

Product Assessment Report

AXIL 2000

Augustus 2016, updated 2018

|  |  |
| --- | --- |
| R4BP ref. no: BC-MX019838-96 |  |
| Authorisation/Registration no: BE2015-0017 |  |
| Granting date/entry into force of authorisation/ registration: |  |
| Expiry date of authorisation/ registration: 31/07/2020 |  |
| Active ingredient: Propiconazole,Tebuconazole, IPBC |  |
| Product type: 8 |  |

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

Contents

[1 General information about the product application 4](#_Toc411506208)

[1.1 Applicant 4](#_Toc411506209)

[1.1.1 Person authorised for communication on behalf of the applicant 4](#_Toc411506210)

[1.2 Current authorisation holder 4](#_Toc411506211)

[1.3 Proposed authorisation holder 4](#_Toc411506212)

[1.4 Information about the product application 5](#_Toc411506213)

[1.5 Information about the biocidal product 5](#_Toc411506214)

[1.5.1 General information 5](#_Toc411506215)

[1.5.2 Information on the intended use(s) 5](#_Toc411506216)

[1.5.3 Information on active substance(s) 9](#_Toc411506217)

[1.5.4 Information on the substance(s) of concern 10](#_Toc411506218)

[1.6 Documentation 11](#_Toc411506219)

[1.6.1 Data submitted in relation to product application 11](#_Toc411506220)

[1.6.2 Access to documentation 11](#_Toc411506221)

[2 Summary of the product assessment 11](#_Toc411506222)

[2.1 Identity related issues 11](#_Toc411506223)

[2.2 Classification, labelling and packaging 13](#_Toc411506224)

[2.2.1 Harmonised classification of the biocidal product 13](#_Toc411506225)

[2.2.2 Labelling of the biocidal product 13](#_Toc411506226)

[2.2.3 Packaging of the biocidal product 14](#_Toc411506227)

[2.3 Physico/chemical properties and analytical methods 14](#_Toc411506228)

[2.3.1 Physico-chemical properties 14](#_Toc411506229)

[2.3.2 Analytical methods 21](#_Toc411506230)

[2.4 Risk assessment for Physico-chemical properties 23](#_Toc411506231)

[2.5 Efficacy 23](#_Toc411506232)

[2.5.1 Function and Field of Use Envisaged 23](#_Toc411506233)

[2.5.2 Effects on Target Organisms 24](#_Toc411506234)

[2.5.3 Discussion and conclusion 27](#_Toc411506235)

[2.5.4 Mode of Action 29](#_Toc411506236)

[2.5.5 Occurance of resistance 29](#_Toc411506237)

[2.6 Exposure assessment 30](#_Toc411506238)

[2.6.1 Description of the intended use(s) 30](#_Toc411506239)

[2.6.2 Assessment of exposure to humans and the environment 30](#_Toc411506240)

[2.7 Risk assessment for human health 97](#_Toc411506241)

[2.7.1 Hazard potential 97](#_Toc411506242)

[2.7.2 Exposure 106](#_Toc411506243)

[2.7.3 Risk Characterisation 106](#_Toc411506244)

[2.7.4 Summary of the Human Health Risk Assessment 113](#_Toc411506245)

[2.8 Risk assessment for the environment 114](#_Toc411506246)

[2.8.1 Effects Assessment 114](#_Toc411506247)

[2.8.2 Exposure Assessment. 114](#_Toc411506248)

[2.8.3 Risk Characterisation for the environment 114](#_Toc411506249)

[2.8.4 Summary of the Environmental Risk Assessment 118](#_Toc411506250)

[2.9 Substitution/Exclusion criteria and Comparative assessment 118](#_Toc411506251)

[2.9.1 Active substances in the biocidal product and criteria for substitution and exclusion 118](#_Toc411506252)

[2.9.2 Screening phase of comparative assessment 119](#_Toc411506253)

[2.9.3 Conclusion on comparative assessment 122](#_Toc411506254)

[2.10 Measures to protect man, animals and the environment 122](#_Toc411506255)

[2.10.1 Applicant’s proposal 122](#_Toc411506256)

[2.10.2 Comments and conclusion 126](#_Toc411506257)

[3 Proposal for decision 127](#_Toc411506258)

[3.1 Summary of use conditions and restrictions for Axil 2000 127](#_Toc411506259)

[3.2 Necessary issues accounted for in the product label 129](#_Toc411506260)

[3.3 Requirement for further information 130](#_Toc411506261)

[Annex 1: Summary of Product Characteristics (SPC) 132](#_Toc411506262)

[Annex 2: Confidential Annex to PAR 142](#_Toc411506285)

[Annex 3: List of documents/studies provided in support of Axil 2000 143](#_Toc411506291)

[Annex 4: Toxicology and metabolism – active substance(s) 147](#_Toc411506292)

[Annex 5: Toxicology – Biocidal Product 150](#_Toc411506299)

[Annex 6 Safety for professional operators 151](#_Toc411506301)

# General information about the product application

## Applicant

|  |  |
| --- | --- |
| **Company Name:** | BERKEM SAS |
| **Address:** | Marais Ouest |
| **City:** | Gardonne |
| **Postal Code:** | F-24680 |
| **Country:** | France |
| **Telephone:** | +33 5 53 63 81 00 |
| **Fax:** | +33 5 53 63 81 25 |
| **E-mail address:** | reglementation@berkem.com |

### Person authorised for communication on behalf of the applicant

|  |  |
| --- | --- |
| **Name:** | Mr CUBIZOLLES Laurent |
| **Function:** | Regulatory affairs manager |
| **Address:** | Marais Ouest |
| **City:** | Gardonne |
| **Postal Code:** | F-24680 |
| **Country:** | France |
| **Telephone:** | +33 5 53 63 81 00 |
| **Fax:** | +33 5 53 63 81 25 |
| **E-mail address:** | reglementation@berkem.com |

## Current authorisation holder[[1]](#footnote-1)

|  |  |
| --- | --- |
| **Company Name:** | BERKEM SAS |
| **Address:** | Marais Ouest |
| **City:** | Gardonne |
| **Postal Code:** | F-24680 |
| **Country:** | France |
| **Telephone:** | +33 5 53 63 81 00 |
| **Fax:** | +33 5 53 63 81 25 |
| **E-mail address:** | reglementation@berkem.com |

## Proposed authorisation holder

|  |  |
| --- | --- |
| **Company Name:** | BERKEM SAS |
| **Address:** | Marais Ouest |
| **City:** | Gardonne |
| **Postal Code:** | F-24680 |
| **Country:** | France |
| **Telephone:** | +33 5 53 63 81 00 |
| **Fax:** | +33 5 53 63 81 25 |
| **E-mail address:** | reglementation@berkem.com |

## Information about the product application

|  |  |
| --- | --- |
| **Application received:** | 15/09/2015 |
| **Application reported complete:** | 10/11/2015 |
| **Type of application:** | Major change on request |
| **Further information:** | - |

## Information about the biocidal product

### General information

|  |  |
| --- | --- |
| **Trade name:** | AXIL 2000 |
| **Manufacturer’s development code number(s), if appropriate:** | Lab 2012\_006 |
| **Product type:** | PT8 (wood preservative) |
| **Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex/R4BP):** | Propiconazole : 0,75 %  Tebuconazole : 0,75 %  IPBC : 0,75 % |
| **Formulation type:** | Microemulsion (ME) |
| **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 directive 98/8/EC (yes/no);**  **If yes: authorisation/registration no. and product name:**  **or**  **Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):** | No  No |

