconazole	0.17	0.0047
Propiconazole	0.16	0.0042

3.2 Testing procedure

3.2.1 Timber

The timber boards used to make the panels were commercially sourced rough sawn Pinus Sylvestris, dimension 760 mm x 100 mm x 25 mm. Seven boards were used on each panel. The wood was chosen to maximise the amount of sapwood in each board and minimise the number of knots. Each board had at least one large face and both side faces made entirely of sapwood. This was to ensure that the surfaces directly exposed to rainfall and sunlight consisted entirely of sapwood.

The average oven dry density of the boards was 455 kg m^{-3} (see appendix 3). Each board was marked and coded according to the original piece of wood it derived from. Each panel was made up from boards from different pieces of wood; the pieces were chosen to give the same approximate preservative retention for each panel.

3.2.2 Test method

Treatment of Test Boards

The preservative was used at a concentration of 2.7% mass/mass to give a target retention of copper in the sapwood of 1.4 kg m^{-3}. The treatment solution was made up from concentrate prepared in the laboratory.

The boards were treated in the following cycle:
Initial vacuum: 600 mm Hg 45 minutes
Pressure : 12 kg cm^{-2} 1 hour
Final vacuum: 600 mm Hg 20 minutes

The boards were end-sealed at both ends and over-size (785 mm x 100 mm x 25 mm) at the time of treatment. Before being exposed the boards were cut to size (760 mm x 100 mm x 25 mm) and the cut end was not re-end-sealed. This ensured that there was a proportion of end-grain open to leaching and models the presence of end-grain in cladding in use.

After the treatment the boards were dried for 1 month.

Selection of Test Specimens

Fourteen boards were treated. Each board was weighed before and after treatment. This allowed uptake of product to be measured. An estimate was made of the proportion of sapwood in each board. Boards were assigned to one of the two panels in order to ensure panels made up of boards from a variety of source pieces of wood and of the same approximate overall preservative retention.

The data on the uptake of the individual boards are shown in Table B7.1.1-1. The average retention data for each panel are shown in Table B7.1.1-2.

The wood panels were mounted over stainless steel leachate collection devices. These allow the water run-off from the panels to be collected, the volume recorded and the concentration analysed. The devices were essentially large stainless steel funnels that direct run-off in to water kegs. The devices were constructed to prevent rain hitting the panels from the rear. The panels were positioned facing approximately south-west which is the direction from which the prevailing winds blow. The devices and mounted panels in use are shown in Figure B7.1.1-1.

A complete suite of environmental parameters were recorded on-site by a Davis Instruments VantagePro wireless weather station. The output was recorded by a data logger and downloaded and analysed by the Weatherlink software package. The suite of parameters includes rainfall, wind (direction and strength), and ultra-violet radiation intensity.

An initial test was set up with untreated Scots pine wood panels mounted over apparatus made of the same material as the vertical collection apparatus. The leachates were collected and analysed to confirm background levels of active substances.

After drying, the boards were mounted over the leachate collectors using specially designed stainless steel clips fixed to the rear of the boards. The total surface area exposed to rain was taken as 0.8155 m2 for each panel. This assumes there was leaching from the main broad outward facing side and the two long narrow sides. The rear face of the wood was not directly exposed to the weather and was not expected to be wetted.

The panels were exposed to the weather and not disturbed further. The leachate was collected in plastic kegs underneath the collection devices. Leachate was collected after every major rain event. If there was less than 1 L of leachate, the sample was stored in the dark in a fridge at 5°C.

The date and time of each leachate sample extracted was noted. The weather data were then analysed to determine the amount of rain falling during the sampling period. This allows results to be standardised in terms of active lost per mm rain over the sampling period. The results from the replicate panels were averaged to obtain an overall result.

The resulting extracts are analysed using HPLC with UV detection using Arch method HT10-53. The leachates from 166 days (275 mm rain) onwards were analysed using GC with an NP detector due to the lower concentration in these samples.

Separate samples of leachate water were sent to external laboratories for copper analysis by ICP.

Table B7.1.1-3a and Table B7.1.1-3b show the leachate data for panels A and B respectively. Table B7.1.1-4a and Table B7.1.1-4b show the analysis data from the methanol extracts of leachates and copper analysis.

3.2.3 Calculations

Short-term leach rates are simply calculated from the leachate divided by time of exposure. For the longer term leach rates the data required some analysis and extrapolation before leaching rates suitable for risk assessments could be derived. The two year results were extrapolated using two methods:

1) Take the sampling date nearest to two years and extrapolate the figures to calculate the projected leaching at 1440 mm rain. The time point nearest to two calendar years was 719 days, 1172.4 mm rain. The emission data are extrapolated assuming active substances leach at the rate determined over the next sampling point (719 – 761 days).

2) Take the sampling date nearest to 1440 mm rain and extrapolate figures to the exact 1440mm value. There was a sampling point at 1441mm total rainfall so this was used without

any interpolation.

In each case (1) and (2) the cumulative leaching flux was divided by the relevant number of days to get a daily leaching rate.
The two different methods adopted for extrapolation give very similar results. This indicates there is a robustness to the data as they were not particularly sensitive to the extrapolation method used to derive leaching rates.

4 Results

4.1 Results of test

The results are presented over calendar years and over standard rain years (720 mm rain, in 365 days). The variability with time is of secondary interest due to the natural variability of rainfall. The results that give greater insight in to the leaching are expressed in losses per mm rain incident on the panels for the standard rain year.

Background levels of active substances were confirmed to be zero (azoles) or very small (copper) (mean 0.001 and 0.006 mg/l for panels A and B respectively; n =26). No adjustment was been made in the test results for these intermittent small results. The effect would be negligible.

See Table B7.1.1-3 to B7.1.1-10 and Figure B7.1.1- 2 to B7.1.1-10.

Year 1 Results

The time point nearest to a calendar year was 373 days, 647.6 mm rain. Since this was very close to 365 days and the temporal variation is of secondary importance in determining leaching no interpolation was carried out.

The losses for the standard rain year are estimated by finding the actual rainfall amount less than but nearest to the standard 30 day figure (59.18 mm) or standard 1 year figure (720 mm). The samples used for interpolation were:

Sample 1: 78.8 mm rain to get 30 days standard rain year

(NB there was no sampling point less than 59.18 mm due to weather conditions after exposure)

Sample 13: 699.4 mm rain to get 720 mm standard rain year

Sample 14: 746 mm rain

The plots of active substance lost per mm of rainfall show some scatter. The scatter was most pronounced for the copper leaching. This is due to the effect of wind direction. The amount of rain incident on a vertical panel was critically dependant on wind direction. The same absolute rainfall can produce vastly differing amounts of leachate (hence leaching) if the wind is in opposite directions. In the case of the panels facing approximately west, an easterly wind during rainfall produces very little leachate. This indicates that times of the order of 1 year are the appropriate timescale over which reliable information can be extracted from this test; this timescale allows for the full range of ambient weather conditions, wind directions, rainfall amounts and types etc.

The leachates were analysed more frequently in this study than suggested in NT509, which added to the apparent scatter in the flux rate results. However, there was no effect on the average leach rates calculated over extended periods due to this more frequent analysis.

Tebuconazole	**Average Total Flux mg m^{-2}**	**Average Flux Rate mg m^{-2} day^{-1}**
Calendar year	2.11	-
Standard Rain year		
0 – 59.18 mm (0 – 30 days)	0.47	0.016
59.18 – 720 mm (30 – 365 days)	1.69	0.005

Propiconazole	**Average Total Flux mg m^{-2}**	**Average Flux Rate mg m^{-2} day^{-1}**
Calendar year	2.24	-
Standard Rain year		
0 – 59.18 mm (0 – 30 days)	0.53	0.018
59.18 – 720 mm (30 – 365 days)	1.75	0.005

Copper	**Average Total Flux mg m^{-2}**	**Average Flux Rate mg m^{-2} day^{-1}**
Calendar year	334.58	-
Standard Rain year		
0 – 59.18 mm (0 – 30 days)	34.88	1.16
59.18 – 720 mm (30 – 365	319.70	0.95

days)		

Year 2 Results

After two years of the test the actual rainfall amount (1172.4 mm) had diverged markedly from the standard rain year amount (1440 mm) due to natural weather conditions.

The calculated leach rates showed a decrease in the leaching rate from the year 1 result confirming that a steadily reducing leaching rate can be expected over the life of the wood.

Leaching between year 1 and 2:

Active substance	**Extrapolation method**	**Total Flux** mg m^{-2}	**Average Daily Flux** mg $m^{-2}day^{-1}$
Tebuconazole	1	0.41	0.0011
	2	0.37	0.0010
Propiconazole	1	0.25	0.0007
	2	0.24	0.0006
Copper	1	233.03	0.64
	2	182.56	0.50

0 – 2 Year Leaching Rates

Active substance	**Average Daily Flux** mg $m^{-2}day^{-1}$	
	Method (1)	Method (2)
Tebuconazole	0.0031	0.0030
Propiconazole	0.0029	0.0028
Copper	0.8	0.73

Due to the method of calculation used, the above data are greater than the 1 – 2 year flux rate calculated in the previous section.

4.1.1 Leach rate for risk assessment

For risk assessments the 1 – 2 year leaching rates can be assumed to persist in to the future. This would give a worst case assessment as, in reality, the leaching rates would continue to decrease. However, treating the whole span of the test as one time period and using this to derive rates give slightly higher figures. If a precautionary approach is considered to be more suitable the 30 day – 2 years rates are higher than the 1 – 2 year rates and would be suitable for use in this case.

Results summary:

Retention rates		
kg/m^2	**Intended**	**Actual (test)**
Copper	1.4	1.43
Tebuconazole	0.028	0.028

Propiconzole	0.028	0.028
Leached over time		
mg/m²	**T1 – 30 d**	**T2 – 2 yrs**
Copper	34.8	5840
Tebuconazole	0.48	22.63
Propiconzole	0.54	21.17
Daily leach rate		
mg/m²/day	**T1 – 30 d**	**T2 > 2 yrs**
Copper	1.16	0.8
Tebuconazole	0.016	0.0031
Propiconzole	0.018	0.0029

5 Applicant's Summary and conclusion

5.1 Materials and methods

Timber treated with Tanalith E (3462) to a loading of 1.43 kg m^{-3} copper in sapwood was mounted vertically over a leachate collection system. After each significant rain event the leachate was collected and stored. Once sufficient quantity was collected (> 1l) the leachate was analysed for copper, tebuconazole and propiconazole content. This allows a determination of the flux rate of the active substances over the course of the test.

The initial use of untreated wood panels allowed a monitoring of background levels of biocides. There were none recorded.

5.2 Results and discussion

After the first calendar year (373 days, 647.6 mm rain) the cumulative fluxes are: tebuconazole 2.11 mg m^{-2}; propiconazole 2.24 mg m^{-2}; copper 334.58 m gm^{-2}.

Standardised losses for a standard rain year (720 mm rain, 365 days) are:

Active substance	**Total Flux**	**Average Daily Flux**
	mg m⁻²	**mg m⁻² day⁻¹**
0 – 30 days		
Copper	34.88	1.16
Propiconazole	0.53	0.018
Tebuconazole	0.47	0.016
30 days – 1 year		
Copper	319.70	0.95
Propiconazole	1.75	0.005
Tebuconazole	1.69	0.005

Standardised losses over the second standard rain year can be calculated in two ways:
1) Take the sampling date nearest to two years and extrapolate the figures to calculate the projected leaching at 1440 mm rain.
2) Take the sampling date nearest to 1440 mm rain and

extrapolate figures to the exact 1440mm value.

Results for method (1)

Active substance	**Total Flux**	**Average Daily Flux**
	mg m^{-2}	**mg m^{-2} day^{-1}**
1 year – 2 years		
Copper	233.03	0.64
Propiconazole	0.25	0.0007
Tebuconazole	0.41	0.0011

Results for method (2)

Active substance	**Total Flux**	**Average Daily Flux**
	mg m^{-2}	**mg m^{-2} day^{-1}**
1 year – 2 years		
Copper	182.56	0.50
Propiconazole	0.24	0.0006
Tebuconazole	0.37	0.0010

These two methods show good agreement for the azole leaching and some difference for the copper leaching. Overall, the agreement indicates a robustness to the data. The leaching rates over the second year show considerable decrease compared to the first year data.

The leaching rates over the second year can be taken as input data for Environmental Scenario Documents. These can be taken as persisting in to the future to provide longer term rates. Alternatively leaching rates can be derived using the cumulative leaching over the first two years. This provides long term leaching rates that are higher and provides a *worst case* set of figures.

