**October 2020**

Following an application for a minor change, the authorisation of Tanalith E 3462 was changed with respect to the application rate for UC 4 reads for use class 4 niche use (transmission poles) to 15.3 - 44.44 kg/m3.

**October 2018**

Following an application for a major change, the authorisation of Tanalith E 3462 was changed with respect to the active substance (replacement of basic copper carbonate with granulated copper).

We refer to the file: ‘Addendum to PAR October 2018’

**November 2017**

Following submission of post-authorisation data by the authorisation holder (shelf life study), and evaluation by the eCA Netherlands, the provisional shelf life claim of 2 years was confirmed.

We refer to the file ‘Changes and amendments November 2017’.

**September 2017**

Following an application for an administrative change, new manufacturers for the active substance propiconazole were added.

**April 2015**

Following an administrative change by the evaluating competent authority (correction), the authorisation number NL-0008998-0000 was assigned and an additional manufacture for the active substance propiconazole was added.

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: | 3rdof 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

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# General information about the product application

## 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 |

### 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 |
| **Fax:** | N/a |
| **E-mail address:** | timberprotectionadvice.ukca@lonza.com |

## Current authorisation holder

Product is currently not auhorised in the Netherlands.

## 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 |

## 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 |

## Information about the biocidal product

### 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 Regulation 528/2012 (yes/no):** | No |

### 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/m3  for use class 4: 15.3 - 27.8 kg/m3  for use class 4 niche use (transmission poles): 15.3 - 44.44 kg/m3  \*For use in railway sleepers (UC3), UC4 retentions (up to 27.8 kg/m3) 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. |
|  |  |

### 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. |

### 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 |

## Documentation

### 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.

### 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.

# Summary of the product assessment

## 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.

## Classification, labelling and packaging

### 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 | Signal word: | Danger |
|  | GHS07 |  | |
|  | GHS09 |  | |
| 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)

### 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.*

## 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.

### 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. 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, HDPE stability, weight change, active substance content.  See table 2.3.1-1 for more details. | Woolley, A.J., 2012a |
|  | 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: 0.177%  Tebuconazole: 0.183% | Kinematic viscosity  14.3mm2/s at 20°C  7.16mm2/s at 40°C | Woolley, A.J., 2012 |
| 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.

### 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 |

#### 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 HNO3 and water and brought into the copper calibration range, matching the 2%v/v HNO3 in reagent water of the calibration standards.

Validation data for Wolman E (CA-C)

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*

r2 = 0.9999, y = 10548x-44.564, range 0 – 20 mg Cu/L (6 concentrations)

Validation for Tanalith E 8000 and Tanalith E 9000

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 RSDr of 1.97%.

*Linearity*

r2 = 1.000, y = 1.76.107 x + 1.09.106, range 0 – 20 mg Cu/L (6 concentrations and duplicate injections at each concentration)

Conclusion

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% H3PO4

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: r2 = 1.000, y = -3.7783 x + 193.004, range 0 – 10 mg ai/L, n = 6 with duplicate injections.

Tebuconazole: r2 = 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 RSDr 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 RSDr of 3.50%.

10 replicate injections resulted in an RSD of 0.114%.

*Linearity*

Propiconazole: r2 = 1.000, y = 3.13.106 x + 4.64.105, range 0 – 24 mg ai/L, n = 10.

Tebuconazole: r2 = 1.000, y = 3.25.106 x + 1.68.105, 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.

## 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.

## Effectiveness against target organisms

### 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 product** |
| **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 application  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/m3  for use class 4: 15.3 - 27.8 kg/m3  for use class 4 niche use (transmission poles): 15.3 - 44.44 kg/m3  \*For use in railway sleepers (UC3), UC4 retentions  (up to 27.8 kg/m3) 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 |