### Information on the intended use(s)

|  |  |
| --- | --- |
| **Overall use pattern (manner and area of use):** | Wood preservative intended to preventive treatment of construction wood UC3 against brown rotting fungi and to preventive treatment of fresh-cut wood against sapstain and moulds. The intended ways of application : automated spraying, flow-coating (deluge) and dipping. The product is for industrial use only.  Under following conditions: biocidal product diluted at 5% w/w, applied by dipping to freshly sawn timber, the product is authorised in treatment of wood which will be used in materials intended to come into indirect contact with food and/or feeding stuff. |
| **Target organisms:** | * Brown rot fungi. It acts against wood destroying fungi (basidiomycete fungi, e.g. *Coniophora puteana*, *Gloeophyllum trabeum* and *Poria placenta*.) * Sapstain and moulds. It acts against sapstain and moulds on fresh-cut wood |
| **Category of users:** | For industrial use only |
| **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:** | * For UC3 efficacy: Axil 2000 is used at a 10 % dilution. The product is intended to be used by automated spraying and flow coating (deluge) at an application rate of 120 g/m² (15 L/m³) RTU product (at 1/10 dilution) * For sapstain and moulds efficacy: Axil 2000 is used at a 5 % dilution. The product is intended to be used by immersion during 20 sec minimum. |
| **Potential for release into the environment (yes/no):** | Yes |
| **Potential for contamination of food/feedingstuff (yes/no)** | No. Axil 2000 is not used on materials which are in direct contact with food and/or feeding stuff. |
| **Proposed Label according to Dir. 99/45 EC** | Xi : Irritating (symbol)  N : Dangerous for the environment (symbol)  R43: May cause sensitisation by skin contact.  R51/53 : Harmful to aquatic organisms, may cause long term adverse effects in the aquatic environment  S23: Do not breath mist/spray  S24: Avoid contact with skin.  S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  S36/37/39: Wear suitable protective clothing/gloves/eye protection  S51: Use only in well-ventilated areas  S60: This material and its container must be disposed of as hazardous waste.  S61: Avoid release to the environment. Refer to special instructions/safety data sheets |
| **Proposed Label according to Regulation (EC) 1272/2008** | Pictogram GHS07, GHS09  Signal word: warning  Skin Sens. cat. 1  Aquatic chronic cat. 2  H317: May cause an allergic skin reaction  H411: Toxic to the aquatic life with long lasting effects  P280: protective gloves/protective clothing/eye protection/face protection  P261: Avoid breathing mist/spray  P302+P352: ON SKIN: Wash with soap and water  P333+P313: If skin irritation or a rash occurs: Get medical advice/attention  P273: Avoid release to the environment  P391: collect spillage  P501: Dispose of contents and container in accordance with all local, regional, national and international regulations |
| **Use Restrictions:** | * White rot fungi claim is not part of this application (eff report) * For industrial use only (eff report, tox report) * A top coat is required after treatment with Axil 2000 (eff). The coat should be a top-coat which does not contain biocides. This top-coat has to be stable under the standard EN 927-2 in order to limit biocide leaching all along the service-life of wood. * Due to the presence of tebuconazole, the use of Axil 2000 for treatment of wood inside housing areas (with the exeption of window frames and external doors) is not recommended (see CAR for inclusion on to Annex I doc. 1- p.6) * Appropriate and suitable PPE has to be used by professionals. Risk for professional users is unlikely when appropriate PPE is used (gloves, impermeable coverall). Please se the confidential version for more details. * No risks associated with industrial application and storage have been considered and it is assumed that RMM such as bunding and recycling / collection of waste will ensure no   losses.  Application processes and storage of freshly treated wood at industrial sites and joineries must be carried out within a contained area:  • Situated on impermeable hard standing,  • With bunding to prevent run-off and  • A recovery system in place  Such measures to ensure collection of leachate for recycling or  appropriate disposal as hazardous waste will prevent losses to soil, STP and surface water.  Material and/or container must be disposed of as hazardous waste.   * The treated wood cannot be in contact with livestock. So the product should not be used to treat wood of stables, cages and fences in contact with livestock |

### Information on active substance(s)[[2]](#footnote-2)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Active substance chemical name:** | Propiconazole | | Tebuconazole | IPBC | |
| **CAS No:** | 60207-90-1 | | 107534-96-3 | 55406-53-6 | |
| **EC No:** | 262-104-4 | | 403-640-2 | 259-627-5 | |
| **Purity (minimum, g/kg or g/l):** | 930 g/kg | | 950 g/kg | 980 g/kg | |
| **Inclusion directive:** | 2008/78/EC | | 2008/86/EC | 2008/79/EC | |
| **Date of inclusion:** | 1/04/2010 | | 1/04/2010 | 1/07/2010 | |
| **Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):** | Yes | | yes | yes | |
| **Manufacturer of active substance(s) used in the biocidal product:** |  | | | | |
| **Company Name:** | Lanxess Deutschland GmbH, Industrial & Environmental Affairs | Syngenta Crop Protection AG | Lanxess Deutschland GmbH, Industrial & Environmental Affairs | Lanxess Deutschland GmbH, Industrial & Environmental Affairs | Troy Chemicals Company BV |
| **Address:** | Kennedyplatz 1 | - | Kennedyplatz 1 | Kennedyplatz 1 | Uiverlaan 12e – P.O. Box 132 |
| **City:** | Koln | Monthey | Koln | Koln | Maassluis |
| **Postal Code:** | 50569 | 1870 | 50569 | 50569 | 3140 AC |
| **Country:** | Germany | Switzerland | Germany | Germany | Netherlands |
| **Telephone:** | +49.2143065109 | +41(0)61.323.71.70 | +49.2143065109 | +49.2143065109 | +31.105927494 |
| **Fax:** | +49.2143034143 | - | +49.2143034143 | +49.2143034143 | +31. 105928877 |
| **E-mail address:** | - | - | - | - | - |
|  |  |  |  |  |  |

### Information on the substance(s) of concern

The full composition of the biocidal product, including the non-active ingredients is provided in R4BP and in the Member State Confidential Annex to this PAR.

Apart from the active substances, the biocidal product contains dangerous substances at a concentration of non-relevance for the classification/labelling of Axil 2000 and no further consideration has to be given. Please se the confidential version for more details.

No substances of concern that required evaluation have been identified in the formulation.

## Documentation

### Data submitted in relation to product application

No new data on the active substances have been submitted in relation to the product application.

Data for the relevant formulation has been submitted on physical-chemical properties, efficacy, toxicological properties and leaching data has been submitted with the product application. All these data have been evaluated.

In the aim to defend the application for major change “The treatment of wood which will be used in materials intended to come into indirect contact with food and/or feeding stuff” the applicant has submitted a report of monitoring the emission transfer of active substances to foodstuffs during storage on pallets treated with the biocidal product.

### Access to documentation

The applicant has submitted for each active ingredient a letter of access of the data owners.

Lanxess Deutschland GmbH has granted the right to reference the proprietary data on propiconazole as used for the annex I inclusion of propiconazole. Lanxess Deutschland GmbH has taken over the business from Janssen Pharmaceutica NV, who owned the data used for Annex I inclusion of propiconazole.

Syngenta Crop Protection AG has granted access to the studies owned by Syngenta and filed in support of the BPD registration of propiconazole.

A letter of Access to the BPD 98/8/EC dossier of IPBC, including all underlying studies and reports, is granted from Troy Chemicals Company BV to the applicant Berkem SAS for support of the product dossier of Axil 2000.

A letter of Access to the BPD 98/8/EC dossier tebuconazole, including all underlying studies and reports, is granted from Lanxess Deutschland Gmbh to the applicant Berkem SAS for support of the product dossier of Axil 2000.

These Letters of Access are valid for the Belgian market and have been submitted to the Belgian CA.

# Summary of the product assessment

## Identity related issues

Axil 2000 is a fungicidal wood preservative. It is a waterbased microemulsion containing the active ingredients tebuconazole, propiconazole and IPBC each at the individual concentration of 0,75 %.

The active concentrates used in the formulation of Axil 2000 are:

* Preventol MP 100, which contains the active ingredient IPBC identified at Annex I of the BPD;
* Wocosen Technical, which contains the active ingredient propiconazole identified at Annex I of the BPD;
* Preventol A8, which contains the active ingredient tebuconazole identified at Annex I of the BPD

The manufacture and manufacturing sites for the production of the active ingredients are the same as those evaluated during Annex I inclusion.

As these active concentrates are exactly identical as these identified at Annex I, the Belgian CA believe that there are no issues raised regarding the technical equivalence of the active ingredients.

Please se the confidential version for more details on the composition.

The following information was provided which the Belgian CA believe are sufficient to identify these substances:

* the applicant provided the SDS for all non-active ingredients

The identification of the biocidal product (full composition) is given the Member State Confidential Annex to this PAR or R4BP.

## Classification, labelling and packaging

The classification/labelling of Axil 2000 is based on the classification/labelling information according tot Annex VI to Regulation (EC) N° 1272/2008, information on Safety Data Sheets and the results of the submitted (eco) toxicological studies with the biocidal product..

### Harmonised classification of the biocidal product

The proposed classification of Axil 2000 based on current classification and labelling rules is shown in the following tables.