Rates derived using method (1)

Active substance	**Average Daily Flux**
	mg m^{-2} day^{-1}
30 days – 2 years	
Tebuconazole	0.0031
Propiconazole	0.0029
Copper	0.8

Rates derived using method (2)

Active substance	**Average Daily Flux**
	mg m^{-2} day^{-1}
30 days – 2 years	
Tebuconazole	0.0030
Propiconazole	0.0028
Copper	0.73

5.3 Conclusion

The semi-field test assembly is able to deliver consistent leaching data. There is good agreement between the two replicate panels indicating consistency.

The data requires some analysis and extrapolation before leaching rates suitable for risk assessments can be derived. The two different methods adopted for extrapolation give very similar results. This indicates there is a robustness to the data in that it is not particularly sensitive to the extrapolation method used to derive leaching rates.

For risk assessments the 1 – 2 year leaching rates can be assumed to persist in to the future. This would give a worst case assessment as, in reality, the leaching rates would continue to decrease. However, treating the whole span of the test as one time period and using this to derive rates give slightly higher figures. If a precautionary approach is considered to be more suitable the 30 day – 2 years rates are higher than the 1 – 2 year rates and would be suitable for use in this case.

5.3.1 Reliability

5.3.2 Deficiencies — No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*09-08- 2014*
Materials and Methods	*Applicant's version is acceptable*
Results and discussion	*Applicant's version is acceptable*
Conclusion	*Daily leaching rates to be used for risk assessment purpose according to method 1:*

Daily leach rate		
mg/m²/day	**T1 – 30 d**	**T2 > 2 yrs**
Copper	1.16	0.8
Tebuconazole	0.016	0.0031
Propiconzole	0.018	0.0029

Reliability	*1*
Acceptability	*Acceptable*
Remarks	*No data on the Quality Assurance (QA) standard of the testing laboratory at the testing time. According to TNsG on data requirements (p. 142) exposure studies (e.g. leaching study) should be done to suitable QA standards.*
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*

Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table B7.1.1-1: Retention Data and Panels Assigned

Board	Mass before treatment (g)	Mass post treatment (g)	Mass uptake (g)	Estimate fraction sapwood	Solution uptake whole wood (kgm^{-3})	Product uptake Whole wood (kgm^{-3})	Solution uptake sapwood (kgm^{-3})	Product uptake sapwood (kgm^{-3})	Panel assigned
VT2-2	1124.75	2086.1	961.35	1	489.86	13.23	489.86	13.23	A
VT2-3	1171.4	2050.8	879.4	1	448.10	12.10	448.10	12.10	B
VT5-1	852.78	2281.65	1428.87	1	728.09	19.66	728.09	19.66	B
VT5-2	841.4	2282	1440.6	1	734.06	19.82	734.06	19.82	A
VT6-2	1003.66	2375.2	1371.54	1	698.87	18.87	698.87	18.87	B
VT6-3	1031.5	2316.93	1285.43	1	655.00	17.68	655.00	17.68	A
VT9-1	978.58	2213.48	1234.9	1	629.25	16.99	629.25	16.99	A
VT9-2	980.18	2180.14	1199.96	1	611.44	16.51	611.44	16.51	B
VT10-1	998.67	1976.58	977.91	1	498.30	13.45	498.30	13.45	B
VT10-2	999.69	1879.26	879.57	1	448.19	12.10	448.19	12.10	A
VT11-1	1064.09	2387.32	1323.23	1	674.26	18.20	674.26	18.20	A
VT11-4	1074.1	2328.59	1254.49	0.95	639.23	17.26	672.87	18.17	B
VT12-1	917.72	1835.69	917.97	0.95	467.76	12.63	492.37	13.29	B
VT12-4	971.92	1820.62	848.7	0.9	432.46	11.68	480.51	12.97	A

Table B7.1.1-2: Overall Retention Data for the Replicate Panels

Active Substance	Panel A average whole wood uptake (kgm^{-3})	Panel A average sapwood uptake (kgm^{-3})	Panel B average whole wood uptake (kgm^{-3})	Panel B average sapwood uptake (kgm^{-3})
Product	15.67	15.86	15.78	16.01
From Formulation				
Tebuconazole	0.028	0.029	0.028	0.029
Propiconazole	0.028	0.029	0.028	0.029
Copper	1.41	1.43	1.42	1.44
By Analysis				
Tebuconazole	0.027	0.028	0.027	0.028
Propiconazole	0.024	0.025	0.024	0.025
Copper	1.41	1.43	1.42	1.44

Table B7.1.1-3A: Leachate Data for Panel A

Sample	Date	Time	Rain (mm)	Cumulative Rain (mm)	Sample (ml)	ml/mm
Exposed	20/06/2007	16:00				
SF92a1	06/07/2007	09:30	78.8	78.8	1729.29	21.95
SF92a2	18/07/2007	11:00	45.2	124	1575	34.85
SF92a3	24/09/2007	13:30	73.6	197.6	2396.12	32.56
SF92a4	03/12/2007	08:55	77.4	275	3514.08	45.40
SF92a5	02/01/2008	10:00	35.8	310.8	2415.86	67.48
SF92a6	10/01/2008	10:10	20.4	331.2	2507.09	122.90
SF92a7	22/01/2008	09:20	68.6	399.8	2460.05	35.86
SF92a8	04/02/2008	09:00	11	410.8	2344.18	213.11
SF92a9	04/03/2008	09:05	20.4	431.2	1868.18	91.58
SF92a10	14/03/2008	08:55	19.6	450.8	2399.75	122.44
SF92a11	09/06/2008	09:45	154.4	605.2	2256.45	14.61
SF92a12	27/06/2008	09:40	42.4	647.6	2599.66	61.31
SF92a13	14/07/2008	09:20	51.8	699.4	2119.52	40.92
SF92a14	04/08/2008	08:40	46.6	746	2668.29	57.26
SF92a15	27/08/2008	08:40	77.4	823.4	1923.9	24.86
SF92a16	01/10/2008	09:30	65	888.4	1496.58	23.02
SF92a17	31/10/2008	09:10	28.2	916.6	1359.76	48.22
SF92a18	21/01/2009	09:50	82.6	999.2	2224.59	26.93
SF92a19	18/05/2009	09:00	136	1135.2	2278.48	16.75
SF92a20	08/06/2009	09:30	37.2	1172.4	720.26	19.36
SF92a21	20/07/2009	10:30	93.2	1265.6	3186.76	34.19
SF92a22	26/08/2009	14:00	56.6	1322.2	2344.5	41.42
SF92a23	07/10/2009	10:00	37.6	1359.8	3567.61	94.88
SF92a24	25/11/2009	12:00	81.2	1441	1739.43	21.42

Table B7.1.1-3B: Leachate Data for Panel B

Sample	Date	Time	Rain (mm)	Cumulative Rain (mm)	Sample (ml)	ml/mm
Exposed	20/06/2007	16:00				
SF92b1	06/07/2007	09:30	78.8	78.8	1451.58	18.42
SF92b2	18/07/2007	11:00	45.2	124	1247.79	27.61
SF92b3	24/09/2007	13:30	73.6	197.6	2147.62	29.18
SF92b4	03/12/2007	08:55	77.4	275	3138.42	40.55
SF92b5	02/01/2008	10:00	35.8	310.8	2196.28	61.35
SF92b6	10/01/2008	10:10	20.4	331.2	2276.62	111.60
SF92b7	22/01/2008	09:20	68.6	399.8	2165.6	31.57
SF92b8	04/02/2008	09:00	11	410.8	2230.32	202.76
SF92b9	04/03/2008	09:05	20.4	431.2	1724.63	84.54
SF92b10	14/03/2008	08:55	19.6	450.8	2249.86	114.79
SF92b11	09/06/2008	09:45	154.4	605.2	1421.59	9.21
SF92b12	27/06/2008	09:40	42.4	647.6	2008.87	47.38
SF92b13	14/07/2008	09:20	51.8	699.4	1238.49	23.91
SF92b14	04/08/2008	08:40	46.6	746	2029.7	43.56
SF92b15	27/08/2008	08:40	77.4	823.4	1719.02	22.21
SF92b16	01/10/2008	09:30	65	888.4	1282.15	19.73
SF92b17	31/10/2008	09:10	28.2	916.6	1204.05	42.70
SF92b18	21/01/2009	09:50	82.6	999.2	2021.07	24.47
SF92b19	18/05/2009	09:00	136	1135.2	1761.8	12.95
SF92b20	08/06/2009	09:30	37.2	1172.4	755.46	20.31
SF92b21	20/07/2009	10:30	93.2	1265.6	2697.8	28.95
SF92b22	26/08/2009	14:00	56.6	1322.2	1741.27	30.76
SF92b23	07/10/2009	10:00	37.6	1359.8	3143.37	83.60
SF92b24	25/11/2009	12:00	81.2	1441	1482.29	18.25

Table B7.1.1-4A: Methanol Extract Data and Sample Concentrations for Panel A Leachates

Sample	Analysis of Methanol Extract				Original Sample Concentrations		
	Mass of Methanol Extract (g)	Tebuconazole ppm	Propiconazole ppm	Mass of Water Extracted(g)	Tebuconazole ppm	Propiconazole ppm	Copper ppm
SF92a1	8.5354	39	41	1026.97	0.3241	0.3408	20.3
SF92a2	8.3313	22	21	1033.27	0.1774	0.1693	7.77
SF92a3	8.0387	11	13	1040.99	0.0849	0.1004	13.6
SF92a4	8.3186	5.49	6.65	1029.88	0.0443	0.0537	9.28
SF92a5	8.2216	6.26	6.12	1044.03	0.0493	0.0482	11.4
SF92a6	8.1873	6.79	6.73	1029.84	0.0540	0.0535	8.27
SF92a7	7.9245	6.9	7.23	1041.3	0.0525	0.0550	12.3
SF92a8	8.2155	4.67	4.29	1044.28	0.0367	0.0338	6.49
SF92a9	8.1645	4.34	4.65	1035.51	0.0342	0.0367	7.24
SF92a10	8.123	4.39	4.3	1032.38	0.0345	0.0338	5.24
SF92a11	8.1897	1.12	1.08	1047.81	0.0088	0.0084	6.57
SF92a12	7.9364	2.74	2.53	1046.16	0.0208	0.0192	8.13
SF92a13	8.1297	1.92	1.56	1036.14	0.0151	0.0122	5.34
SF92a14	8.1163	2.04	1.59	1039.29	0.0159	0.0124	5.63
SF92a15	7.6967	2.29	1.65	1038.57	0.0170	0.0122	7.72
SF92a16	8.1984	1.54	1.14	1038.91	0.0122	0.0090	6.95
SF92a17	8.4444	2.18	1.47	1024.67	0.0180	0.0121	8.66
SF92a18	8.5879	2.24	1.41	1041.89	0.0185	0.0116	6.57
SF92a19	8.0795	1.48	1.18	1029.92	0.0116	0.0092	4.98
SF92a20	8.2293	2.03	1.54	718.36	0.0233	0.0176	4.87
SF92a21	7.3116	2.77	1.48	972.66	0.0208	0.0111	9.48
SF92a22	8.3414	1.45	1.08	1026.13	0.0118	0.0088	4.67
SF92a23	7.8389	0.89	0.54	1005.42	0.0069	0.0042	4.38
SF92a24	7.8999	1.19	0.58	961.15	0.0098	0.0048	8.52

Table B7.1.1-4B: Methanol Extract Data and Sample Concentrations for Panel B Leachates

Sample	Analysis of Extract				Original Sample Concentrations		
	Mass of Methanol Extract (g)	Tebuconazole ppm	Propiconazole ppm	Mass of Water Extracted (g)	Tebuconazole ppm	Propiconazole ppm	Copper ppm
SF92b1	8.4027	36	41	1014.93	0.2952	0.3362	21.9
SF92b2	8.1093	25	22	1029.37	0.1960	0.1725	8.67
SF92b3	8.0177	9	14	1032.16	0.0699	0.1087	14.8
SF92b4	8.2978	4.86	5.88	1034.52	0.0390	0.0472	10.3
SF92b5	8.2018	5.82	5.79	1048.97	0.0460	0.0457	15.3
SF92b6	8.2926	6.67	6.89	1035.35	0.0532	0.0549	12.5
SF92b7	8.3334	6.27	6.36	1034.92	0.0504	0.0512	15.6
SF92b8	8.1494	4.28	3.95	1037.35	0.0335	0.0309	6.92
SF92b9	8.2907	4.57	4.97	1034.67	0.0364	0.0396	7.97
SF92b10	8.2336	4.51	4.48	1033.02	0.0358	0.0356	6.24
SF92b11	8.2528	1.31	1.2	1032.96	0.0104	0.0095	8.39
SF92b12	7.8522	2.69	2.45	1032.43	0.0204	0.0186	9.78
SF92b13	8.1716	1.98	1.6	1028.34	0.0157	0.0127	7.3
SF92b14	8.2121	2.1	1.66	1019.93	0.0166	0.0131	6.25
SF92b15	7.8736	1.66	1.31	1030.15	0.012688	0.010013	9.72
SF92b16	8.3253	1.49	1.1	1035.72	0.011977	0.008842	7.69
SF92b17	8.2299	2.35	1.62	1036.3	0.018663	0.012865	9.59
SF92b18	8.2568	2.2	1.32	1036.96	0.017518	0.010511	7.86
SF92b19	7.9684	1.75	1.30	1003.87	0.013895	0.010317	6.55
SF92b20	8.3945	1.92	1.00	753.33	0.02138	0.011184	5.91
SF92b21	8.0525	2.23	1.10	954.78	0.018833	0.009306	11.2
SF92b22	8.1402	1.99	1.20	905.32	0.017896	0.010769	6.37
SF92b23	7.815	1.00	0.50	1009.26	0.007745	0.003834	5.27
SF92b24	7.8451	1.49	0.75	873.74	0.013349	0.006723	11.00