### 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.

### 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**

|  |  |  |  |
| --- | --- | --- | --- |
| **Test method** | **Test organism** | **Test results** | **Ref.** |
| EN47 +EN73 | Larvae of *Hylotrupes bajulus* beetle | % mortality at 0 kg/m3 copper (untreated): 3.4%  % mortality at upper toxic value 0.31 kg/m3 copper: 100%  Biol. ref. value: 0.31 kg/m3 copper (equivalent to 3.4 kg/m3 Tanalith E 3462) | B5.10-1 |
| EN47 +EN84 | Larvae of *Hylotrupes bajulus* beetle | % mortality at 0 kg/m3 copper (untreated): 14%  % mortality at upper toxic value 0.31 kg/m3 copper: 100%  Biol. ref. value: 0.31 kg/m3 copper (equivalent to 3.4 kg/m3 Tanalith E 3462) | B5.10-2 |
| EN117 + EN73 | Termites *Reticulitermes santonensis* | Visual assessment at 0 kg/m3 copper (untreated): 4 – 4 – 4  Visual assessment at upper toxic value 0.93 kg/m3: 1 – 0 – 0  Biol. ref. value: 0.93 kg/m3 copper (equivalent to 10.3 kg/m3 Tanalith E 3462) | B5.10-3 |
| EN117 + EN84 | Termites *Reticulitermes santonensis* | Visual assessment at 0 kg/m3 copper (untreated): 4 – 4 – 4  Visual assessment at upper toxic value 0.95 kg/m3: 1 – 0 – 0  Biol. ref. value: 0.95 kg/m3 copper (equivalent to 10.6 kg/m3 Tanalith E 3462) | B5.10-4 |
| EN113 + EN73 | Brown rot fungi **-** *Coniophora puteana*  *- Gloeophyllum trabeum*  *- Poria placenta*  White rot fungi *- Coriolus versicolor* | Lower and upper toxic values (kg/m3 as copper) for individual basidiomycete test fungi:   |  |  |  |  | | --- | --- | --- | --- | |  | Lower toxic value kg/m3 copper | Upper toxic value kg/m3 copper | Mass loss at lower toxic threshold (%) | | *Coniophora puteana* | 0.40 | 0.57 | 2.5 | | *Gloeophyllum trabeum* | - | 0.39 | - | | *Poria placenta* | 0.57 | 0.79 | 4.2 | | *Coriolus versicolor* (pine) | - | - | - | | *Coriolus versicolor* (beech) | 0.37 | 0.60 | 6.7 |   Biol. ref. value (incl white rot): 0.68 kg/m3 copper, equivalent to 7.6 kg/m3 Tanalith E 3462 | B5.10-5 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| EN113 + EN84 | Brown rot fungi **-** *Coniophora puteana*  *- Gloeophyllum trabeum*  *- Poria placenta*  White rot fungi *- Coriolus versicolor* | Lower and upper toxic values (kg/m3 as copper) for individual basidiomycete test fungi:   |  |  |  |  | | --- | --- | --- | --- | |  | Lower toxic value kg/m3 copper | Upper toxic value kg/m3 copper | Mass loss at lower toxic threshold (%) | | *Coniophora puteana* | - | 0.40 | - | | *Gloeophyllum trabeum* | 0.40 | 0.57 | 4.2 | | *Poria placenta* | 0.40 | 0.57 | 5.4 | | *Coriolus versicolor* (pine) | - | 0.40 | - | | *Coriolus versicolor* (beech) | 0.38 | 0.59 | 13.1 |   Biological reference values according to EN 599-1:  For brown rot (and white rot in softwood): 0.49 kg/m3 copper, equivalent to 5.4 kg/m3  Including white rot in hardwood: 0.59 kg/m3 copper, equivalent to 6.6 kg/m3 | B5.10-6 |
| ENV807 + EN84 | Unsterile soil with soft rot fungi (species not specified) | 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):   |  |  |  |  | | --- | --- | --- | --- | | Test product | Product retention kg/m3 | Mean loss in mass (%) | | | 24 weeks | 32 weeks | | Copper/ chromium reference preservative | 1. 0.7 | 1. 1.3 | 1. 4.2 | | X1185 | 1. 0.0\* | 1. 10.6 | 1. 14.3 | | 1. 0.13\* | 1. 2.1 | 1. 2.8 |   \* as copper  Biol. ref. values according to EN 599-1 (equivalent to the nominal effective retention calculated in accordance with ENV 807): 1.38 kg/m3 copper, equivalent to 15.3 kg/m3 Tanalith E 3462 | B5.10-7 |

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/m3 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/m3 and in UC3 and 4 a retention of 10.6 kg/m3 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/m3 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/m3 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/m3 | 3.4 kg/m3 | 3.4 kg/m3 |
| Termites (*Reticulitermes spp.*) | 10.3 kg/m3 | 10.6 kg/m3 | 10.6 kg/m3 |
| Brown and white rot fungi | 7.55 kg/m3 | 7.55 kg/m3 | 7.55 kg/m3 |
| Soft rot fungi | - | - | 15.3 kg/m3 |
| Intended retention on label | 7.6 – 16.67 kg/m3 | 7.6 – 16.67 kg/m3 | normal use: 15.3 – 27.8 kg/m3  transmission poles: 15.3 - 44.44 kg/m3 |

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/m3) 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/m3) are the minimum retention rates for the product in this use class, but for use in transmission poles a higher retention rate may be 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 for this application rate is set at 15.3 - 44.44.kg/m3.