**Table 2.2.1-1: Classification according to Directive 1999/45/EC:**

|  |  |
| --- | --- |
| **Category of danger:** | Xi : Irritating  N : Dangerous for the environment |
| **Risk phrases:** | R43: May cause sensitisation by skin contact  R51/53: Harmful to aquatic organisms, may cause long term adverse effects in the aquatic environment |

**Table 2.2.1-2: Classification according to Regulation (EC) 1272/2008:**

|  |  |  |
| --- | --- | --- |
| **Category of danger:** | Skin Sens. 1  Aquatic Chronic cat. 2 | |
| **Signal Word :** | Warning |  |
| **H Phrases:** | H317  H411 | May cause an allergic skin reaction  Harmful to the aquatic life with long lasting effects |

### Labelling of the biocidal product

The labelling of Axil 2000 according to Directive 1999/45/EC is shown in the following table:

**Table 2.2.2-1: Labelling according to Directive 1999/45/EC:**

|  |  |
| --- | --- |
| **Category of danger:** | Irritating  Dangerous for the environment |
| **Danger symbol(s)** | Xi.  N |
| **Risk phrases:** | R43: May cause sensitisation by skin contact.  R51/53 : Harmful to aquatic organisms, may cause long term adverse effects in the aquatic environment |
| **Safety phrases:** | S23: Do not breath mist/spray  S24: Avoid contact with skin.  S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  S36/37/39: Wear suitable protective clothing/gloves/eye protection  S51: Use only in well-ventilated areas  S60: This material and its container must be disposed of as hazardous waste.  S61: Avoid release to the environment. Refer to special instructions/safety data sheets. |

The labelling of Axil 2000 according to Regulation (EC) N° 1272/2008 is shown in the following table:

**Table 2.2.2-2: Labelling according to Regulation (EC) N° 1272/2008:**

|  |  |
| --- | --- |
| **Pictogram :** | GHS07, GHS09 |
| **Signal word :** | Warning |
| **Indications of danger:** | Skin Sens. cat. 1  Aquatic Chronic cat. 2 |
| **Hazard statement** | H317: May cause an allergic skin reaction  H411: Toxic to the aquatic life with long lasting effects |
| **Precautionary statements:** | P280: protective gloves/protective clothing/eye protection/face protection  P261: Avoid breathing mist/spray  P302+P352: ON SKIN: Wash with soap and water  P333+P313: If skin irritation or a rash occurs: Get medical advice/attention  P273: Avoid release to the environment  P391: Collect spillage  P501: Dispose of contents and container in accordance with all local, regional, national and international regulations |

Based ont the information provided, the Belgian CA agrees with the proposed classification and labelling for the biocidal product.

### Packaging of the biocidal product

The product is supplied to industrial users in containers of 1000 liters.

## Physico/chemical properties and analytical methods

### Physico-chemical properties

For the physico-chemical properties of the active substances reference is made to the CAR’s of these active substances since the necessary letters of access have been supplied for propiconazole (CAS 60207-90-1), tebuconazole (CAS 107534-96-3) and IPBC (CAS 55406-53-6).

A summary of the physical and chemical properties of the biocidal product is given in table 2.3.1-1.

Table 2.3.1-1: Physico-chemical properties of the biocidal product:

| **Subsection (Annex Point/TNsG)** | | **Methods** | **Results** | **Remarks / Justification** | **GLP (Y/N)** | **Reference** |
| --- | --- | --- | --- | --- | --- | --- |
| **B3.1** | **Appearance (IIB3.1/Pt. I-B3.1)** |  | | | | |
| B3.1.1 | Physical state and nature | Visual inspection according to OPPTS 830.630 | Liquid microemulsion (ME) | / | Not Required | Please se the confidential version for more details. |
| B3.1.2 | Colour | Visual inspection according to OPPTS 830.630 | Yellow | / | Not Required | Please se the confidential version for more details. |
| B3.1.3 | Odour | Olfactory inspection according to OPPTS 830.630 | Not significant | / | Not Required | Please se the confidential version for more details |
| **B3.2** | **Explosive properties (IIB3.2/Pt. I-B3.2)** | Waived | Waived | Scientifically unjustified: The formulation does not contain any components that have explosive properties and furthermore there are no structural indications of explosivity. The formulation is an aqueous micro-emulsion and not likely to undergo exothermic reaction. | Waived | Waived |
| **B3.3** | **Oxidising properties (IIB3.3/Pt. I-B3.3)** | Waived | Waived | Scientifically unjustified: The formulation does not contain any components that have oxidative properties and furthermore there are no structural indications of oxidising potential. The formulation is an aqueous micro-emulsion obtained by mixing and therefore not likely to have oxidising properties. | Waived | Waived |
| **B3.4** | **Flash-point and other indications of flammability or spontaneous ignition (IIB3.4/Pt. I-B3.4)** |  | | | | |
| B3.4.1 | Flash point | EC A9 | > 90.2 °C | Test stopped because test substance started to boil. | Y | Please se the confidential version for more details |
| B3.4.2 | Auto-flammability | Waived | Waived | Scientifically unjustified: The formulation does not contain any components that have been classified as flammable. | Waived | Waived |
| B3.4.3 | Other indications of flammability | Waived | Waived | None | Waived | Waived |
| **B3.5** | **Acidity / Alkalinity (IIB3.5/Pt. I-B3.5)** | CIPAC MT75 | pH = 7.12  pH = 6.41 | 1 % in water, at 20 °C  Undiluted, at 20 °C | Y | Please se the confidential version for more details |
| **B3.6** | **Relative density / Bulk density (IIB3.6/Pt. I-B3.6)** | EC A3 | 1,0135 g/cm3 | At 20 °C | Y | Please se the confidential version for more details |
| **B3.7** | **Storage stability / Stability and shelf life (IIB3.7/Pt. I-B3.7)** |  | | | | |
| B3.7.1 | Effects of temperature | CIPAC MT46.3 | Stable after 14 days at 54 °C | Values of IPBC and propiconazole stay unchanged (0,72 %), tebuconazole differs 4 % (0,72 % versus 0.75 %) after 14 days. T0 acceptable. | Not Required | Please se the confidential version for more details |
| CIPAC MT39.3 | Stable after 7 days at 0 °C | Values of IPBC and propiconazole stay unchanged (0,72 %), tebuconazole differs 4 % (0,72 % versus 0.75 %) after 7 days. T0 acceptable. | Not Required |  |
| Shelf life at ambient temperature | Stable after 2 years at 25 °C | Value of IPBC stays unchanged (0.825 %), tebuconazole quasi unchanged (differs 0.14 %: 0.744 % versus 0.743 %) and propiconazole differs 1.5 % (0.68 % versus 0.69 %) after 2 years. T0 acceptable.  pHT0 = 7, pHT2years = 6.8 | Not Required |  |
| B3.7.2 | Effects of light | Waived | Waived | The product is stored and transported in the dark in order to avoid UV-light. | Waived | Waived |
| B3.7.3 | Reactivity towards container material | Waived | Waived | Polyethylene containers have been used since many years without having negative influence on the contained product. | Waived | Waived |
| B3.7.4 | Other | / | / | / | / | / |
| **B3.8** | **Technical characteristics (IIB3.8/Pt. I-B3.8)** |  |  |  |  |  |
| B3.8.1 | Wettability | - | - | Not applicable since biocidal product is not wettable. | - | - |
| Suspensibility | - | - | Not applicable since biocidal product is not water dispersable nor sprayed. | - | - |
| B3.8.2 | Wet sieve analysis | - | - | Not applicable since biocidal product is not used with spray equipment. | - | - |
| B3.8.3 | Emulsifiability | MT 36.3 | No formation of foam during the initial emulsification.  After 30 minutes and 2 hours there was respectively 17.18 ml and 10.8 ml of foam at the maximum dosage. After 30 minutes there was 11.34 ml of foam at the minimum dosage and no foam after 2 hours.  During the re-emulsification test (after 24h), it was observed formation of 21.6 ml of foam at maximum dosage and 15.14 ml of foam at the minimum dosage.   No oil, cream or solid traces were observed. | 2 concentrations were investigated: minimum dosage, corrsponding to 5% dilution and maximum dosage, corresponding to 10% dilution. | Not Required | Please se the confidential version for more details |
| B3.8.4 | Disintegration time | - | - | Not applicable since biocidal product is not a tablet and is not used in a water soluble bag. | - | - |
| B3.8.5 | Attrition / Friability of granules | - | - | Not applicable since biocidal product is not a granule nor a tablet. | - | - |
| Integrity of tablets | - | - | Not applicable since biocidal product is not a tablet nor a granule. | - | - |
| B3.8.6 | Persistence of foaming | CIPAC MT 47.2 | The amount of the persistent foaming produced after 10 seconds was 47.5 ml, 1 minutes was 43.5 ml, 3 minutes was 30.5 ml and 12 minutes was 11ml. | Applicable since biocidal product is not a ready for use product..  The test was performed on the highest in use concentration (10 % dilution). | Y | Please se the confidential version for more details |
| B3.8.7 | Flowability | - | - | Not applicable since the biocidal product is not granular. | - | - |
| Pourability | - | - | Not applicable since the biocidal product is not a suspension. | - | - |
| B3.8.8 | Dustability | - | - | Not applicable since the biocidal product is not granular. | - | - |
|  | **Additional technical properties** |  | | | | |
| B3.8.9 | Burning rate smoke generators | - | - | Not applicable since the biocidal product is no smoke generator. | - | - |
| B3.8.10 | Burning completeness smoke generators | - | - | Not applicable since the biocidal product is no smoke generator. | - | - |
| B3.8.11 | Composition smoke of smoke generators | - | - | Not applicable since the biocidal product is no smoke generator. | - | - |
| B3.8.12 | Spraying pattern aerosols | - | - | Not applicable since the biocidal product is no aerosol. | - | - |
| **B3.9** | **Compatibility with other products (IIB3.9/Pt. I-B3.9)** | - | - | Not applicable since the biocidal product does not require mixing with other products. | - | - |
| **B3.10** | **Surface tension and viscosity (IIB3.10/Pt. I-B3.10)** |  | | | | |
| B3.10.1 | Surface Tension | OECD 115 | 0.03977 Nm-1 | At 25 °C | Y | Please se the confidential version for more details |
| B3.10.2 | Viscosity | OECD 114 | 1.85 x10-6 m2 s-1  3.06 x10-6 m2 s-1 | Kinematic viscosity at 40 °C  Kinematic viscosity at 20°C | Y | Please se the confidential version for more details |
| **B3.11** | **Particle size distribution (IIB3.11/Pt. I-B3.11)** | - | - | Not applicable since the biocidal product is liquid. | - | - |