Table B7.1.1-5A: Tebuconazole Flux Data for Panel A

Sample	No days	Total Rain (mm)	Tebuconazole lost in leachate (mg/m^2)	Cumulative Total Tebuconazole (mg/m^2)	Cumulative loss per mm rain ($mg/m^2/mm$)
	0.00	0	0	0	
SF92a1	15.73	78.8	0.69	0.69	0.009
SF92a2	27.79	124	0.34	1.03	0.008
SF92a3	95.90	197.6	0.25	1.28	0.006
SF92a4	165.70	275	0.19	1.47	0.005
SF92a5	195.75	310.8	0.15	1.62	0.005
SF92a6	203.76	331.2	0.17	1.78	0.005
SF92a7	215.72	399.8	0.16	1.94	0.005
SF92a8	228.71	410.8	0.11	2.05	0.005
SF92a9	257.71	431.2	0.08	2.12	0.005
SF92a10	267.70	450.8	0.10	2.23	0.005
SF92a11	354.74	605.2	0.02	2.25	0.004
SF92a12	372.74	647.6	0.07	2.32	0.004
SF92a13	389.72	699.4	0.04	2.36	0.003
SF92a14	410.69	746	0.05	2.41	0.003
SF92a15	433.69	823.4	0.04	2.45	0.003
SF92a16	468.73	888.4	0.02	2.47	0.003
SF92a17	498.72	916.6	0.03	2.50	0.003
SF92a18	580.74	999.2	0.05	2.55	0.003
SF92a19	697.71	1135.2	0.03	2.58	0.002
SF92a20	718.73	1172.4	0.02	2.60	0.002
SF92a21	760.77	1265.6	0.08	2.69	0.002
SF92a22	797.92	1322.2	0.03	2.72	0.002
SF92a23	839.75	1359.8	0.03	2.75	0.002
SF92a24	888.83	1441	0.02	2.77	0.002

Table B7.1.1-5B: Tebuconazole Flux Data for Panel B

Sample	No days	Total Rain (mm)	Tebuconazole lost in leachate (mg/m^2)	Cumulative Total Tebuconazole (mg/m^2)	Cumulative loss per mm rain (mg/m^2/mm)
	0.00	0	0	0	
SF92b1	15.73	78.8	0.53	0.53	0.007
SF92b2	27.79	124	0.30	0.83	0.007
SF92b3	95.90	197.6	0.18	1.01	0.005
SF92b4	165.70	275	0.15	1.16	0.004
SF92b5	195.75	310.8	0.12	1.28	0.004
SF92b6	203.76	331.2	0.15	1.43	0.004
SF92b7	215.72	399.8	0.13	1.57	0.004
SF92b8	228.71	410.8	0.09	1.66	0.004
SF92b9	257.71	431.2	0.08	1.73	0.004
SF92b10	267.70	450.8	0.10	1.83	0.004
SF92b11	354.74	605.2	0.02	1.85	0.003
SF92b12	372.74	647.6	0.05	1.90	0.003
SF92b13	389.72	699.4	0.02	1.93	0.003
SF92b14	410.69	746	0.04	1.97	0.003
SF92a15	433.69	823.4	0.03	1.99	0.002
SF92a16	468.73	888.4	0.02	2.01	0.002
SF92a17	498.72	916.6	0.03	2.04	0.002
SF92a18	580.74	999.2	0.04	2.08	0.002
SF92a19	697.71	1135.2	0.03	2.11	0.002
SF92a20	718.73	1172.4	0.02	2.13	0.002
SF92a21	760.77	1265.6	0.06	2.20	0.002
SF92a22	797.92	1322.2	0.04	2.23	0.002
SF92a23	839.75	1359.8	0.03	2.26	0.002
SF92a24	888.83	1441	0.02	2.29	0.002

Table B7.1.1-6: Tebuconazole Flux and Percentage Losses averaged over the two panels

Sample No	No of days	Total rain (mm)	Average Total Tebuconazole Flux (mg/m^2)	Average Tebuconazole flux per mm rain in interval (mg/m^2/mm)
	0.00	0	0.00	
1	15.73	78.8	0.61	0.0077
2	27.79	124	0.93	0.0071
3	95.90	197.6	1.14	0.0029
4	165.70	275	1.31	0.0022
5	195.75	310.8	1.45	0.0038
6	203.76	331.2	1.61	0.0077
7	215.72	399.8	1.75	0.0021
8	228.71	410.8	1.85	0.0090
9	257.71	431.2	1.93	0.0038
10	267.70	450.8	2.03	0.0051
11	354.74	605.2	2.05	0.0001
12	372.74	647.6	2.11	0.0014
13	389.72	699.4	2.14	0.0006
14	410.69	746	2.19	0.0010
15	433.69	823.4	2.22	0.0004
16	468.73	888.4	2.24	0.0003
17	498.72	916.6	2.27	0.00102
18	580.74	999.2	2.32	0.00057
19	697.71	1135.2	2.35	0.00023
20	718.73	1172.4	2.37	0.00054
21	760.77	1265.6	2.44	0.00077
22	797.92	1322.2	2.48	0.00064
23	839.75	1359.8	2.51	0.00080
24	888.83	1441	2.53	0.00028

Table B7.1.1-7A: Propiconazole Flux Data for Panel A

Sample	No days	Total Rain (mm)	Propiconazole lost in leachate (mg/m^2)	Cumulative Total Propiconazole (mg/m^2)	Cumulative loss per mm rain ($mg/m^2/mm$)
	0.00	0	0	0	
SF92a1	15.73	78.8	0.72	0.72	0.009
SF92a2	27.79	124	0.33	1.05	0.008
SF92a3	95.90	197.6	0.29	1.34	0.007
SF92a4	165.70	275	0.23	1.58	0.006
SF92a5	195.75	310.8	0.14	1.72	0.006
SF92a6	203.76	331.2	0.16	1.88	0.006
SF92a7	215.72	399.8	0.17	2.05	0.005
SF92a8	228.71	410.8	0.10	2.15	0.005
SF92a9	257.71	431.2	0.08	2.23	0.005
SF92a10	267.70	450.8	0.10	2.33	0.005
SF92a11	354.74	605.2	0.02	2.35	0.004
SF92a12	372.74	647.6	0.06	2.41	0.004
SF92a13	389.72	699.4	0.03	2.45	0.003
SF92a14	410.69	746	0.04	2.49	0.003
SF92a15	433.69	823.4	0.03	2.52	0.003
SF92a16	468.73	888.4	0.02	2.53	0.003
SF92a17	498.72	916.6	0.02	2.55	0.003
SF92a18	580.74	999.2	0.03	2.58	0.003
SF92a19	697.71	1135.2	0.03	2.61	0.002
SF92a20	718.73	1172.4	0.02	2.63	0.002
SF92a21	760.77	1265.6	0.04	2.67	0.002
SF92a22	797.92	1322.2	0.03	2.69	0.002
SF92a23	839.75	1359.8	0.02	2.71	0.002
SF92a24	888.83	1441	0.01	2.72	0.002

Table B7.1.1-7B: Propiconazole Flux Data for Panel B

Sample	No days	Total Rain (mm)	Propiconazole lost in leachate (mg/m^2)	Cumulative Total Propiconazole (mg/m^2)	Cumulative loss per mm rain ($mg/m^2/mm$)
	0.00	0	0	0	
SF92b1	15.73	78.8	0.60	0.60	0.008
SF92b2	27.79	124	0.26	0.86	0.007
SF92b3	95.90	197.6	0.29	1.15	0.006
SF92b4	165.70	275	0.18	1.33	0.005
SF92b5	195.75	310.8	0.12	1.45	0.005
SF92b6	203.76	331.2	0.15	1.61	0.005
SF92b7	215.72	399.8	0.14	1.74	0.004
SF92b8	228.71	410.8	0.08	1.83	0.004
SF92b9	257.71	431.2	0.08	1.91	0.004
SF92b10	267.70	450.8	0.10	2.01	0.004
SF92b11	354.74	605.2	0.02	2.03	0.003
SF92b12	372.74	647.6	0.05	2.07	0.003
SF92b13	389.72	699.4	0.02	2.09	0.003
SF92b14	410.69	746	0.03	2.12	0.003
SF92a15	433.69	823.4	0.02	2.14	0.003
SF92a16	468.73	888.4	0.01	2.16	0.002
SF92a17	498.72	916.6	0.02	2.18	0.002
SF92a18	580.74	999.2	0.03	2.20	0.002
SF92a19	697.71	1135.2	0.02	2.23	0.002
SF92a20	718.73	1172.4	0.01	2.24	0.002
SF92a21	760.77	1265.6	0.03	2.27	0.002
SF92a22	797.92	1322.2	0.02	2.29	0.002
SF92a23	839.75	1359.8	0.01	2.30	0.002
SF92a24	888.83	1441	0.01	2.32	0.002

Table B7.1.1-8: Propiconazole Flux and Percentage Losses averaged over the two panels

Sample No	No of days	Total rain (mm)	Average Total Propiconazole Flux (mg/m^2)	Average Propiconazole flux per mm rain in interval ($mg/m^2/mm$)
	0.00	0	0.00	
1	15.73	78.8	0.66	0.0084
2	27.79	124	0.96	0.0065
3	95.90	197.6	1.25	0.0039
4	165.70	275	1.45	0.0027
5	195.75	310.8	1.59	0.0037
6	203.76	331.2	1.74	0.0078
7	215.72	399.8	1.90	0.0022
8	228.71	410.8	1.99	0.0083
9	257.71	431.2	2.07	0.0041
10	267.70	450.8	2.17	0.0050
11	354.74	605.2	2.19	0.0001
12	372.74	647.6	2.24	0.0013
13	389.72	699.4	2.27	0.0005
14	410.69	746	2.31	0.0008
15	433.69	823.4	2.33	0.0003
16	468.73	888.4	2.35	0.0002
17	498.72	916.6	2.36	0.0007
18	580.74	999.2	2.39	0.0003
19	697.71	1135.2	2.42	0.0002
20	718.73	1172.4	2.43	0.0003
21	760.77	1265.6	2.47	0.0004
22	797.92	1322.2	2.49	0.0004
23	839.75	1359.8	2.51	0.0004
24	888.83	1441	2.52	0.0001

Table B7.1.1-9A: Copper Flux Data for Panel A

Sample	No days	Total Rain (mm)	Copper lost in leachate (mg/m^2)	Cumulative Total Copper (mg/m^2)	Cumulative loss per mm rain ($mg/m^2/mm$)
	0.00	0	0.00	0.00	0.00
SF92a1	15.73	78.8	43.05	43.05	0.55
SF92a2	27.79	124	15.01	58.05	0.47
SF92a3	95.90	197.6	39.96	98.01	0.50
SF92a4	165.70	275	39.99	138.00	0.50
SF92a5	195.75	310.8	33.77	171.77	0.55
SF92a6	203.76	331.2	25.42	197.20	0.60
SF92a7	215.72	399.8	37.10	234.30	0.59
SF92a8	228.71	410.8	18.66	252.96	0.62
SF92a9	257.71	431.2	16.59	269.54	0.63
SF92a10	267.70	450.8	15.42	284.96	0.63
SF92a11	354.74	605.2	18.18	303.14	0.50
SF92a12	372.74	647.6	25.92	329.06	0.51
SF92a13	389.72	699.4	13.88	342.94	0.49
SF92a14	410.69	746	18.42	361.36	0.48
SF92a15	433.69	823.4	18.21	379.57	0.46
SF92a16	468.73	888.4	12.75	392.33	0.44
SF92a17	498.72	916.6	14.44	406.77	0.44
SF92a18	580.74	999.2	17.92	424.69	0.43
SF92a19	697.71	1135.2	13.91	438.60	0.39
SF92a20	718.73	1172.4	4.30	442.90	0.38
SF92a21	760.77	1265.6	37.05	479.95	0.38
SF92a22	797.92	1322.2	13.43	493.37	0.37
SF92a23	839.75	1359.8	19.16	512.54	0.38
SF92a24	888.83	1441	18.17	530.71	0.37