### Dose / mode of action / known limitations / resistance

#### Dose

Table 2.5.4.1.1 Application and retention rates in the analytical zone (kg/m3) for the claimed target organisms and use classes

|  |  |  |  |
| --- | --- | --- | --- |
| **Use class** | **Target organisms** | **Application rate (% w/v)** | **Retention rate in the analytical zone (kg/m3)** |
| 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 | 15.3 - 44.44 |

\*Please note that for use in railway sleepers (UC3), UC4 retentions (up to 27.8 kg/m3) are recommended.

#### Mode of action

Copper  
It is known that the biologically active ion derived from the use of copper oxide and copper carbonate is Cu2+ 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 Cu2+ 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.

#### 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]](#footnote-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 (**d**e**m**ethylation **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, 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.

## Exposure assessment

### 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/m3

for use class 4: 15.3 - 27.8 kg/m3

for use class 4 niche use (transmission poles): 15.3 - 44.44 kg/m3

Please note that for use in railway sleepers (UC3), UC4 retentions (up to 27.8 kg/m3) are recommended.

### Assessment of exposure to humans and the environment

#### 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.

#### 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.

## 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.

### Hazard potential

#### 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.

#### 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/m3 (1 ppm) 8h-TWA value and the 7.6 mg/m3  (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”

#### 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 (LD50) 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 LD50 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”

### 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 /m3 | | 16.67 | 27.77 | 44.44 |
| Solution uptake (l/m3)\*\*\* | | 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/m3) | 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/professional use** | **General public**  ***Non-primary professional and non-professional use and consumers*** | **Via the environment** |
| Inhalation | Yes | Yes | Yes | No |
| Dermal | Yes | Yes | Yes | No |
| Oral | No | No | Yes | No |

#### 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/m3. 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 AELlong-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 AELlong-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/m3 in-use product. The indicative Exposures (Water based) are: hands 1080 mg/cycle, body 8570 mg/cycle and inhalation 1.9 mg/m3.

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  clothing, no  RPE | **UC4 Normal use** | **Copper** | 0.032 | 0.041 | 78.0 |
|  | **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/m3; 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/m3. 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”.

#### 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:

Acute exposure

Adults (consumers) - Acute handling, cutting and sanding treated timbers Infants - Acute chewing preserved timber off-cuts

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.

*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/cm2 (as agreed for copper in the WPCTF dossier with a copper loading of 3.42 kg/m3; worst case for the copper loading of 2.5 kg/m3 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 cm2

Dislodgeable copper = 48 cm2 x 0.002 mg/cm2 = 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/m3)** | **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/m3)** | **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.

#### 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 cm2,. 2.5 mg/cm3 copper or 0.05 mg/cm3 propiconazole or 0.05 kg.cm3 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/m3 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/m3 for UC3, which assumes 100 % sapwood and is unrealistic, additional calculations have been carried out using a value of 200 l/m3 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 (m2)** | **Wood consumption (m3/d)** | **Tongue surface area (m2)** | **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./m3) 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/m3 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/m3 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/m3 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/m3 (1 ppm) 8h-TWA value and the 7.6 mg/m3  (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.

Mixing and loading

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/m3 (1 ppm) 8h-TWA value and the 7.6 mg/m3  (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.

Application phase and post-application phase

The worker exposure limit of 2.5 mg/m3 (1 ppm) 8h-TWA value and the 7.6 mg/m3  (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 AELof 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.

### 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.

#### 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’.

#### 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

#### 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.

## Risk assessment for the environment

### 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 inthe 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

### Exposure Assessment

#### 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)](#bookmark66) 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 /m3 | | 16.67 | 27.77 | 44.44 |
| Solution uptake (l/m3)\*\*\* | | 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/m3) | 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.