### Analytical methods

#### Formulation analysis

For propiconazole: A general analytical method for the determination of propiconazole in a water-based formulation for wood treatment (WOCOSEN 100 SL) was developed and evaluated in the Confidential Annex (B4.1/02). The HPLC-UV method was acceptable at the a.i. evaluation stage of BPD.

For tebuconazole: A general analytical method for the determination of tebuconazole in a water-based wood preservative was developed and evaluated in Doc III B 4.1. The HPLC-UV method was accepted.

For IPBC: 4 general analytical methods for the determination of IPBC in a water-based model formulation have been developed by Arch, Bayer, Sostram and Troy and have been evaluated in the Confidential Documents III A 4.1. The reversed phase HPLC-UV methods have all 4 been accepted and are similar to the methods described for the analysis of the active substance as manufactured.

|  |  |
| --- | --- |
|  | **Principle of method** |
| **Technical active substance as manufactured:** | Propiconazole: *(Doc II A, section 1.4)*  GC-FID packed column with internal standard  Tebuconazole: *(Doc II A, section 1.4)*  GC-FID capillary column with internal standard  IPBC: *(Doc III A 4.1 Bayer, Troy…Confidential)*  Reversed phase HPLC-UV with external calibration and GC-FID |
| **Impurities in technical active substance:** | Propiconazole: *(Doc II A, section 1.4)*  (cis/trans-isomers) HPLC using a 250 x 4 mm Li-Chrosorb Si 60 column, n-hexane/ethanol mixtures as eluent and UV-detection at 230 nm  (by-products) GC-FID using a 15 m x 0.32 mm capillary column coated with a 1.0 µm film of SE-54 with internal standard calibration  Tebuconazole: *(Doc II A, section 1.4)*  (by-products) GC-FID using a capillary column with internal standard  IPBC: *(Doc III A 4.1 Bayer, Troy… Confidential)*  Reversed phase HPLC-UV with external calibration and GC-FID |
| **Active substance in the formulation:** | Propiconazole: *(Confidential Annex B 4.1/02)*  HPLC with UV detector with external standard  Tebuconazole: *(Doc II B, section 1.3)*  HPLC with UV detector with external standard  IPBC: *(Doc III B, Water Based, section B4.1)*  HPLC with UV detector and external calibration |

The Applicant consideres this method valid for the determination of the active substances at the present concentrations, which was accepted. Results are given in Table 2.3.2-1.

**Table 2.3.2-1: Analytical method for formulation analysis:**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sample** | **Test Substance** | **Analytical Method** | **Number of Measurements / Fortification Range** | **Linearity** | **Specificity** | **Recovery Rate (%)** | | | **Limit of Quantitation**  **(LOQ)** | **Reference** |
| **Range** | **Mean** | **RSD** |
| **Axil 2000**  (Lab 2012 006) | Propiconazole | HPLC-UV | The matrix has been spiked with 1 mg/ml. | Single measurement of 5 concentrations between 0.5 - 1.4 mg/ml  Correlation  coefficient: 0.9983 | No significant interferences were observed. | Validation was done on 15 samples.  Range: 93.47 - 95.66 %  Mean: 94.57 %  RSD: 1.98 % | | | 0.1519 mg/ml | Please se the confidential version for more details |
| Tebuconazole | HPLC-UV | The matrix has been spiked with 1 mg/ml. | Single measurement of 5 concentrations between 0.5 - 1.4 mg/ml  Correlation  coefficient: 0.9967 | No significant interferences were observed. | Validation was done on 6 samples.  Range: 96.76 - 99.45 %  Mean: 98.1 %  RSD: 2.43 % | | | 0.0971 mg/ml |
| IPBC | HPLC-UV | The matrix has been spiked with 0.85 mg/ml. | Single measurement of 5 concentrations between 0.5 - 1.4 mg/ml  Correlation  coefficient: 0.9981 | No significant interferences were observed. | Validation was done on 6 samples.  Range: 97.91 - 99.75 %  Mean: 98.73 %  RSD: 1.85 % | | | 0.0896 mg/ml |

#### Residue analysis

Analytical methods for the determination of propiconazole residues in relevant environmental media (soil, air, water) have not been submitted for the biocidal product since these points have already been covered by the data set for the active substance, which can be found in Document II A, Section 1.4.

Analytical methods for the determination of tebuconazole residues in relevant environmental media (soil, air, water) have not been submitted for the biocidal product. These points have already been covered by the data set for the active substance, which can be found in Document II A, Section 1.4.

Analytical methods for the determination of IPBC residues in relevant environmental media (soil and water) have not been submitted for the biocidal product. These points have already been covered by the data set for the active substance, which can be found in Document II A, Section 1.4. Residues in air were not necessary because IPBC is not volatile and spray applications only involve non-respirable particles.

##### The applicant has submitted a study concerning the emission transfer of the active substances IPBC, propiconazole and tebuconazole to foodstuffs stacked on Axil 2000 treated pallet planks. Please see the relevant section in the part 2.6.2.2. Human Exposure Assessment. The applicant has also submitted the validation of the analytical methods for the three active substances, used in the study described above. This is summarized in the following table:

**Table 2.3.2-1: Analytical method for transfer study:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sample** | **Test Substance** | **Analytical Method** | **Number of Measurements / Fortification Range** | **Linearity** | **Specificity** | **Recovery Rate (%)** | **Limit of Quantitation**  **(LOQ)** | **Reference** |
| **Axil 2000**  (Lab 2012 006) | Propiconazole | UPLC-MS/MS | The accuracy was evaluated by using the spiked-placebo recovery method: samples were spiked at a high (0.1 mg L-1) and low (0.001 mg L-1) concentration to determine the recovery at the maximum and minimum concentration the active ingredients were expected to be measured (n=3). | R²: 0.9992 | No significant interferences were observed. | Range:  90.6 – 94.2% for shelf  89.0 - 96.3% for powdered sugar  93.7 – 96.2% for flower  94.0 – 94.8% for cheese  87.8 - 96.8% for lentils  89.1 - 93.6% for maizena | LOQ: 0.5 ug/l  LOD: 0.15 ug/l | Please se the confidential version for more details |
| Tebuconazole | UPLC-MS/MS | The accuracy was evaluated by using the spiked-placebo recovery method: samples were spiked at a high (0.1 mg L-1) and low (0.001 mg L-1) concentration to determine the recovery at the maximum and minimum concentration the active ingredients were expected to be measured (n=3). | R²: 0.9995 | No significant interferences were observed. | Range:  93.8 – 96.8% for shelf  90.9 – 97.6% for powdered sugar  96.5 – 97.2% for flower  92.9 – 93.3% for cheese  93.5 – 96.7% for lentils  90.8 – 91.5% for maizena | LOQ: 0.5 ug/l  LOD: 0.15 ug/l |
| IPBC | UPLC-MS/MS | The accuracy was evaluated by using the spiked-placebo recovery method: samples were spiked at a high (0.1 mg L-1) and low (0.001 mg L-1) concentration to determine the recovery at the maximum and minimum concentration the active ingredients were expected to be measured (n=3). | R²: 0.9971 | No significant interferences were observed. | Recovery: 89%  RSD: 1.3% | LOQ: 30 ug/l  LOD: 9 ug/l |

##### Justification of non-submission of data on the substances of concern

Not applicable since there are no substances of concern.