Table B7.1.1-9B: Copper Flux Data for Panel B

Sample	No days	Total Rain (mm)	Copper lost in leachate (mg/m^2)	Cumulative Total Copper (mg/m^2)	Cumulative loss per mm rain ($mg/m^2/mm$)
	0.00	0	0.00	0.00	0.00
SF92b1	15.73	78.8	38.98	38.98	0.49
SF92b2	27.79	124	13.27	52.25	0.42
SF92b3	95.90	197.6	38.98	91.22	0.46
SF92b4	165.70	275	39.64	130.86	0.48
SF92b5	195.75	310.8	41.21	172.07	0.55
SF92b6	203.76	331.2	34.90	206.96	0.62
SF92b7	215.72	399.8	41.43	248.39	0.62
SF92b8	228.71	410.8	18.93	267.32	0.65
SF92b9	257.71	431.2	16.86	284.17	0.66
SF92b10	267.70	450.8	17.22	301.39	0.67
SF92b11	354.74	605.2	14.63	316.01	0.52
SF92b12	372.74	647.6	24.09	340.10	0.53
SF92b13	389.72	699.4	11.09	351.19	0.50
SF92b14	410.69	746	15.56	366.75	0.49
SF92a15	433.69	823.4	20.49	387.24	0.47
SF92a16	468.73	888.4	12.09	399.33	0.45
SF92a17	498.72	916.6	14.16	413.48	0.45
SF92a18	580.74	999.2	19.48	432.96	0.43
SF92a19	697.71	1135.2	14.15	447.11	0.39
SF92a20	718.73	1172.4	5.47	452.59	0.39
SF92a21	760.77	1265.6	37.05	489.64	0.39
SF92a22	797.92	1322.2	13.60	503.24	0.38
SF92a23	839.75	1359.8	20.31	523.56	0.39
SF92a24	888.83	1441	19.99	543.55	0.38

Table B7.1.1-10: Copper Flux and Percentage Losses Averaged Over the Two Panels

Sample No	No of days	Total rain (mm)	Average Total Copper Flux (mg/m^2)	Average Copper flux per mm rain in interval ($mg/m^2/mm$)
	0.00	0	0.00	
1	15.73	78.8	41.01	0.52
2	27.79	124	55.15	0.31
3	95.90	197.6	94.62	0.54
4	165.70	275	134.43	0.51
5	195.75	310.8	171.92	1.05
6	203.76	331.2	202.08	1.48
7	215.72	399.8	241.35	0.57
8	228.71	410.8	260.14	1.71
9	257.71	431.2	276.86	0.82
10	267.70	450.8	293.17	0.83
11	354.74	605.2	309.58	0.11
12	372.74	647.6	334.58	0.59
13	389.72	699.4	347.06	0.24
14	410.69	746	364.05	0.36
15	433.69	823.4	383.40	0.25
16	468.73	888.4	395.83	0.19
17	498.72	916.6	410.13	0.51
18	580.74	999.2	428.83	0.23
19	697.71	1135.2	442.86	0.10
20	718.73	1172.4	447.75	0.13
21	760.77	1265.6	484.79	0.40
22	797.92	1322.2	498.31	0.24
23	839.75	1359.8	518.05	0.52
24	888.83	1441	537.13	0.24

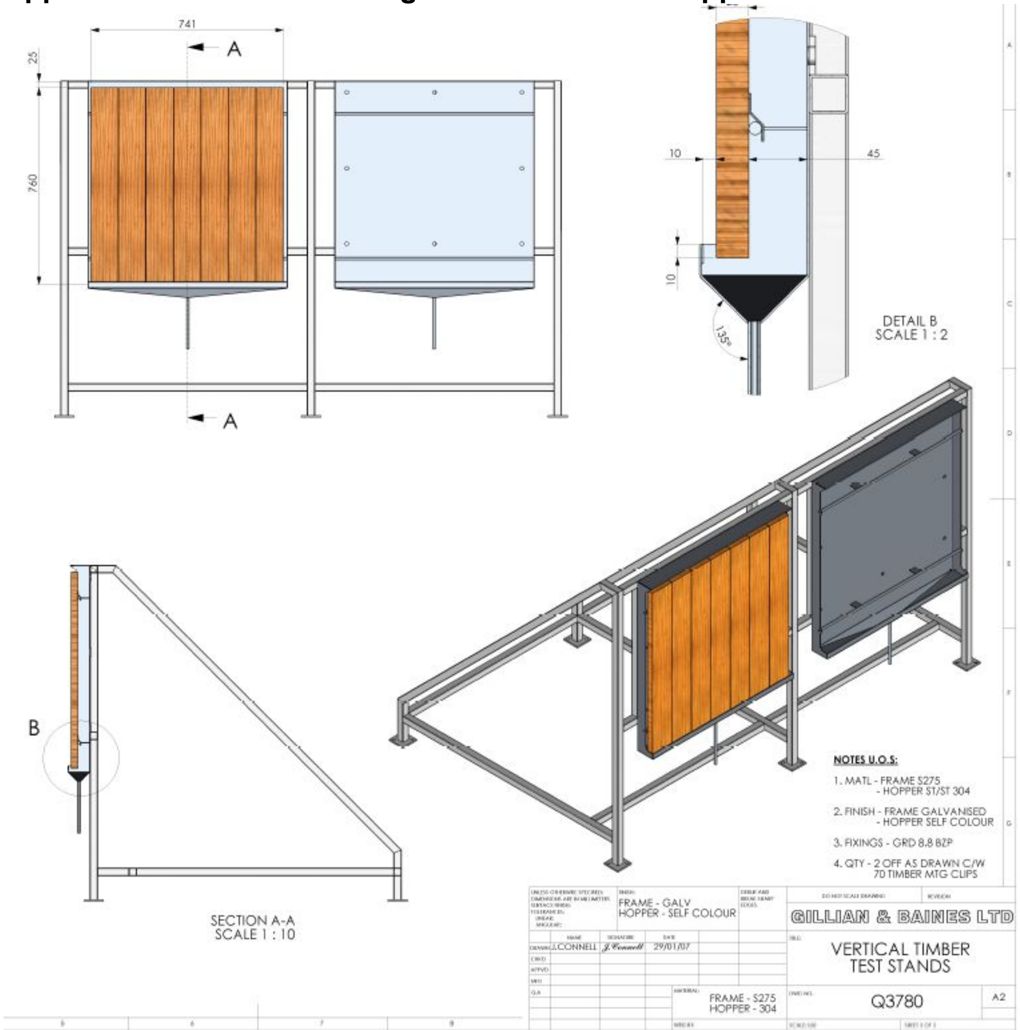
Figure B7.1.1-1: The Leachate Collection Devices with Mounted Panels

Figure B7.1.1-2: Graphical Representation of Average Tebuconazole Losses

Figure B7.1.1-3: Graphical Representation of Average Propiconazole Losses

Figure B7.1.1-4: Graphical Representation of Average Copper Losses

Appendix 1: Detailed Drawings of the Collection Apparatus



N.B. The drawings show the collection apparatus attached to a free-standing mounting frame. This frame was not included in the final design as it was possible to mount the apparatus in the correct orientation without it.

Section B7.1-2 Annex Point IIB, VIB7.1	**Foreseeable routes of entry into the environment on the basis of the use envisaged**	
		Official use only
	1 Reference	
1.1 Reference	IVB7_1_2	
1.2 Data protection	Yes	
1.2.1 Data owner	Arch Timber Protection (part of Lonza)	
1.2.2		
1.2.3 Criteria for data protection	Data on new b.p. for authorisation	
	2 Guidelines and Quality Assurance	
2.1 Guideline study	Yes This test was conducted according to one of a series of OECD draft laboratory protocols to assess the emissions of active substances from treated timber under Hazard Class 4 conditions of use.	
2.2 GLP	No	
2.3 Deviations	The study was conducted in accordance with a draft OECD leaching test protocol that was modified to reflect the best understanding of the proposed protocol at the time of the test.	
	3 Materials and Methods	
3.1 Test material	Tanalith E 3462 The preservative was diluted to give a target retention of copper of 2.5 kg m^{-3} in the test blocks. The treatment solution was made up from concentrate prepared in the laboratory. It was analysed for active ingredients to ensure that the solution was within the specification for that used at treatment plants.	
3.1.1 Lot/Batch number	Not reported	
3.1.2 Specification	Not reported	
3.1.3 Purity	Not reported	
3.1.4 Stability	Not reported	
3.1.5 Composition of	The concentrations of the active substances in the treatment solution were confirmed by analysis carried out by Arch Technical Support Service.	

Section B7.1-2 Annex Point IIB, VIB7.1	**Foreseeable routes of entry into the environment on the basis of the use envisaged**	
Product	The treatment solution contained; 0.39 % Copper 0.0089 % Tebuconazole 0.0081 % Propiconazole	
3.2 Testing procedure		
3.2.1 Timber	The test specimens were planed sapwood of Scotch Pine, Pinus sylvestris, with dimensions 80 x 35 x 15 mm. The wood was sourced commercially and so typical of in-use timber. Each specimen was 100% sapwood and free from knots as specified in the protocol, with between 5 and 10 growth rings per cm. The wood blocks used in the test had an average density of 554 kg m^{-3}.	
3.2.2 Test method	Treatment of Test Specimens The specimens were end sealed with four coats of nitro-cellulose lacquer before preservative treatment. Each specimen selected for leaching was end sealed again after treatment as there was some evidence of cracking in the end seal lacquer during treatment. The specimens were treated at the Arch Timber Protection Technical Centre using the small pilot plant. The specimens were placed on stickers in a vessel and immersed in treatment solution Tanalith E 3462. The preservative was diluted to give a target retention of copper of 2.5 kg m^{-3} in the test blocks and specimens were treated in the following cycle: Initial vacuum: 600mm Hg (45 minutes) Pressure: 12 bar (60 minutes) After the treatment the small blocks were dried in a conditioning chamber for 4 weeks. The blocks were stood on glass rods and inverted weekly. For the first two weeks the chamber was sealed, in the third week it was gradually opened and in the fourth week it was uncovered. The small wooden blocks dry very quickly if left open to ambient air due to their surface area:volume ratio. This method of drying ensures a gradual drying of the blocks in order to mimic the behaviour of commercially treated timber. Selection of Test Specimens 24 wood blocks were prepared and individually numbered. Each was weighed prior to treatment. The blocks were weighed again immediately after treatment and solution uptake calculated. Six blocks that were within ±5% of the mean retention were selected for testing. The six blocks selected had an average copper retention of 2.69 kg m^{-3}.	

Section B7.1-2 Annex Point IIB, VIB7.1	**Foreseeable routes of entry into the environment on the basis of the use envisaged**	
	<u>Test Procedure</u> After conditioning, the six blocks were separated in to two sets of three. A set of three untreated end-sealed test blocks were also prepared as a reference set. The total surface area exposed to water for each set of three blocks was 240 cm^2. The nominal volume of water used for immersion was 600 ml. This gives a wood surface to leachate volume ratio of 40 m^2 m^{-3}. Each set of three blocks was separately placed in 1 litre beakers containing approximately 600 g de-ionised water with the blocks mounted on glass rods that which were suspended from a wood block. The exact amount of water was noted and recorded. The entire arrangement was covered with plastic cling film that was secured by an elastic band to reduce losses due to evaporation. The three separate replicate beakers were stored on the bench top. The water was changed according to a pre-determined timetable. At each water change, the leachate from each beaker was poured in to separate sample bottles and weighed. The uptake of water during the leaching period was noted. The sets of three blocks were then transferred to clean 1 L beakers and fresh deionised leachate water added. The temperature and relative humidity of the laboratory was recorded throughout the test. <u>Analysis of Leachates</u> A 100 ml (approximate) portion of each leachate was stored separately in a fridge and sent for analysis for copper concentration. The remaining leachate was concentrated in to 10 ml of methanol using Solid Phase Extraction (SPE). Copper analysis was carried out using an inductively coupled plasma technique at an off-site NAMAS accredited laboratory. The azole analysis was carried out by Arch (US) using GC with FID detection.	
3.2.3 Calculation s	The short term leaching rates derived in these tests can be extrapolated to longer exposure times using methods outlined in Annex 2 of the OECD ESD for Wood Preservatives. This will allow average daily flux rates for the active substances to be estimated. These can be used in the BPD risk assessment documents. The estimate is calculated by extrapolating the daily emission rate against times plots (see figures 2 and 5). The cumulative emission after longer times is estimated by summing discrete individual daily losses. This allows an average daily leaching rate to be calculated over specified times.	