#### 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.

Use class 3: Wood exposed to weather, but not directly in contact with water or soil

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/m3, 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/m3)** | | **Cumulative leaching (mg/m2)** | | **Daily leach rate (mg/m2/day)** | |
| **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/m3 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 inTable 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/m3)** | | **Cumulative leaching (mg/m2)** | | **Daily leach rate (mg/m2/day)** | |
| **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/m3 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/m3 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/m3, 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)](#bookmark76). 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/m2/day)** | **Cumulative Leaching rate**  **(mg/m2/day)** |
| *10 years exposure* | | |
| Copper  Tebuconazole  Propiconazole | 0.447 0.0182 0.0298 | 1631.55 66.43 108.77 |
| *20 years exposure* | | |
| Copper  Tebuconazole  Propiconazole | 0.2418 0.0107 0.0172 | 1765.14 78.11 125.56 |
| *20 – 60 years exposure* | | |
| Copper  Tebuconazole  Propiconazole | 0.0147 0.0014 0.002 | 214.62 20.44 29.2 |
|  | | |
| *60 years exposure\** | | |
| Copper  Tebuconazole  Propiconazole | 0.0904 0.0045 0.0071 | 1979.76 98.55 154.76 |

\* 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)](#bookmark76) 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 |

### 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 m³/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 m2 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

### Predicted environmental concentrations

#### 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:



where:

C(t) the concentration in the concerning compartment at time t;

Eleach 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);

Cini 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).

#### 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 (Koc). 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.

#### 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.

#### 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).

#### 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.

#### 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.

### 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).

#### 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.

#### 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 |
| 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 .

#### IN-SERVICE USE

##### Soil compartment

Metabolite 1,2,4-triazole

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 |
| 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/m3 for the above soil part of the pole and the UC4 retention rate of 2.5 kg Cu/m3 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/m3 is a factor 1.6 higher than the actual retention rate of 2.5 kg Cu/m3 for UC4 and a factor 2.8 higher than the actual retention rate of 1.43 kg Cu/m3 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/m3 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 |
| 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/m3 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.

##### 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** | **PECsoil** | **PEClocalsoil 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/ m² lost in a 5 year period of 1 g propiconazole/ m² 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/m2 treated wood which is significantly greater than the 0.023 g tebuconazole/m2 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 | m2 |
| 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 m2 of treated wood over an initial assessment period | Qleach\*,time1 | 5.79E-07 | 5.14E-07 | kg/m2 |
| Cumulative quantity of a.s. leached out of 1 m2 of treated wood over a longer assessment period | Qleach\*,time2 | 2.27E-05 | 2.42E-05 | kg/m2 |
| 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 (Qleach,time1/TIME1)\*365] | PEARLAnnum,time1 | 0.03082 | 0.02736 | kg/ha/year |
| PEARL applications per year (Qleach,time2/TIME2) | PEARLAnnum,time2 | 0.00497 | 0.00529 | kg/ha/year |
| PEARL applications per application [PEARLAnnum,time 1/10] | PEARLApplic,time1 | 0.00308 | 0.00274 | kg/ha/appl. |
| PEARL applications per application [PEARLAnnum,time 2/10] | PEARLApplic,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:

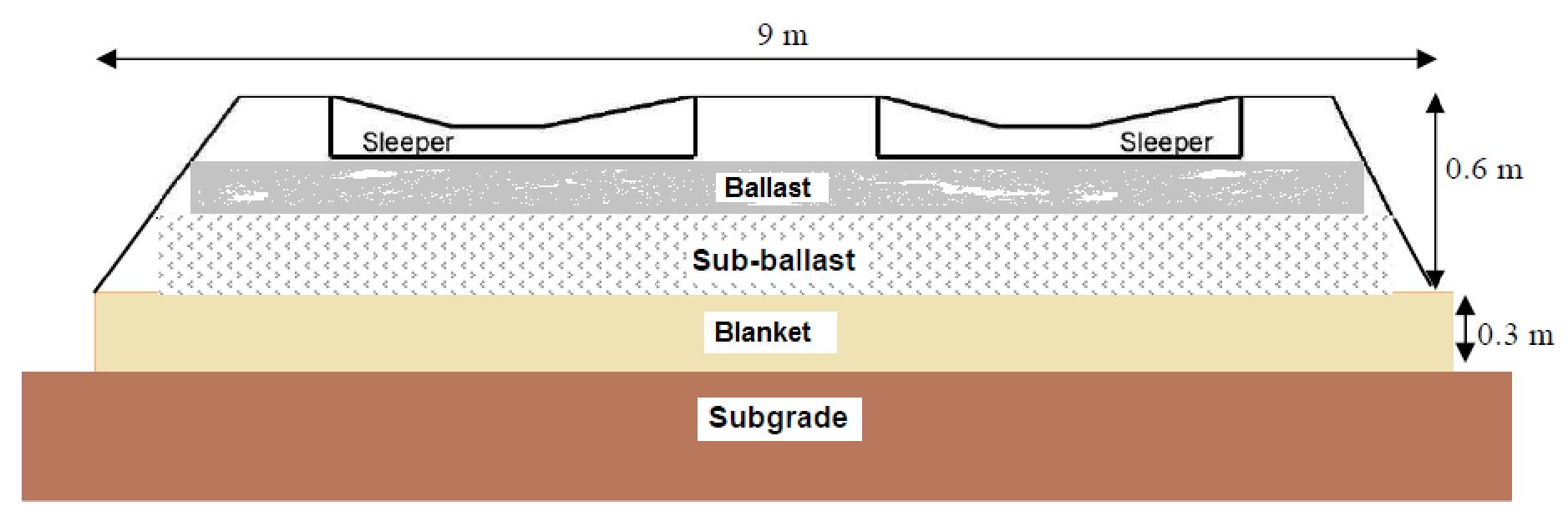
* Service life of industrially pre-treated wooden railway sleepers (UC3)
* Soil beneath ballast is considered to be part of the techno sphere, the receiving environmental compartment covered by the scenario is therefore groundwater
* Two railway lines crossing a field of one hectare
* Models under discussion 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 | m2 |
| Number of sleepers in a rectangular field of 1 hectare | Nsleepers | 2583 | 2583 | 2583 | /ha |
| Duration of the initial assessment period | 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 m2 of treated wood over an initial assessment period | Q\*leach,time1 | 7.43E-04 | 3.12E-05 | 2.66E-05 | kg/m2 |
| Cumulative quantity of a.s. leached out of 1 m2 of treated wood over a longer assessment period | Q\*leach,time2 | 1.77E-03 | 1.26E-04 | 7.81E-05 | kg/m2 |
| Cumulative quantity of a.s. leached over the initial assessment period on one hectare | 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.

##### 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.

##### 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.

Jetty in the lake and sheet piling in the waterway

**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 |
| **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.

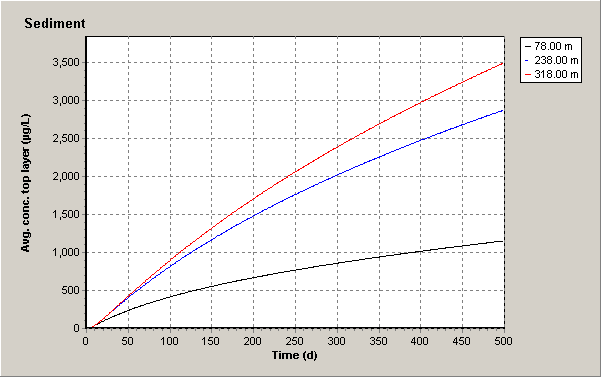
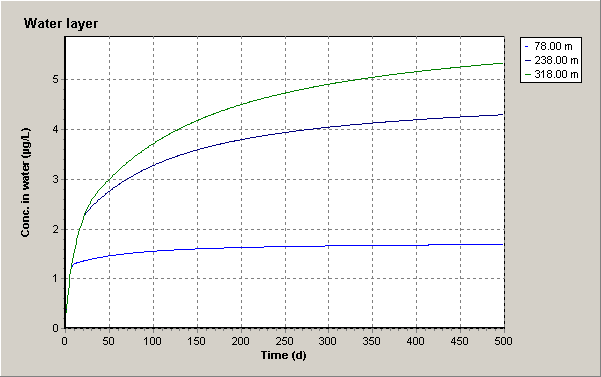
The TOXSWA 1.0 model represents emission to a standard Dutch ditch of one meter width, 30 cm deep, and 320 m long where water flows with 10 m/d. To simulate sheet pilings on both sides, the ditch’s dimensions were adjusted as follows:

* 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/m²/d which is applied to the water surface for 500 successive days (maximum number of events). The organic matter-water partition coefficient (Kom, 175440 L/kg) was derived from the measured partition coefficient between water and suspended matter (Kp) 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.

##### 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.

## 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.

# 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.

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. [↑](#footnote-ref-1)