## Risk assessment for Physico-chemical properties

Axil 2000 is not explosive, not auto-flammable and not oxidizing. Furthermore Axil 2000 is considered stable against storage at ambient temperature for 2 years. No classification/labelling results from the physico-chemical properties of Axil 2000.

## Efficacy

### Function and Field of Use Envisaged

Axil 2000 is recommended to be approved as a fungicidal product for wood preventive treatment to protect wood construction (joinery, sidings, .. etc) in Use Class 3 against brown rotting fungi such as *Coniophora puteana*, *Gloeophyllum trabeum* and *Poria placenta*. Please note that the white rot fungi claim is not part of this application.

The label claims that Axil 2000 is “effective against wood rotting basidiomycetes (brown rot fungi) in preventive treatment of wood construction”.

The product is for industrial use only using the surface application method automated spraying, flow coating (deluge).

A top coat is required to be applied after treatment with the product. This coat should be a top-coat which does not contain biocides. This top-coat has to be stable under the standard EN 927-2 in order to limit biocide leaching all along the service-life of wood.

According to the Applicant, Axil 2000 is intended to be used by automated spraying, flow coating (deluge) as follows:

10 L Axil 2000 = 100 L RTU product used at an application rate of 80 – 120 g/m2 (15-20 L/m3).

In addition, ***Axil 2000*** is recommended to be approved as a fungicidal product for wood preventive treatment to protect fresh-cut wood against sapstain and moulds.

The label claims that ***Axil 2000*** is “effective against sapstain and moulds in preventive treatment of fresh-cut wood for minimum 3 months”.

According to the Applicant, ***Axil 2000*** is intended to be used by immersion (20 sec. minimum) as follow : 5 L ***Axil 2000*** = 100 L RTU product (5% dilution in water).

Due to the presence of tebuconazole in the product, its use for treatment of wood inside housing areas is not recommended (see CAR for inclusion on to Annex I doc.1 – p.6).

### Effects on Target Organisms

#### Efficacy data available from Annex I for the active substances

Propiconazole (CAS N° 60207-90-1)

According to the Assessment Report for inclusion to Annex I, propiconazole is a fungicide used for wood preservation (PT8) active against wood rotting fungi, wood staining fungi and moulds in wood HC 2 and 3.

Propiconazole inhibits the fungal growth.

For amateur users, the application techniques are brushing and spraying, both indoors and outdoors for *in situ* treatment of wood.

Tebuconazole (CAS N°10734-96-3)

Tebuconazole has been evaluated for its use in wood preservation (Product Type 8 of the Biocidal Products Directive) up to Hazard Class 4a and 4b. As a fungicide, tebuconazole interferes with basic metabolism of the fungal cell wall and contents. In combination products e.g., with propiconazole, especially well-balanced efficacy against a broad range of wood rotting fungi can be achieved combined with minimising the amounts of each active.

Applied in both solvent- and water based formulations, tebuconazole can be used by industrial as well as professional and amateur users.

As mentionned in the Assessment Report for inclusion to Annex I, Tebuconazole is not recommended for treatment of wood inside housing areas (with the exception of window frames and external doors, which will usually be treated on or before installation).

IPBC ( CAS N° 55406-53-6)

According to the Assessment Report for inclusion to Annex I, IPBC is a fungicide used for wood preservation (PT8) up to and including Hazard Class 3. IPBC is active against wood rotting and wood disfiguring fungi by interfering with the cell membrane permeability. IPBC has a carbamate structure. The target sites of carbamates in fungi are cell membrane permeability and fatty acids (according to the information provided by FRAC (Fungicide Resistance Action Committee).

IPBC is, in most cases, combined in the formulated products with other active substances like other fungicides (propiconazole, tebuconazole, carbendazim) or insecticides, e.g. permethrin. IPBC-based products, in solvent- and water-based formulations, can be used by industrial as well as professional and amateur users.

IPBC can be used for pre-treatment treatment but also for protective treatment *in situ* in brush application by amateur users.

#### Efficacy data provided on support of Axil 2000

The applicant has submitted only one efficacy study in support of the product. Please se the confidential version for more details.

The study was carried out in accordance to EN 113 standard after leaching procedure according to EN 84 (for wood hazard classes 2 and 3) and after evaporative ageing procedure according to EN 73 (for wood hazard classes 2).

According to the section 5.2.18 of the EN-599/2009 standard (p.15) and the table 3a (p.22), “Products proposed for superficial treatment and intended for use class 3 under a paint or other coating applied before exposure in use shall be tested either according to CEN/TS 839 after EN 73 and EN 84 separately or in accordance with EN 113 after EN 73 and EN 84 separately, or according to EN 330 as well as with EN 113 after EN 73”.

Based on the outcome of these test results, the test-formulation is effective against brown rotting fungi at a rate of 4,2 kg/m3 (see table 1) by a vaccum-pressure procedure. According to the section 5.2.15 of the EN-599/2009 standard (p.13), this biological reference value established in kg/m3 can be deemed to be equivalent to 8,4 g/m2.

Thus, the critical values of the product Axil 2000is :8,4 x 1 / 0.75 = 11,2 g/m2

As the product product Axil 2000 is intended to be used at a 10% dilution, the critical values of the product Axil 2000is therefore 112 g/m2.

In addition, ***Axil 2000*** is recommended to be approved as a fungicidal product for wood preventive treatment to protect fresh-cut wood against sapstain and moulds.

The label claims that ***Axil 2000*** is “effective against sapstain and moulds in preventive treatment of fresh-cut wood for minimum 3 months”.

The applicant has submitted one efficacy study in support of the product. Please se the confidential version for more details.

The study (field test) was performed in accordance to the CEN/TS15082 (2005) European standard and in compliance with all the requirements there mentioned (wood species used to perform the test is maritime pine *Pinus pinaster*, wood specimens with a cross-section of 100 mm x 20 mm and 1000 mm long, …).

Based on the outcome of these test results, the test-formulation used at 5% during a 20 sec. immersion procedure is effective against sapstain and moulds for 3 months on fresh-cut wood : according to the requirements mentioned in the section 8 of the standard (untreated compared to treated test specimens with 1,5% reference formulation), the test is valid. And, for open stacked test specimens, 100% have an attack intensity value of 0 (attacked surface = 0%) after 3 months of exposure.

### Discussion and conclusion

The product Axil 2000is based on 3 active substances (IPBC, propiconazole and tebuconazole) at 0.75% each, without an insecticide. To remind, the white rot fungi claim is not part of this application.

The test-formulation exhibits a good degree of efficacy against brown rotting fungi when applied by vacuum-pressure at a rate of 4,2 kg/m3 according to the results of an efficacy test carried out in accordance to EN 113 standard (after EN 73 ageing procedure and EN 84 leaching procedure).

*Axil 2000* does also exhibit a good degree of efficacy against sapstain and moulds on fresh-cut wood for 3 months when used at 5% during a 20 sec. immersion procedure.

According to several sections of the EN 599-2009 standard (i.e. 5.2.15 and 5.2.18 sections + section B1.b via the section A4.a), the BE RMS considers that the results can be extrapolated to the product Axil 2000for which authorisation is sought. The variation in the content of the co-formulants between the three tested formulations is minimal, around 1%. This variation does not require new testing, according the Annex A of the EN599.

Regarding efficacy of wood preservatives we follow the guidance on re-testing after making variations in product formulation (EN 599-2009 section B1.b via the section A4.a). It is prescribed that if the content is below 10% then a change in concentration up to 20% would not require re-testing.

Furthermore, the submitted data is acceptable in that it meets the data requirements as set out in the TNsG on *Product Evaluation*, Appendices to Chapter 7, Product Type 8.

Therefore, when the product Axil 2000is used at a 10% dilution, it does exhibit a good degree of efficacy against brown rotting fungi when applied by automated spraying, flow coating (deluge) at an minimal application rate of 112 g/m2 (RTU form).

According to the Applicant and the label claim, Axil 2000 (in a RTU 1/10 diluted product) is intended to be used automated spraying, flow coating (deluge) at an application rate between 80 and 120 g/m2 (10-15 L/m3).