Section B7.1-2 Annex Point IIB, VIB7.1	**Foreseeable routes of entry into the environment on the basis of the use envisaged**

The procedure outlined in the ESD is followed:

1) Log-log plots are produced from the basic data plots.
2) The log-log plots are then fitted to a function with a known mathematical form.
3) The function allows projected emissions and hence daily rates to be calculated.

The OECD ESD Annex suggests fitting second order functions to the log-log data plots. The present work deviates from this suggestion and fits first order functions. It has been noted that when fitting second order functions there can be serious difficulties with non-convergence of the estimated leaching at longer times. If the best fit to the log-log points is a curve which has a positive coefficient to the second order term then the long-time leaching will be projected to be infinite. Only if the points are fitted by a curve with a negative coefficient will there be a convergent result. Thus this technique is not consistent in correctly modelling the long term end-point that cumulative leaching from the wood must be finite.

If the data points are fitted by a first order plot then the coefficient to the linear term will always be negative. This is due to the fact that the basic data points will always show decreasing values over the periods of the test. This negative coefficient leads to leaching estimates that are always convergent and correctly model the end-point that leaching from the wood must be finite.

The choice of always fitting data to first order equations guarantees long-time convergence with a consistent extrapolation technique between tests.

The Log-log data points are shown in Table 7 and the plots of this data are shown in figures 6 – 8. It should be noted that since copper data exists up to 52 days all this data has been used in the extrapolation. This is in contrast to the azole data which only extends over 36 days. The most reliable estimates will be made using all of the available data. The linearity of the copper plot is good and removing the longer time points would have a minor effect.

The process gives the equations below:

Substance	Equation
Copper	Ln(Em rate) = -0.9918Ln(time)+5.1951
Tebuconazole	Ln(Em rate) = -0.8838Ln(time)+1.8245

Propiconazole	Ln(Em rate) = -0.8568Ln(time)+1.9405

4 Results

4. 1Results of test

The duration of immersion, amounts of leachate collected, and uptakes are recorded in Table 7.1.2-1.

Analysis of Leachates

The analysis results for the individual leachates are shown in Table B7. 1.2-2. The overall results presented are average values for the two replicate sets of three blocks. Therefore, the final values represent the mean of 6 individual blocks.

Leach rate data

1. *Short-term (TIME1 data)*

Note: A data point was taken at 31 days due to the time tabling of the test. This was taken as the 30 day data. The impact of this is considered to be very minor.

40 Copper

The daily flux and the cumulative emissions of copper are shown in Table B7. 1.2-3 and Figures B7. 1.2-1 and B7. 1.2-2 respectively.

After 30 days the following results are found:

Mean average daily flux rate: 23.97 mg m^{-2} day^{-1}

Cumulative emission: 743.22 mg m^{-2}

At the conclusion of the test – 36 days, the following results are found:

Mean average daily flux rate: 21.23 mg m^{-2} day^{-1}

Cumulative emission: 764.16 mg m^{-2}

The copper emission was monitored for a further 16 days.

Day 52 Mean average daily flux rate: 15.91 mg m^{-2} day^{-1}

Cumulative emission: 827.07 mg m^{-2}

c) Propiconazole

The daily flux and the cumulative emissions of propiconazole are shown in Table B7. 1.2-4 and Figures B7. 1.2-3 and B7. 1.2-5 respectively.

After 30 days the following results are found:

Mean average daily flux rate: 1.01 mg m^{-2} day^{-1}

Cumulative emission: 31.16 mg m^{-2}

At the conclusion of the test – 36 days, the following results are found:

Mean average daily flux rate: 0.91 mg m^{-2} day^{-1}

Cumulative emission: 32.81 mg m^{-2}

d) Tebuconazole

The daily flux and the cumulative emissions of tebuconazole are shown in Table B7. 1.2-5 and Figures B7. 1.2-4 and B7. 1.2-5 respectively.

After 30 days the following results are found:

Mean average daily flux rate: 0.86 mg m^{-2} day^{-1}

Cumulative emission: 26.63 mg m^{-2}

At the conclusion of the test – 36 days, the following results are found:

Mean average daily flux rate: 0.78 mg m^{-2} day^{-1}

Cumulative emission: 27.93 mg m^{-2}

2. *Long-term (TIME2 data)*

The Log-log data points are shown in Table B7. 1.2-6 and the plots of this data are shown in Figures B7. 1.2-6 to B7. 1.2-8. As copper data exists up to 52 days all these data have been used in the extrapolation compared to the azole data which only extend over 36 days.

The total cumulative emission for 3650 days (10 years) and 7300 days (20 years) was derived using the available equations given in Section 4.23. The 20 – 60 year value is obtained by summing the rate over that interval and then divided by the relevant number of days;

Active Substance	10 years exposure
Copper	0.4470
Tebuconazole	0.0182
Propiconazole	0.0298

Active Substance	20 years exposure
Copper	0.2418
Tebuconazole	0.0107

Propiconazole	0.0172

Active Substance	20 – 60 years exposure
Copper	0.0147
Tebuconazole	0.0014
Propiconazole	0.0020

4.1.1 Leach rate for risk assessment

Results summary:

Retention rates		
kg/m^2	**Intended**	**Actual (test)**
Copper	2.5	2.5
Propiconzole	0.05	0.05
Tebuconazole	0.05	0.05
Leached over time		
mg/m^2	**T1 – 30 d**	**T2 – 20 yrs**
Copper	743.22	1765.14
Propiconzole	31.16	125.56
Tebuconazole	26.63	78.11
Daily leach rate		
mg/m^2/day	**T1 – 30 d**	**T2 – 20 yrs**
Copper	23.97	0.2418
Propiconzole	1.01	0.0172
Tebuconazole	0.86	0.0107

5 Applicant's Summary and conclusion

5.1 Materials and methods

Timber pretreated with Tanalith E 3462 to 2.5 kg m^{-3} copper was subjected to a leaching test protocol (draft) issued by the OECD, which was modified to reflect the best understanding of the proposed protocol at the time of the test.

This test consists of the full, continuous immersion of pretreated timber in water for at least 30 days. In the present case this was extended to 36 days for the azoles and 52 days for copper. The leachate water was changed according to defined timetables and analysed for concentrations of active substances.

The leachate data were analysed for short-term (30 d) and long-term (10 – 20 years) immersion.

5.2 Results and discussion

Short-term leaching data (initial – 30 days)*

Substance	Cumulative emission over test (mg m^{-2})	Duration of test (days)	30 days Cumulative emission [TIME1] (mg m^{-2})	0 – 30 days Average daily flux (mg m^{-2} day^{-1})

Section B7.1-2 Annex Point IIB, VIB7.1	**Foreseeable routes of entry into the environment on the basis of the use envisaged**

Copper	827.07	52	743.22	23.97
Tebuconazole	27.93	36	26.63	0.86
Propiconazole	32.81	36	31.16	1.01

*Data based on 31 day samples

Long-term leaching data (up to 20 years)

Active Substance	**Average daily leaching rate (mg m^{-2}day^{-1})**		**Cumulative leaching rate (mg m^{-2})**	
	10 years exposure	**20 years exposure**	**10 years exposure**	**20 years exposure**
Copper	0.4470	0.2418	743.22	1765.14
Tebuconazole	0.0182	0.0107	31.16	125.56
Propiconazole	0.0298	0.0172	26.63	78.11

5.3 Conclusion The copper was shown to initially be leached at quite high rates but this quickly reduced after only a few days (see Figure B7. 1.2-1) . The azoles showed a similar pattern with no marked difference in leaching behaviour between the two substances tested.

5.3.1 Reliability 1

5.3.2 Deficiencies No – noting that this study was undertaken using a draft protocol and modifications to immersion and leachate exchanges are unlikely to have had any significant effect.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*09-08- 2014*
Materials and Methods	*Applicant's version is acceptable*
Results and discussion	*Applicant's version is acceptable*

Section B7.1-2 Annex Point IIB, VIB7.1	**Foreseeable routes of entry into the environment on the basis of the use envisaged**
Conclusion	*Daily leaching rates to be used for risk assessment purposes:*
Reliability	*1*
Acceptability	*Acceptable*
Remarks	*No data on the Quality Assurance (QA) standard of the testing laboratory at the testing time. According to TNsG on data requirements (p. 142) exposure studies (e.g. leaching study) should be done to suitable QA standards.*

$mg/m^2/day$	T1 – 30 d	T2 – 20 yrs
Copper	23.97	0.2418
Propiconzole	1.01	0.0172
Tebuconazole	0.86	0.0107

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table B7. 1.2-1: Duration of immersion, amounts of leachate collected and uptakes

Day	Time	Set of blocks a			Set of blocks b			Reference Blocks		
		Mass of water in beaker (g)		Specimen Uptake (g)	Mass of water in beaker (g)		Specimen Uptake (g)	Mass of water in beaker (g)		Specimen Uptake (g)
		Start	Sample Point		Start	Sample Point		Start	Sample Point	
0	**10:55**	-	-	-	-	-	-	-	-	-
1	**10:55**	602.8	569.91	32.89	604.3	572.72	31.58	603.05	575.5	27.55
2	**11:30**	602.97	595.4	7.57	603.12	594.7	8.42	605.92	598.69	7.23
3	**11:30**	601.93	598.11	3.82	602.42	599.09	3.33	601.18	595.77	5.41
7	**12:30**	604.52	597.28	7.24	602.71	595.36	7.35	601.98	588.1	13.88
10	**10:50**	604.23	598.8	5.43	604.81	599.6	5.21	605.9	599.42	6.48
16	**10:10**	604.4	594.88	9.52	601.64	592.48	9.16	604.53	592.86	11.67
21	**11:05**	600.17	595.25	4.92	602.51	597.39	5.12	601.42	594.32	7.1
27	**12:15**	602.4	595.93	6.47	602.8	595.97	6.83	601.43	594.48	6.95
31	**13:35**	604.13	601.3	2.83	603.99	601.6	2.39	602.1	599.29	2.81
36	**13:45**	601.11	596.6	4.51	602.59	598.16	4.43	600.48	595.52	4.96
42	**11:25**	605.86	600.75	5.11	605.86	601.45	4.41	603.02	598.28	4.74
48	**12:10**	605.7	600.69	5.01	601.75	596.43	5.32	602	595.49	6.51
52	**09:51**	605.58	601.77	3.81	600.42	596.7	3.72	600.42	596.23	4.19

Table B7. 1.2-2: Analysis Results

Day	Set of Blocks a			Set of Blocks b			Reference Blocks		
	Copper µg/ml	Tebuconazole µg/ml	Propiconazole µg/ml	Copper µg/ml	Tebuconazole µg/ml	Propiconazole µg/ml	Copper µg/ml	Tebuconazole µg/ml	Propiconazole µg/ml
0	-	-	-	-	-	-	-	-	-
1	8.12	0.25	0.28	9.66	0.23	0.26	0	0.01	0.00
2	2.71	0.16	0.18	2.6	0.14	0.16	0	0.01	0.00
3	1.8	0.11	0.13	1.65	0.09	0.11	0	0.00	0.00
7	6.13	0.16	0.18	5.83	0.15	0.17	0	0.01	0.00
10	3.38	0.12	0.14	3.13	0.12	0.14	0	0.00	0.00
16	3.94	0.10	0.12	3.72	0.10	0.12	0	0.00	0.00
21	1.98	0.09	0.11	1.6	0.09	0.11	0	0.01	0.00
27	1.46	0.07	0.09	1.16	0.07	0.09	0	0.00	0.00
31	0.943	0.06	0.07	0.741	0.05	0.07	0	0.00	0.00
36	0.963	0.06	0.07	0.72	0.05	0.06	0	0.00	0.00
42	1.03			0.832			0		
48	1.01			0.788			0		
52	0.772			0.602			0		

Table B7. 1.2-3: Copper: Flux Rates and Cumulative Emission

Day	Emission Rate (mg/m^2/day)			Cumulative Emission (mg/m^2)
	Treated Blocks		Net Mean Emission Rate	
	Set a	Set b		
1	192.82	230.52	211.67	211.67
2	67.23	64.43	65.83	277.50
3	44.86	41.19	43.02	320.52
7	38.14	36.16	37.15	469.11
10	28.11	26.07	27.09	550.37
16	16.28	15.31	15.79	645.12
21	9.82	7.97	8.89	689.59
27	6.04	4.80	5.42	722.12
31	5.91	4.64	5.28	743.22
36	4.79	3.59	4.19	764.16
42	4.30	3.48	3.89	787.48
48	4.21	3.26	3.74	809.91
52	4.84	3.74	4.29	827.07

Table B7. 1.2-4: Propiconazole: Flux Rates and Cumulative Emission

Day	Emission Rate (mg/m^2/day)			Cumulative Emission (mg/m^2)
	Treated Blocks		Net Mean Emission Rate	
	Set a	Set b		
1	6.55	6.32	6.44	6.44
2	4.45	3.89	4.17	10.61
3	3.33	2.86	3.10	13.70
7	1.13	1.03	1.08	18.03
10	1.17	1.16	1.17	21.53
16	0.48	0.51	0.50	24.51
21	0.54	0.53	0.53	27.18
27	0.37	0.35	0.36	29.35
31	0.46	0.44	0.45	31.16
36	0.34	0.32	0.33	32.81

Table B7. 1.2-5: Tebuconazole: Flux Rates and Cumulative Emission

Day	Emission Rate ($mg/m^2/day$)			Cumulative Emission (mg/m^2)
	Treated Blocks		Net Mean Emission Rate	
	Set a	Set b		
1	5.84	5.42	5.63	5.63
2	3.98	3.39	3.69	9.32
3	2.86	2.33	2.59	11.91
7	0.99	0.91	0.95	15.70
10	1.02	0.98	1.00	18.70
16	0.42	0.42	0.42	21.21
21	0.45	0.43	0.44	23.43
27	0.30	0.29	0.30	25.20
31	0.38	0.34	0.36	26.63
36	0.28	0.24	0.26	27.93

Table B7. 1.2-6: Data for long-term Log-log Plot

Day	Copper		Tebuconazole		Propiconazole	
	Ln(time)	Ln(Cum emm)	Ln(time)	Ln(Cum emm)	Ln(time)	Ln(Cum emm)
1	0	5.36	0	1.73	0	1.86
2	0.69	5.63	0.69	2.23	0.69	2.36
3	1.10	5.77	1.10	2.48	1.10	2.62
7	1.95	6.15	1.95	2.75	1.95	2.89
10	2.30	6.31	2.30	2.93	2.30	3.07
16	2.77	6.47	2.77	3.05	2.77	3.20
21	3.04	6.54	3.04	3.15	3.04	3.30
27	3.30	6.58	3.30	3.23	3.30	3.38
31	3.43	6.61	3.43	3.28	3.43	3.44
36	3.58	6.64	3.58	3.33	3.58	3.49
42	3.74	6.67				
48	3.87	6.70				
52	3.95	6.72				

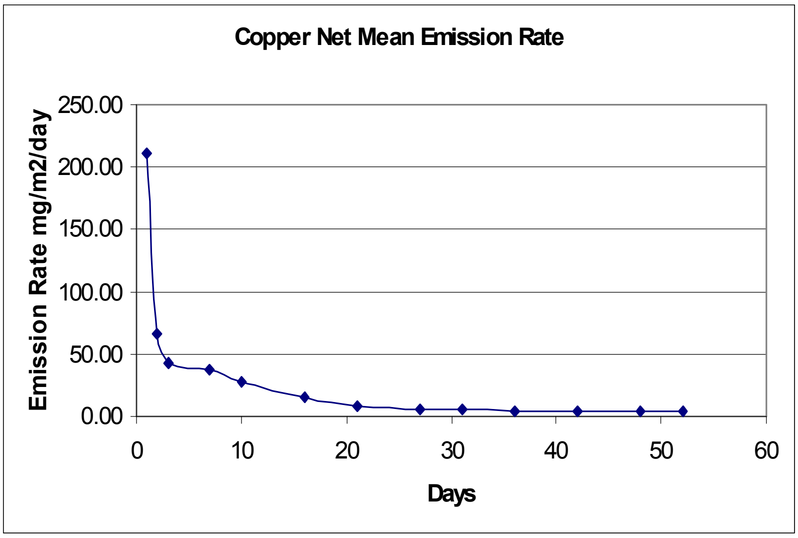


Figure B7. 1.2-1: Copper: Daily Flux Rate

Figure B7. 1.2-2: Copper: Cumulative Emission

Figure B7. 1.2-3: Propiconazole: Daily Flux Rate

Figure B7. 1.2-4: Tebuconazole: Daily Flux Rate

Figure B7. 1.2-5: Cumulative Azole Emission

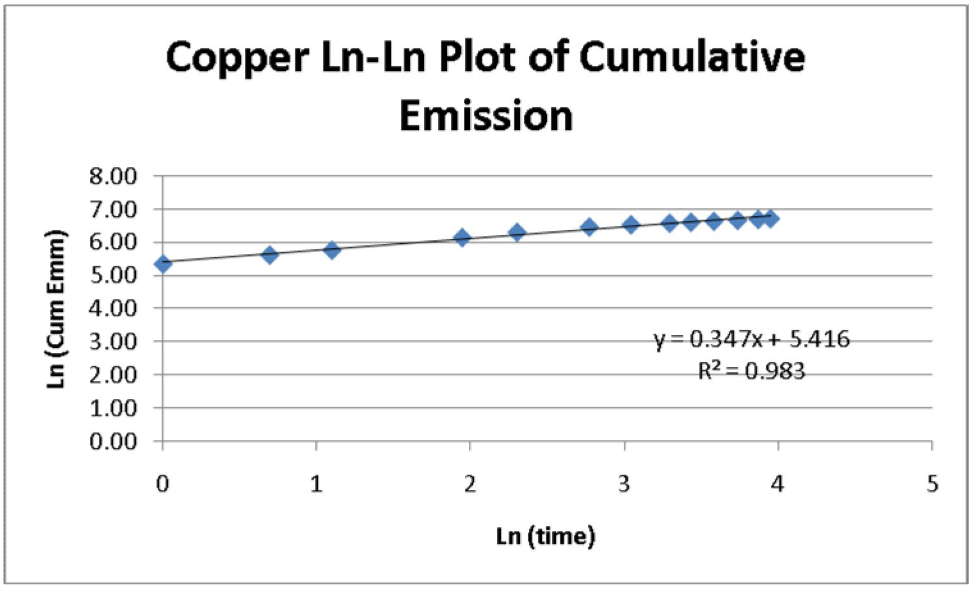


Figure B7. 1.2-6: Log-Log Plot of the Copper Cumulative Emission data

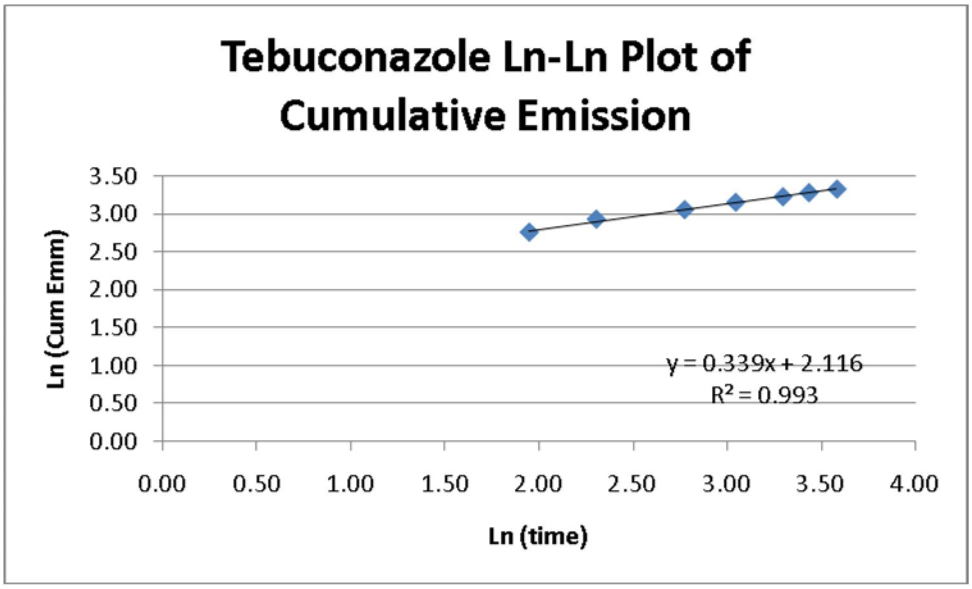


Figure B7. 1.2-7: Log-Log Plot of the Tebuconazole Cumulative Emission data

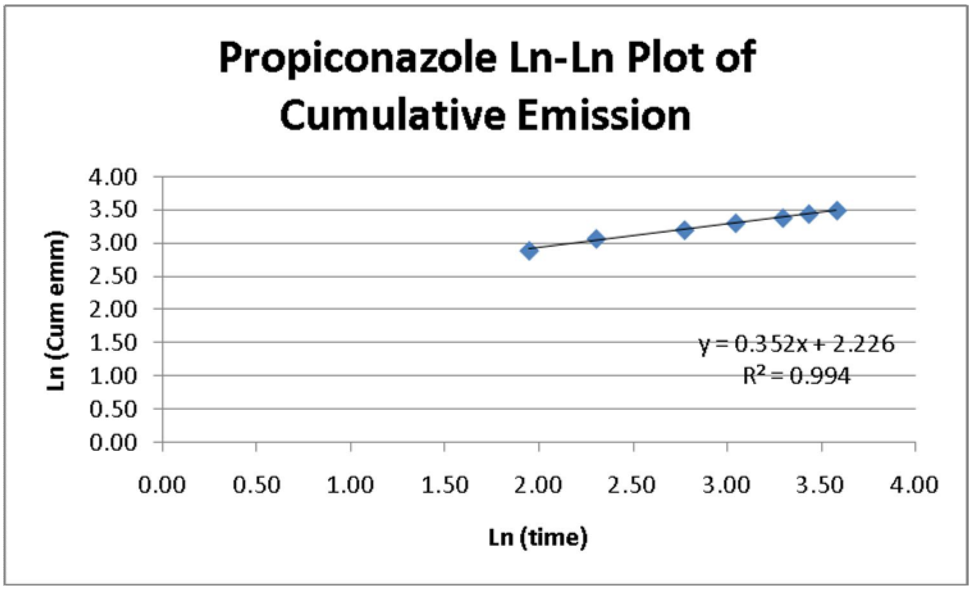


Figure B7. 1.2-8: Log-Log Plot of the Propiconazole Cumulative Emission data

Section B7.2 **Annex Point IIB, VIB7.2**	**Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance itself**

Section B7.2 **Annex Point IIB, VII.7.2**	**Effects on reproduction and growth rate with an invertebrate species** *Daphnia magna*	
	1 REFERENCE	**Official use only**
1.1 Reference	IVB7_1_1	
1.2 Data protection	Yes	
1.2.1 Data owner	Arch Timber Protection	

Section B7.2 Annex Point IIB, VII.7.2	Effects on reproduction and growth rate with an invertebrate species *Daphnia magna*	
1.2.2 Companies with letter of access		
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes, OECD 202 (1984)	
2.2 GLP	Yes	
2.3 Deviations	No	
	3 MATERIAL AND METHODS	
3.1 Test material	Tanalith 3485	
3.1.1 Lot/Batch number		
3.1.2 Specification	(see table below)	
3.1.4 Description of test substance	Dark blue liquid	
3.1.7 Method of analysis		
3.3 Reference substance	No	
3.3.1 Method of analysis for reference substance	Not applicable	
3.4 Testing procedure		
3.4.1 Dilution water	Details are given in table B7.2-1	
3.4.2 Test organisms	*Daphnia magna*, details are given in table B7.2-2	
3.4.3 Handling of offspring	Survival and reproduction of the daphnids were monitored daily	

Specification (3.1.2):

Formulation % w/w	Tanalith 3485
Copper carbonate	22.5
Boric acid	4.9
Tebuconazole	0.49
Monoethanolamine	41.6
2-ethylhexanoic acid	3.1
Di-2-ethylhexyl phthalate	3.42
Nonyl phenol 12 ethoxylate	0.99
Silicone defoamer	0.57
Water	22.43

Section B7.2 **Annex Point IIB, VII.7.2**	**Effects on reproduction and growth rate with an invertebrate species** *Daphnia magna*	
3.4.4 Test system	Details are given in table B7.2-3	
3.4.5 Test conditions	Details are given in table B7.2-4	
3.4.6 Duration of the test	21 days	
3.4.7 Test parameter	Mortality, growth, reproduction	
3.4.8 Examination / Sampling	Survival and reproduction were monitored daily, growth was determined at the end of the test	
3.4.10 Statistics	Not given	
	4 RESULTS	
4.1 Range finding test	Performed	
4.1.1 Concentrations	0.0, 0.18, 0.32, 0.56, 1.0, 1.8 mg/L under static conditions for a period of 2 days	
4.1.2 Number/ percentage of animals showing adverse effects	At the end of the exposure period, no □mmobilization in concentrations ≤ 0.23 mg/L and 100 percent in concentrations ≥0.80 mg/L.	
4.1.3 Nature of adverse effects	Mortality	
4.2 Results test substance		
4.2.1 Initial concentrations of test substance	0.0, 0.032, 0.056, 0.10, 0.18, 0.32	
4.2.2 Actual concentrations of test substance	Details are given in table B7.2-5	
4.2.3 Effect data	The cumulative number of dead animals as well as the number of offspring are given in table B7.2-6 21-day EC_{50}r, NOEC, LOEC values are given in table B7.2-7	
4.2.4 Concentration / response curve	No plot given	
4.3 Results of controls	Mortality in the dilution control and the solvent control were 2 and 8 percent, respectively. These values are within the range of validity. Details are given in table B7.2-6	
4.4 Test with reference substance	Not performed	
4.4.1 Concentrations	Not applicable	
4.4.2 Results	Not applicable	