About the lower application rate of 80 g/m2, no efficacy test has been submitted to support it.

Therefore, following all the conclusions above, the application rate claimed on the label by the Applicant should be modified by mentioning an application rate of 120 g/m2 (with the RTU form).

Furthermore, *Axil 2000* used at 5% for 20 sec. immersion is effective against sapstain and moulds on fresh-cut wood for 3 months. This corresponds to the application rate of 5 g/m².

Based on the information provided, the Belgian CA believes that the efficacy of Axil 2000 is sufficiently demonstrated.

**Table 2.5.3-1: Claimed matrix for Axil 2000**

|  |  |  |
| --- | --- | --- |
| **Categories** | **Matrix wording** | **Code for product** |
| **Wood category** | softwood | A.10 |
| **Wood product** | solid wood | B.10 |
| **Application aim and Field of use** | preventive treatment  Use Class 3  Temporary preventive treatment / green sawn timber | C.40  D.31 – D.32  D. 20 |
| **Method of application**  **and rate** | Superficial application by automated spraying, flow coating (deluge)  Application rate (UC 3 coated) :  120 g/m² RTU product (at 1/10 dilution)  Superficial application / dipping treatment | E.10; E20; E31  F12  F.14 |
|  |
| **Targeted organisms** | Brown rot fungi  Wood discolouring fungi : Sapstain fungi & Mould fungi | G10  G21.1; 22 |

### Mode of Action

The mode of action can be deduced from the active substances. Details on mode of action for the active ingredients can be found in the active substance dossiers.

### Occurance of resistance

According to the Annex I CAR for IPBC and the Fungicide Resistance Action Committee (FRAC) Code List (<http://frac.info/publication/publication.htm>) the risk of resistance formation against carbamate fungicides is regarded to be low to medium (Resistance Management required).

Propiconazole and Tebuconazole are DeMethylation Inhibitor (DMI) fungicides with Sterol Biosynthesis Inhibitor (SBI) Class I. According to the Frac Code List, DMI fungicides show no cross resistance to other SBI classes. There are big differences in the activity spectra of DMI fungicides. Resistance to DMI fungicides is known in various fungal species. Several resistance mechanisms are known incl. target site mutations in cyp51 (erg 11) gene, e.g. V136A, Y137F,

A379G, I381V; cyp51 promotor; ABC transporters and others. It is considered generally wise to accept that cross resistance is present between DMI fungicides active against the same fungus, and the risk of resistance formation against DMI fungicides is regarded to be medium (Resistance management required).

According to the Annex I CARs for tebuconazole and propiconazole, for wood preservation with tebuconazole-and propiconazole-containing products, cases of resistances are not reported or known up to the time being.

## Exposure assessment

### Description of the intended use(s)

Axil 2000 is a fungicidal wood preservative for industrial use only. Its fields of use are

* Use Classe 3 to protect wood construction (joinery, window frames, sidings, .. etc ). The biocidal product is a water-based concentrate that will be diluted in water (dilution rate: 10%). The treatment is performed by surface application (automated spraying, flow-coating). A top coat is required to be applied after treatment with the product. This coat should be a top-coat which does not contain biocides. This top-coat has to be stable under the standard EN 927-2 in order to limit biocide leaching all along the service-life of wood.
* Preventive efficacy for fresh-cut wood against sapstain and moulds. The biocidal product is a water-based concentrate that will be diluted in water (dilution rate: 5%). The treatment is performed by surface application (short dipping).

See also Table 2.5.3-1: Claimed matrix for Axil 2000**.**

### Assessment of exposure to humans and the environment

#### Environmental exposure assessment

Table 2.6.2.1-1 Summary of intended uses

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Axil 2000** | | | | |
| **MG/PT** | **Field of use envisaged** | | **Likely concentrations at which A.s. will be used** | **Use Class** |
| PT08 (Wood preservatives)  Main group 02 | **Industrial uses** | | |  |
| Tunelling aspersion/ Flow coating | | * 0.75%Tebuconazole * 0.75% Propiconazole * 0.75% IPBC * 120g/m² * Dilution rate 10% w/w * 15-20L/m³ | UC 3 |
| **Anti sapstain and mould for fresh cut wood** | | |  |
| Short dipping | * 0.75%Tebuconazole * 0.75% Propiconazole * 0.75% IPBC * 120g RTU/m² * Dilution rate 5% w/w | |  |

Axil 2000 is packaged in 1000L containers. The product is restricted to industrial use only.

##### Fate and distribution in the environment.

The environmental risk evaluation of Axil 2000 is given below.

All the data refer to the chapter 'Fate and distribution in the environment' and 'Effects on environmental organisms' from Doc IIA as well as from Doc IIB for the active substances Tebuconazole, Propiconazole and IPBC. A summary is presented below for each of the active substance.

**TEBUCONAZOLE**

Tebuconazole is stable to hydrolysis. Direct photodegradation of Tebuconazole in water is low and the substance may be considered photolytically stable in both water and soil. However, indirect photolysis of Tebuconazole may occur in water. The solubility of Tebuconazole in water is 29 mg/L at 20°C.

Tebuconazole is not readily biodegradable and biodegradation half-life in surface water is estimated to be about 198 days. However, Tebuconazole will be adsorbed to the sediment and therefore a dissipation half-life in surface water is estimated to be 43 days in a water/sediment study. Tebuconazole is not metabolized rapidly in soil in laboratory experiments: the half-life for primary degradation is greater than one year. In field studies the dissipation half-life is 77 days.

Tebuconazole has a low mobility potential (Koc = 992 mL/g). The BCF bioaccumulation factor for fish varies from 31 to 93. However, the higher value includes the metabolites as well. For the risk assessment, a BCF of 78 is used since this value seems to be the highest reliable value found.

1,2,4-Triazole is the primary metabolite from the degradation of Tebuconazole. However it appears to breakdown more rapidly in soil than Tebuconazole.

The risk quotients are more favorable for the metabolites than for Tebuconazole for both the aquatic and terrestrial environment and therefore the metabolite will not be considered further in the risk assessment.

Air will not be an environmental compartment of concern for Tebuconazole used in wood preservatives because of the very low vapour pressure of this compound (1.7 10-6 Pa at 20°C) and these wood preservatives are not applied by spraying. It should however be noted that the calculated DT50 of Tebuconazole in air is more than 2 days and it is therefore considered persistent in air.

**PROPICONAZOLE**

Propiconazole is moderately soluble in water having water solubility of around 100 mg/L at pH 7 at 20°C. Propiconazole is very slightly volatile having vapour pressure around 5.6 10-5 Pa at 25°C. Hydrolysis and direct photolysis do not play a major role in the degradation of Propiconazole in surface waters. Propiconazole is not readily biodegradable. If Propiconazole enters a water body, a large quantity will be instantaneously removed from the aqueous phase by rapid adsorption to suspended sediments. The subsequent degradation in the aquatic system will be mainly of biological nature. Dissipation half-life of 6.4 days in water and degradation half-life of 636 days in water/sediment system are used in the PEC calculations. There was no metabolite accounting > 10% of the active substance found in the water/sediment key study.

In the laboratory studies the half-life of Propiconazole in soil ranged from 29 to 72 days with a median of 45 days at 20 to 25 °C. Mineralization of Propiconazole was < 5% of the applied radioactivity in all studies and the amount of non-extractable increased even up to around 50% at 120 days but never exceeded 70% of the applied radioactivity.

The maximum dissipation half-life of 129 days in soil derived from field studies is used as the worst case in the PECsoil calculations for Propiconazole when risk after 30 days (TIME 1) is considered. The geometric mean dissipation half-life of 177 days in soil (from field studies) is used in the PECsoil calculations for Propiconazole when risk after several years (TIME 2) is considered.

In the laboratory studies there were two degradation products of Propiconazole accounting more than 10% of the active substance in soil (1,2,4-triazole and CGA 118 245). Degradation half-life of 1,2,4- triazole was around 9.3 days in soil and degradation half-life of CGA 118 245 was around 1 day in soil.

Propiconazole adsorbs very rapidly to soils with most of the short-term (24 hrs) adsorption taking place within an hour or less. With an arithmetic mean of Koc (adsorption) = 944 mL/g (Koc = 1000 mL/g in EUSES calculation) Propiconazole is regarded as slightly mobile in soil. The two degradation products of Propiconazole accounting for more than 10% in the soil degradation studies are considered mobile in soil. Arithmetic mean values for 1,2,4-triazole and CGA 118 245 are Koc (adsorption) = 69 mL/g and Koc (adsorption) = 129 mL/g, respectively.

Log Kow of Propiconazole is 3.7 implying a slight bioaccumulation potential. Propiconazole is slightly bioaccumulative to fish with a BCF of 180. Based on the estimation of BCF for terrestrial bioconcentration, Propiconazole is not bioaccumulative to terrestrial organisms.

The estimated half-life of Propiconazole in the troposphere is between 10.2 and 42 hours assuming the OH concentration (5\*105) given in the TGD (Part II, 2003, equation 28) and a 24-hour day.

**IPBC**

IPBC is stable to hydrolysis. Direct photodegradation of IPBC in water is low and the substance may be considered photolytically stable in water. The water solubility of IPBC is 168 mg/L at 20°C.

IPBC is not readily biodegradable but is primary biodegradable according to Zahn-Wellens test. The biodegradation half-life in surface water is estimated to about 1.4 hour at 20-22°C. IPBC is metabolised rapidly in soil in laboratory experiments, the half-life is estimated to be 2.1 hour at 20-22°C. In degradation of IPBC, the primary degradate was propargyl-butyl-carbamate (PBC).

PBC was found in hydrolysis, aerobic soil, and anaerobic aquatic metabolism studies. In hydrolysis, PBC was the only degradation product identified.

In soil, PBC was degraded to CO2, bound soil residues and an unidentified metabolite. In anaerobic aquatic environments (sediment/water), PBC was degraded to 2-propenyl-butyl-carbamate (2-PBC) and 2 unidentified degradates (less than 10%), CO2 and possibly CH4. The metabolite 2-PBC is only formed at a percentage > 10% in the water phase under anaerobic conditions. QSAR estimation indicates a toxicity of this metabolite is comparable to that found for IPBC. Therefore in this case it is not considered necessary to ask for experimental ecotoxicological data for this metabolite.

Iodine will be evaluated by Sweden as an active substance for disinfectant and an effect and risk assessment will therefore not be performed here.

IPBC has a medium to high mobility potential (Koc = 126 mL/g by HPLC method).

The bioaccumulation potential is not significant based on a log Pow value of 2.8.

Air will not be an environmental compartment of concern for IPBC used in wood preservatives because of the low vapour pressure of this compound (2.36 10-3 Pa at 25°C). It should also be noted that the calculated DT50 of IPBC in air is only about 15 hours and is therefore not considered persistent in air.

##### Emission to environmental compartments.

###### Emission scenarios.

The product Axil 2000 is a water-based concentrated product for use only as a fungicidal wood preservative for the treatment of timber against wood destroying fungi. Axil 2000 is for industrial use and anti sapstain mould for fresh cut wood. Its field of use is respectively to the above described process Use Class 3 (Tunelling aspersion/ Flow coating) and against sapstain/moulds (Short dipping).

The environmental exposure assessments of the active substances were determined with the Emission Scenario Document (ESD) developed for Product Type 08 (wood preservatives) by OECD: OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Emission Scenario Document for Wood Preservatives. The emission scenarios estimate the emission of wood preservatives from two stages of their life cycle:

Industrial use

- 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 application and storage of treated wood prior to shipment, the emission scenarios used for the product Axil 2000 cover:

• Industrial preventive processes - Automated spraying process (Flow-coating)

Antisapstain mould of fresh cut wood

• Industrial preventive processes – Short Dipping

For all the three Axil 2000 active substances: Tebuconazole, Propiconazole and IPBC, the environmental risk assessment has been calculated from semi-field leaching rates used in evaluation of products similar to Axil 2000.

No determination of regional concentrations has been made, since the wood preservative uses outlined are not considered to be of sufficiently large scale (according to TNsG for Risk Assessment for existing substances, Part II, 2003, p.15).

The exposed environmental compartments that may potentially be impacted during life cycle of Axil 2000 are:

Table 2.6.2.1.2.1-1 Environmental compartment potentially exposed

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Air (outdoors) | Sewage treatment plant | Surface water and sediment | Soil | Ground  Water\* |
| Application process | yes | yes | yes | no | no |
| Treated wood in service | no | no | yes | yes | yes |
| Short dipping | | | | | |
| Application process | yes | yes | yes | no | no |
| Treated wood in service | no | no | no | no | no |

*\* Indirect exposure via leaching of the substance in soil*

1- Automated spraying

Automated spraying is surface treatment mostly applied at sawmills and carpentry shops.

Process description:

Spray/deluge systems consist of longitudinal or transversal boxes that apply a diluted preservative to the wood on a continuously moving convey or belt. Wood logs are fed into the mill and debarked, and are cut into lengths of various degrees. Workers, called sorters inspect the wood pieces either before or after the spray boxes. This is done to eliminate wood that is damaged or has knots, or is already discoloured due to fungi. The wood enters the spraying box that applies the preservative to the surface of the wood for a period of 3 - 5 seconds. The particle size of the spray is a critical parameter for the effectiveness of the treatment. Spray boxes are relatively contained. Splashguards surround the spraying boxes to eliminate any droplets of spray from the rest of the mill area. Droplets are large enough to prevent the respiration of preservative solution.

After the spray boxes, the treated wood is stacked or sorted for shipment off-site. At sawmills, the treated wood does not remain in storage for long time periods. Wood is generally shipped off-site to manufacturers within 2-3 days after treatment. Longer storage periods occur at carpentry shops.

Emission pathways:

Air: Emissions can occur to the air directly due to spray drift and evaporation from the spray box and from the treated (wet) wood after it exits from the spray box and dries on the belt or in the sorting tray, and as it is bundled for stacking at the sorting and stacking areas. Sorting is the process whereby workers sort the treated wood according to its size and appearance into different stacks where the wood is bundled for placement in the yard. Ventilation in most cases is via fans only.

The product Axil 2000 is a water-based product and the active substances show a very low vapour pressure. It can be concluded that emission to aerial compartment is negligible when using the product.

Water: Mill/carpentry floors are cemented, so run-off is generally collected and recycled via drip pads. However, unintentional spills, floor cleaning, equipment cleaning and washing waters, drag-out on tires may reach the facility drain. The facility drain is assumed to drain into the public sewage treatment plant (STP).

Emission can occur to water by run-off of water from unpaved storage into adjacent surface water body after rain event.

Soil: Emission can occur to the soil by wood preservative components leaching due to rainfall.

2- Dipping

Dipping and immersion are superficial application processes and are typically used in sawmills and carpentry / joinery shops. Water or organic solvent based products may be used. They are batch processes and may be automatic or manual in operation. In either case they involve the submerging of a pack or single piece (only in small scale operations) of wood into a dipping tank filled with ready for use wood preservative solution. Packs of wood are typically loaded on automatic equipment (e.g. a hydraulic mast) and lowered into the dipping tank. The dipping tanks may be heated in cold climate conditions.

The immersion period lasts anything from a very short period of a few minutes to over one hour depending on the end use application of the treated commodity and the application rate of the wood preservative. After the required immersion period the packs or pieces of wood, which are slightly raised at one end to aid liquid run off, are hoisted out of the liquid and usually held above the open tank for excess liquid to fall back into the dipping tank and be re-used. When the excess liquid has been drained, the pieces or packs of wood are moved to a post treatment conditioning location which is usually bunded and the timber is allowed to dry before being moved off-site or used on site. Any further drips are contained and recycled.

Some installations may have local exhaust ventilation. The release of wood preservatives from

the treating installation or where the treated timber is stored into a surface water drain or drain connected to a STP is not permitted and so any installation where this occurs is in contravention of environmental protection legislation and the licence to operate the treatment process.

Even though release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore in EU member state countries, the corresponding emission pathway (facility drain to STP to surface water) is nevertheless a worst case, the assessment of which can be of relevance outside the EU. Consequently, this emission pathway is also reflected in Figure below.

See OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, of 27-Sept-2013, p.45.

The product Axil 2000 is used in short dipping treatment (minimum 1 minute). Then, the time to reach resistance to leaching of the product in the material treated is at least 4 hours after dipping under cover. Moreover, after the treatment, wood must be stored in a covered and paved area to reduce the leaching during use.

Emission pathways

The dipping baths are usually open and can lead to emissions to air by evaporation and codistillation with water or solvent. A distinction is made between wood preservative products dissolved in water and those using organic solvents as the carriers for the active substance. Only those using organic solvents can evaporate into the air.

Mill/carpentry floors are cemented, so run-off is generally collected and recycled. However, unintentional spills, floor cleaning, equipment cleaning and washing waters, drag-out on tyres may reach the facility drain.