Section B7.2 Annex Point IIB, VII.7.2	**Effects on reproduction and growth rate with an invertebrate species** *Daphnia magna*	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The test was conducted according to OECD 202 (1984). It was a semi-static test system and *Daphnia magna* was used as the test species.	
5.2 Results and discussion		
5.2.1 NOEC	0.102 mg/L	
5.2.2 LOEC	0.137 mg/L	
5.2.3 $EC_{50}r$	0.203 mg/L	
5.3 Conclusion	The mortality in the control was 20 %. Also the number of offspring produced per parent animal exceeded 20. Therefore, the validity criteria can be considered as fulfilled (see table B7.2-8). Based on the results, NOEC and LOEC were determined to be 0.102 mg/L and 0.137 mg/L, respectively. The $EC_{50}r$ was calculated to be 0.203 mg/L. All values based on mean measured test concentration.	
5.3.1 Other Conclusions	Not applicable	
5.3.2 Reliability	1	
5.3.3 Deficiencies	No	
	Evaluation by Competent Authorities	

	Evaluation by Rapporteur Member State
Date	*09-08-2014*
Materials and Methods	*Applicant's version is acceptable*
Results and discussion	*Applicant's version is acceptable*
Conclusion	*NOEC and LOEC were determined to be 0.102 mg/L and 0.137 mg/L, respectively. The $EC_{50}r$ was calculated to be 0.203 mg/L. All values are based on mean measured test concentrations.*
Reliability	*1*
Acceptability	*Acceptable*
Remarks	*None*
	Comments from ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Section B7.2 **Annex Point IIB, VII.7.2**	**Effects on reproduction and growth rate with an invertebrate species** *Daphnia magna*	
Remarks		

Table B7.2-1: Dilution water

Criteria	Details
Source	Groundwater from chalk borehole WRc Medmenham
Salinity	Not given
Alkalinity	233 to 253 mg/L as $CaCO_3$
Hardness	280 to 290 mg/L as $CaCO_3$
pH	7.60 – 8.42
Ca / Mg ratio	61:1
Na / K ratio	9.1:1
Oxygen content (% Air Saturated Value)	94 – 97
Conductance	
TOC	Not given
Holding water different from dilution water	No

Table B7.2-2: Test organism

Criteria	Details
Strain / Clone	*Daphnia magna* IRCHA clone type 5
Source	WRc Medmenham Laboratory.
Age	Less than 24 hours
Breeding method	Pathenogenetically reproducing cultures
Kind of food	Algae *Chlorella vularis var. viridis*
Amount of food	1 mg carbon /L water 1.2 *$10^{5\ cells}$ /ml
Feeding frequency	Algae were added daily continuously during the course of the test (21 days).
Pretreatment	None
Feeding of animals during test	Yes, Daphnids were fed daily continuously during the course of the test.

Table B7.2-3: Test system

Criteria	Details
Test type	*Semi-static*
Renewal of test solution	Every Monday, Wednesday, Friday to day 21 (test end)
Volume of test vessels	1000 mL containing 400 ml test solution
Volume/animal	40 mL/animal
Number of animals/vessel	10
Number of vessels/ concentration	4
Test performed in closed vessels due to significant volatility of TS	No

Table B7.2-4: Test conditions

Criteria	Details
Test temperature	20 ± 2 ºC
Dissolved oxygen (%ASV)	94 -97
pH	7.48 – 7.55
Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	Not given
Photoperiod	14 hours light, 10 hours dark, 30 minute simulation of dawn and dusk.

Table B7.2-5: Actual concentrations of test substance

Nominal concentrations of test substance (mg/L)	Measured concentration (mg/L)			
	Day 0	Day 21	Mean	Percent of Nominal
Control	0.038	0.076	0.057	
0.032	0.068	0.083	0.076	238
0.056	0.106	0.098	0.102	182
0.1	0.152	0.121	0.137	137
0.18	0.197	0.189	0.193	107
0.32	0.303	0.265	0.284	89

Table B7.2-6: Effect data

Mean measured concentrations (µg/L)	Cumulative number of dead animals		Number of offspring	
	Per treatment	% Mortality	Total	Per reproductive day
Control	2	20	817	38
0.076	1	10	979	47
0.102	8	10	971	46
0.137	3	63	556	26
0.193	6	55	480	23
0.284	7	65	398	19

Table B7.2-7: Toxicity values

21-dayEC_{50}[1] (mg/L)	95 % C.L. (µg/L)	NOEC[1] (mg/L)	LOEC (mg/L)
0.203	0.12 – 0.286	0.102	0.137

Table B7.2-8: Validity criteria for invertebrate reproduction test according to OECD Guideline 202

	Fulfilled	Not fulfilled
Mortality of parent animals ≤ 20% at test termination	yes	
Mean control fecundity exceeded 20 juveniles per adult	yes	

Criteria for poorly soluble test substances	n.a.	n.a.

Annex 3: Input parameters for modelling

Compound	Copper	Propiconazole	Tebuconazole	1,2,4-triazole
Molecular mass (g mol^{-1})	63.54	342	307.8	69.1
Log Kow	8.50E-07	3.72	3.49	-1.0
Koc (l kg^{-1})	106000	944	992	69
Vapour pressure (Pa)	1.00E-09	5.60E-05 @ 25°C	1.70E-06 @ 20°C	0.22 @ 25°C
Water solubility at 20 °C (mg l^{-1})	100000*	100	29	7.00E05
Henry constant	1.30E-12	9.20E-05	1.00E-05	0.155
Log H	11.9	-4.04	-5.0	-0.801
Characterisation of biodegradability	Not biodegradable	Not biodegradable	Not biodegradable	Not biodegradable
Surface water				
Half-life @ test temperature	-	6.4	46.0	n/a
Test temperature (°C)	-	20	12.0	n/a
Calculated environmental half-life [@12°C] DT_{50} (d)	-	12.1	46.0	n/a
Soil				
Half-life @ test temperature DT_{50} (d)	-	129 (field study for PECsoil calculations) 43 (lab study for PEC groundwater calculations)	77.0 (field study for PECsoil calculations)	1.68 (fast phase)** 60.5 (slow phase)** 9.3 (lab study)
Test temperature (°C)	-	20***	***	20***
Calculated environmental half-life [@12°C] DT_{50} (d)	-	***	***	17.6 (lab study for PECsoil calculations)
Maximum formed in Soil Compartment (%)	-	n/a	n/a	100** 43 (from propiconazole) 9 (from tebuconazole)

n/a: not available or not applicable (copper)

*Based on soluble copper ions. Data obtained from Cu RAR

** DT50 values are derived from field studies according to a PPPD review published in January 2014. Thus DT50 values cannot be combined with a formation fraction (or max. obs.%) from a laboratory study. In principle it can be combined with a formation fraction (or max. obs.%) from a field study in which the parent was dosed. A formation fraction (or max. obs.%) is, however, not available for 1,2,4-triazole. Therefore a worst/case formation fraction of 1 should be used in the modelling for groundwater.

Additionally in the case of 1,2,4-triazole the Freundlich exponent 1/n conservatively was not set at 1 but a mean 1/n of 0.92 was derived. To correct for this it is considered appropriate to use doubling of the application rate and then dividing the final answer by two.

*** Temperature related recalculation of the results from field dissipation studies is not made because recalculation is required from laboratory degradation results only (TNsG on Data Requirements). The reported temperature is only valid for laboratory DT50 values.

The new field dissipation study with 1,2,4-triazole is used for PECsoil. The lab study DT50 of 17.6 d at 12°C is used for the calculation of PECsoil, including the maximum formation fraction in lab.
The reasons for use of a different input for the PECsoil calculations as compared with the data used for PECgroundwater is that PEARL takes into account long term degradation of the parent and formation of 1,2,4-triazole, which is not modelled in the PECsoil. Furthermore the different parent compounds are rather stable in soil. Therefore the calculation would thus overestimate the risk in soil for 1,2,4-triazole.

Annex 4: Calculation of the PECs for the aquatic and terrestrial compartment

Cumulative leaching

Cumulative leaching over the initial and remaining assessment period is calculated according to (modified from formulas 7.5 and 7.6 from the ESD (version 2000[2]):

$$E_{comp,leach,time1} = \frac{AREA \cdot Q_{leach,time1}}{time1}$$

$$E_{comp,leach,time2} = \frac{AREA \cdot (Q_{leach,time2} - Q_{leach,time1})}{time2}$$

where:

- $E_{comp,\ leach,\ time1}$ average daily emission to compartment X (water or soil) of the active ingredient due to leaching over the first 30 days;
- $E_{comp,\ leach,\ time2}$ average daily emission to compartment X (water or soil)of the active ingredient due to leaching over the remaining assessment period (product's service life minus 30 days);
- AREA area of the surface painted or plastered (125 m² for emission to soil, 20 m² for emission directly to water);
- $Q_{leach,\ time1}$ cumulative quantity of an active ingredient leached out of 1 m² of the treated object over the first 30 days;
- $Q_{leach,\ time1}$ cumulative quantity of an active ingredient leached out of 1 m² of the treated object during the remaining assessment period;
- time1 duration of the initial assessment period (30 days[3])
- time2 duration of the remaining assessment period (product's service life minus 30 days).

Aquatic environment

Concentration in stagnant surface water during the initial and remaining assessment period is calculated as follows (modified from formula 7.11 of the ESD version 2000[4]):

initial assessment period (0 ≥ t ≤ time1):

$$PEC_{water}(t) = \frac{Elocal_{water,time1}}{V_{water} \cdot 1000 \cdot k_{water}} - \left[\frac{Elocal_{water,time1}}{V_{water} \cdot 1000 \cdot k_{water}} - Clocal_{water,appl}\right] \cdot e^{-t \cdot k_{water}}$$

remaining assessment period (t>time1):

$$PEC_{water}(t) = \frac{Elocal_{water,time2}}{V_{water} \cdot 1000 \cdot k_{water}} - \left[\frac{Elocal_{water,time2}}{V_{water} \cdot 1000 \cdot k_{water}} - Clocal_{water,time1}\right] \cdot e^{-(t-30) \cdot k_{water}}$$

where:

- $PEC_{water}(t)$ concentration in local stagnant water at time=t (mg/L)
- t time (d);
- V_{water} volume of the receiving water (1000 m³)
- k_{water} first order rate constant for removal from water (/d)
- $Clocal_{water,\ applic}$ initial concentration in water during application (mg/L)

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[2] In the latest draft (2013) these formulas are numbered 3.5 and 3.6, respectively)
[3] Adjustment of time1 may be necessary depending on the active substance's leaching behaviour
[4] In the latest draft (2013) this formula is numbered 3.11

The concentration in the water was is subsequently corrected for sorption to suspended matter according to the TGD.

Terrestrial environment
Concentration in soils during the initial and remaining assessment period is calculated as follows (modified from formula 7.11 of the ESD version 2000):

initial assessment period (0 ≥ t ≤ time1):

$$PEC_{soil}(t) = \frac{Elocal_{soil,time1}}{V_{soil} \cdot RHO_{soil} \cdot k_{soil}} - \left[\frac{Elocal_{soil,time1}}{V_{soil} \cdot RHO_{soil} \cdot k_{soil}} - Clocal_{soil,appl} \right] \cdot e^{-t \cdot k_{soil}}$$

remaining assessment period (t>time1):

$$PEC_{soil}(t) = \frac{Elocal_{soil,time2}}{V_{soil} \cdot RHO_{soil} \cdot k_{soil}} - \left[\frac{Elocal_{soil,time2}}{V_{soil} \cdot RHO_{soil} \cdot k_{soil}} - Clocal_{soil,time1} \right] \cdot e^{-(t-30) \cdot k_{soil}}$$

where:

- PEC_{soil} concentration in local soil at time=t (mg/kg wwt)
- t time (d);
- V_{soil} volume of the receiving soil (12.5 m³)
- RHO_{soil} bulk density of wet soil (1700 kg/m³)
- k_{soil} first order rate constant for removal from soil (/d)
- $C_{localsoil, applic}$ initial concentration in soil during application (mg/kg wwt)

Annex 5: Leaching from paints, plasters, and fillers applied in urban areas

This scenario is endorsed by the Technical Meeting at TMIV-2013, Helsinki, Finland and send to the CA for finalisation (BMU 07-02-2014).

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Version information:
Version 5, November 2013, for endorsement at TMIV-2013.

Note to the reader
The underlying document concerns the final version of our proposal to calculate the emission from preservatives applied in paints and coatings (PT07), wood (PT08), polymerised materials (PT09), and masonry (PT10) applied in urban areas. The first version was introduced at TMII-2012, the second at TMIV-2012 where it was decides that:

- plasters are applied 4 kg/m²;
- the surface of silicone caulks in bathrooms are 0.12 m²;
- the market share is 100% unless sufficiently substantiated with tonnage data;
- no additional scenarios for suburban areas where rainwater is collected and discharged to surface water directly will be included in the current proposal

Moreover, the surface of sealants applied outdoors was lowered from 2 to 0.45 m² per house. This value was agreed during the discussion concerning tebuconazole at TMIV-2012.

Version 3 was discussed during TMII-2013 where it was decided to:

- add a remark concerning the service life of plasters which may vary among different types (DK);
- adjust the surface of silicone caulks around windows as the suggested value was based on vertical joints between houses (DK);
- add a reference to DE's proposal for direct emission to surface water via separated sewer systems (STP bypass);
- include a reference to DE's proposal for roof membranes;

Version 4 was discussed during TMIII-2013. Some small corrections were suggested. The current version (5) is the final version for endorsement at TMIV-2013.

Thanks to those who submitted useful comments on our draft version. Their suggestions and improvements are incorporated in the underlying document.

Introduction
The current emission scenarios for (in-can) preservation of paints and coatings, wood preservatives, preservatives for fibrous and polymerised materials, and masonry preservatives consider direct exposure from a single house to adjacent soil and surface water, while preserved materials are also applied in urban areas where waste water is collected and discharged to the sewer system. Although the ESD for PT10 offers a city scenario, the emission is however calculated from the treatment of one house only, which may result in an underestimation of the actual risks. In the current document a city scenario in which the emission to the sewer system of preservatives applied in an urban environment is presented. This scenario calculates the daily emission of preservatives that are spilled during application or lost by leaching during the preserved product's service life. Depending on the configuration of the sewer system the preservatives are discharged to the sewage

treatment plant (STP), or directly to surface water and sediments in case when rain water is collected separately without being mixed with domestic, institutional, and industrial waste water. Final predicted environmental concentrations (PECs) are calculated with SimpleTreat and the Technical Guidance Document (TGD) when discharged to the STP. In case of emission to a separated sewer systems, the STP is bypassed, and effluent volumes and dilution factors must be adjusted accordingly. PECs are then estimated according to the proposal for the assessment of direct emission to surface water. Note that the city scenario only concerns downtown areas considered paved. Suburbs are not considered in this scenario as houses are usually surrounded by gardens and sewage systems meant for precipitation are not necessarily connected to an STP.

Product authorisation requires data on leaching over the initial assessment period (30 days) and the longer assessment period (service life) to assess environmental exposure of in-can preservatives (PT06) when applied to preserve paints, plasters, joints sealants, and other building materials during storage, film preservatives (PT07), wood preservatives (PT08), fibre, leather, rubber and polymerised materials preservatives (PT09), and masonry preservatives (PT10). Especially for PT06, leaching data for all different types of paints, coatings and plasters is not always available. Therefore two methodologies are proposed: one when leaching data is available and a worst case approach that considers 100% leaching during the preserved product's service life.

The city scenario

Normal case approach: leaching data is available
An average sewer system receives waste water from 4000 houses. However, these houses contribute differently to the environmental emission as some are recently painted or plastered and others were treated longer ago. For the recently painted houses leaching is expected to be rapid, while leaching from surfaces painted or plastered in the past is slow or even negligible. It is assumed that the ratio recently painted houses to houses painted more than 30 days ago will not change in time as it is unlikely that all houses are painted or plastered simultaneously. For example, the leaching rate of an active substance from a paint will change from fast to slow when a house was painted 30 days ago, but will be replaced by another house for which repainting was necessary as the paint reached the end of its service life.In an ideal situation leaching data from long-term (field) studies are available from which a leaching rate (for PT08) or cumulative leaching (input for PT10) for the initial (30 days) and the longer (service life) assessment period can be derived.

The proposed city scenario strongly depends on parameters for which little knowledge is available yet. For the city scenario the following defaults are advised :

- a service life of:
  - 5 years for paints (which is also proposed in the revised ESD for wood preservatives) and sealants around windows and doors outside;
  - 10 years for indoor fillers (sealants);
  - 25 years for outdoor joint fillers and outdoor façade plasters;
- products holding the specific preservative is applied on all houses in a city (f_{house} = 1.0). These value may be reduced when sufficiently substantiated with tonnage data;
- the surface of:
  - a standard house is 125 m² (default for wood preservatives);
  - joint fillers applied between bricks per house of 125 m² is 35 m² (see appendix);
  - exterior windows frames and doors is 5.57 m² per house
  - sealants around windows and doors on a standard house is 0.31 m²;
  - joint fillers between tiles in the wet area of bathrooms is 0.24 m²;
  - sealants in bathrooms is 0.12 m².

Relevant values for roof membranes are found in the proposal for the emission from roof membranes which was discussed at TMII-2013. Considering this, the daily emission to an STP can be estimated by using the formulas and defaults as proposed below.

$$N_{houses,initial} = \frac{T_{initial}}{T_{servicelife}} \cdot N_{house} \cdot f_{house} \quad (1$$

$$N_{houses,longer} = \frac{T_{longer}}{T_{servicelife}} \cdot N_{house} \cdot f_{house} \quad (2$$

$$E_{local} = \frac{(N_{house,initial} \cdot Q_{leach,time1} \cdot AREA)}{T_{initial}} + \frac{(N_{house,longer} \cdot Q_{leach,time2} \cdot AREA)}{T_{longer}} \quad (3$$

where:

- $N_{house,initial}$ number of houses in a city recently treated (-);
- $N_{house,longer}$ number of houses in a city treated more than 30 days ago (-);
- $T_{initial}$ time for the initial assessment period (30 d);
- T_{longer} time for the longer assessment period (d) (remaining service life, see Table 1);
- $T_{service\ life}$ service life (d) (see Table 1)
- N_{house} number of houses in a city (4000);
- f_{house} fraction of the houses on which paints, plasters, or fillers are applied (market share = 1.0);
- E_{local} daily emission to the sewer (kg/d);
- $Q_{leach,time1}$ cumulative leaching over 30 days (kg/m²);
- $Q_{leach,time2}$ cumulative leaching over service life minus 30 days (kg/m²);
- AREA area of the treated surface per house (m², see Table 1).

When applying the previously proposed defaults and formulas the daily emission to the sewer can be calculated by using the ratio of houses recently treated (<30 days) or treated more than 30 days ago, based on the service life of the product. These ratios are summarised in Table 1.

Table 1. Service life and number of houses that contributes to leaching for the situation when both initial and longer assessment period leaching data is available.

application	service life (d) ($T_{service\ life}$)	area (m²) (AREA)	time over which leaching is calculated (days)		number of houses from which the actives are leaching (-)	
			initial ($T_{initial}$)	longer (T_{longer})	initial ($N_{houses,\ initial}$)	longer ($N_{houses,\ longer}$)
Indoor applications						
joint fillers (bathroom)	3650	0.24	30	3620	33	3968
sealants (bathroom)	3650	0.12	30	3620	33	3968
Outdoor applications						
paints applied on	1825	125	30	1795	66	1934

façade						
paints applied on window and door frames, and doors	1825	5.57[1]	30	1795	66	1934
plasters applied on façades outdoors	9125	125	30	9095	14	1986
joint sealants applied outdoors	1825	0.31[2]	30	1795	66	1934
joint fillers applied outdoors	9125	35	30	9095	14	1986
roof membranes	See 'Use-based approaches for the estimations of environmental exposure in case of roof membranes' discussed during TMII-2013.					

[1] Surface taken from appendix 6 of the revised ESD for wood preservatives (window and door surfaces for a single-floor 125 m² house);

[2] Surface based on window and door frame perimeters calculated from the dimensions for a single floor 125 m² house as specified in appendix 6 of the revised ESD for wood preservatives.

Worst-case approach: leaching data is lacking

However, leaching data is not always available and, therefore, emissions have to be calculated using a worst-case scenario in which 100% leaching is assumed during the product's service life. The daily emission to the sewer is then calculated as follows:

$$N_{houses,leach} = N_{house} \cdot f_{house} \quad (4$$

$$Q_{leach} = AREA \cdot V_{form} \cdot F_{form} \cdot RHO_{form} \cdot 10^{-3} \quad (5$$

$$E_{local} = \frac{(N_{house,leach} \cdot Q_{leach})}{T_{servicelife}} \quad (6$$

where:

- $N_{house,leach}$ number of houses that are contributing by leaching (-);
- $T_{service\ life}$ service life (d, see Table 2);
- N_{house} number of houses in a city (4000);
- f_{house} fraction of the houses on which paints, plasters, or fillers are applied (1.0, unless sufficiently substantiated with tonnage data);
- Q_{leach} cumulative leaching (100%) over the assessment period (kg/m²);
- AREA area of the treated surface per house (m², see Table 2);
- V_{form} volume of the product applied (m³, see Table 2);
- F_{form} fraction of the active substance in product (-);
- RHO_{form} density of the product (kg/m³, see Table 2);
- E_{local} daily emission to the sewer (kg/d).

Note that the initial and longer assessment period are not separately assessed, because it was assumed that leaching rates for both the initial and longer assessment period are the same. Although this may underestimate leaching from recently treated objects, the total emission is likely overestimated as actual leaching rate for the longer assessment period is expected to be slower. The proposed worst case assumption assumed that leaching rates do not change in time. Table 2 summarise the proposed defaults for service life, i.e. the time over which emission should be assessed.

Table 2. Service life and amount of houses that contributes to leaching for the situation when no leaching data is available

application	service life (d) ($T_{service\ life}$)	area (m²) (AREA)	density (kg/m³) (RHO_{form})	volume applied (L/m²) (V_{form})
Indoor applications				
joint fillers (bathroom)	3650	0.24	1900	0.42
sealants (bathroom)	3650	0.12	1000[1]	5.88
Outdoor applications				
paints applied on façade	1825	125	1400	0.25[2,3]
paints applied on window and door frames	1825	5.57	1400	0.25
plasters applied on façades outdoors	9125	125	1000[1]	4.0
joint sealants applied outdoors	1825	0.31	1000[1]	5.88
joint fillers applied outdoors	9125	35	1900	2.8
Roof membranes	See 'Use-based approaches for the estimations of environmental exposure in case of roof membranes' discussed during TMII-2013.			

1 The dose is already in kg/m². Therefore the density was set to 1000 kg/m³;
2 Two layers;
3 It was demonstrated that this value covers 85% of the paints.

Application phase
Significant release to the STP may occur during the application of a product to which preservatives are added. The daily release during application is calculated as follows:

$$E_{local} = AREA_{house} \cdot V_{form} \cdot F_{form} \cdot RHO_{form} \cdot F_{brush} \cdot N_{house,applic} \cdot 10^{3} \quad (7$$

where:
- E_{local} daily emission to the sewer (kg/d);
- AREA area of the treated surface per house (m², see Table 2);
- V_{form} volume of the product applied (m³, see Table 2);
- F_{form} fraction of the active substance in product (-);
- RHO_{form} density of the product (kg/m³, see Table 2);
- F_{brush} fraction of product lost during application (0.03 for professionals and 0.05 for non-professionals);
- $N_{house,applic}$ number of houses treated per day (see below).

The number of houses treated daily depends on the service life of the product. For paints and joint sealants having a service life of 5 years 800 houses are treated annually when assuming that the product is applied on 100% of the houses in a city. Although this may suggest that 2.2 houses are painted daily, $N_{house,applic}$ have to be three houses per day to compensate for days that are not suitable for painting because of the temperature and/or precipitation. For all other products $N_{house, applic}$ is one.

References

- Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances; Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Part II. European Commission Joint Research Centre, EUR 20418 EN/2, Ispra, Italy, 2003.
- Struijs J. SimpleTreat 3.0: a model to predict the distribution and elimination of chemicals by sewage treatment plants. National Institute for Human Health and the Environment. RIVM report 719101025, Bilthoven, The Netherlands, 1996.
- Revised Emission Scenario Document for Wood Preservatives. Draft 2013. OECD Series on Emission Scenario Documents. Organisation for Economic Co-operation and Development, Paris.
- Proposal for the assessment of direct emission to surface water (PT 7, 9, 10). Proposal by DE discussed at TMII-2013.
- Use-based approaches for the estimation of environmental exposure in case of roof membranes (PT 9). Proposal by DE discussed at TMII-2013.