Concerning storage, a distinction is made between joineries and other facilities. Joineries in which the preservation treatment is applied on wooden articles that have been made to shape, (fence panels, composites, windows, doors and door frames, floors, architrave and decorative features) do not have an open storage area. These treated commodities/articles are immediately further processed (e.g. painted) and are not stored after wood preservation treatment. During storage at other facilities than joineries, soil can be exposed – if the storage place is not covered - due to leaching from treated wood via rainfall, and ground water via leaching of the substance in soil. In addition, surface water can be exposed via rain run-off from the storage place.

Air: The product Axil 2000 is a water-based product and the active substances show very low vapour pressure. It can be concluded that emission to aerial compartment is negligible when using the product.

Water: No direct emission to surface water from the process (as run-off, unintentional spills, floor and equipment cleaning, washing water, …) is foreseen during application phase as the dipping baths and all the contaminated waters go to the facility drain and are recycled or treated in local sewage treatment plant. The emission to sewage treatment plant will be considered.

Soil: The same points during storage of treated wood must be taken into account for the soil contamination. The product Axil 2000 is for use in joinery industry and carpentry shops, therefore, direct soil contamination should not be considered.

Data on the 3 active substances are summarized in the following table:

Table 2.6.2.1.2.1-2 Active substances data

|  |  |  |  |
| --- | --- | --- | --- |
|  | Tebuconazole | Propiconazole | IPBC |
| Molecular mass | 307.8 | 342.2 | 281.1 |
| Melting point | 105°C |  | 65.8°C |
| Vapour pressure [Pa] : | 1.7 10-6 (20°C) | 5.6 10-5 (25°C) | 2.36 10-3 Pa (25 °C) |
| Water solubility [mg.L-1] : | 29 (20°C) | 100 (20°C) | 168 (20°C) |
| log Pow | 3.49 (20°C) | 3.72 (25°C) | 2.81 (25°C) |
| Henry's law constant (Pa.m3/mol) | 1\*10-5 | 0.000092 | 3.38-6.45\*10-3 (25°C) |
| % removal in STP | 21 | 21 | / |
| DT50 soil (days) | 77 | 129 | 2.1 h |
| DT50 water (days) | 198 | 6.4 | 1.4 h |
| DT50 sediment (days) | > 1 year (primary  degradation)  77 d (dissipation) | 636 | 2.2 h |
| Koc (mL/g) | 992 | 944 | 126 |
| PNECsoil [mg/kg wetwt] | 0.1 | 0.1 | 0.005 |
| PNECstp | 0.32 mg/L | 1 mg/l (lanxess proposed value) | 0.44 mg/L |
| PNECsurface water | 0.001 mg/L | 1.6 Jg/l (laxness position) | 0.0005 mg/L |
| PNECsediment [mg/kg] | 0.55 | 0.054 | 0.545 |
| LC50 (96h) fish [mg/L] | 4.4 | 4.3 | 0.067 |
| NOEC (21d) fish [mg/L] | 0.010 | 0.43 | 0.0084 |
| EC50 (48h) daphnia [mg/L] | 2.8 | 10.2 | 0.16 |
| NOEC (21d) daphnia [mg/L] | 0.01 | 0.31 | 0.05 |
| ErC50 (72h) algae [mg/L] | 5.3 | 0.058 | 0.053 |
| EbC50 (72h) algae [mg/L] | 1.96 | / | 0.022 |
| NOEC algae [mg/L] | 0.56 | 0.016 | 0.0046 |
| EC50 Microorganisms (activated sludge) [mg/L] | > 32 | > 100 | 44 |
| EC10 (28d) Sediment dwelling organisms | 2.45 mg/L | / | / |
| NOEC Sediment dwelling organisms | 54.5 mg/kg susp.sdt | 5.4 mg as/kg ww | / |
| LC50 (14d) earthworm | 470 mg/kg dws | 686 mg/kg dw (205 mg/kg ww) | > 1000 mg/kg ds |
| NOEC (56d) earthworm | 5.7 mg/kg dws | 0.998 mg/kg ww | / |
| LC50 (14d) plants | > 100 mg/kg ds | / | / |
| EC50 (14d) plants | 24 mg/kg ds | 4.32 mg/kg ww | 4.92 mg/kg ds |
| EC50 (28d) Mineralisation (carbon and nitrogen) | > 8.3 mg as/kg dw  (C+N) | >1.67 mg/kg dw (N) | 312.5 mg/kg ds (C) |
| NOEC Mineralisation (carbon and nitrogen) | 8.3 mg as/kg dw  (C+N) | 1.67 mg/kg dw (N) | / |
| LD50 bird (mg/kg bw) | 1988 | / | / |
| LC50 (5d) bird (mg as/kg feed) | > 4816 | / | / |
| BCF (fish) | 78 | 180 | / |
| BCF (earthworm) | 28 | 64 | / |

###### Supportive toxicological data on environmental representative organisms: Please se the confidential version for more details.

###### Environmental exposure assessment

###### Calculations of emissions for Tebuconazole.

The environmental exposure assessment of Tebuconazole from Axil 2000 has been determined with Emission Scenario Document (ESD) developed for product type 8 (wood preservatives) by OECD: OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Emission Scenario Document for Wood Preservatives. 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.

In the case of application and storage prior to shipment the emission scenario used for Tebuconazole covers: Automated spraying process and Short dipping processes.

The storage scenario employed in this assessment assumes that the storage area is uncovered and unpaved. However, according to the Annex I inclusion to directive 98/8/EC, in reality freshly treated timber must be stored on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.

In the case of treated wood in service, the following emission scenarios have been run for Tebuconazole for use class 3: Fence, Noise barrier and House.

For the three emission scenarios of treated wood in service, calculations of emissions in soil have been done with Tebuconazole, removal processes in soil taken into account; according to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Part 3.

Axil 2000 is a water-based wood preservative containing 0.75% Tebuconazole, 0.75% Propiconazole and 0.75% IPBC. During application 100g of the product diluted by 10% with water are applied per square meter of wood. So the application rate of each active ingredient is 0.075 g/m2. During short dippping application, 120g of the product diluted by 5% with water are applied per square meter of wood. So the application rate of Tebuconazole is 0.045 g/m².

The leaching behaviour of Tebuconazole from Axil 2000 has been determined with two semi-field testing on timber treated with Axil 2000. Please se the confidential version for more details.

A. Scenario for the product application

a. Emission scenario for automated spraying

Table 2.6.2.1.2.2- 2 Application phase in automated spraying process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| Process: automated spraying scenario | | | | |
| **INPUTS** |  |  |  |  |
| Wood area treated per day | AREAwood-treated | 2000 | [m².d-1] | D |
| Application rate: quantity of a.i. applied per 1 m2 of wood area | Qai | 7.5x10-5 | [kg.m-²] | A |
| Fraction released to facility drain  solubility in water  [1g.l-1] >100 | Ffacilitydrain | 0.03 | [--] | D |
| Fraction released to air  vapour pressure at 20 °C [Pa] < 0,005 | Fair | 0,001 | [--] | D |
| Fraction of spray drift deposition | Fdrift | 0,001 | [--] | D |
| **OUTPUTS** |  |  |  |  |
| Local emission rate to air | Elocalair | 3x10-4 | [kg.d-1] | O |
| Local emission rate to facility drain | Elocalfacilitydrain | 4.5x10-3 | [kg.d-1] | O |
| Local facility drain concentration | Clocalfacilitydrain | 1.74x10-4 | mg/L | O |

D=default, A=based on information of applicant, O=output

Calculations:

Application rate of a.i. (active ingredient) [kg.m-2]:

Qai = Qproduct x Cai

Qai =100 x 0.75% x 10% x10-3 = 7.5x10-5 [kg.m-2]

**Plant: Emissions to local air [kg.d-1]**

Elocalair = AREAWood-Treated x Qai x (Fair +Fdrift)

Elocalair = 2000 x7.5 x10-5x (0.001+0.001) = 3x10-4 [kg.d-1]

**Plant: Emissions to facility drain [kg.d-1]**

Elocalfacilitydrain = AREAWood-Treated x Qai x Ffacilitydrain

Elocalfacilitydrain= 2000 x 7.5 x10-5 x 0.03 = 4.5x10-3 [kg.d-1]

**PECSTP**

Clocalfacilitydrain= Elocalfacilitydrain /FLOWfacilitydrain

The OECD ESD does not give a default value of FLOWfacilitydrain. This can be assumed to be a small creek with a flow of 0.3 m3/s.

Clocalfacilitydrain = 4.5x10-3x106/ (86400x0.3x103) = 1.74x10-4 mg/L

The facility drain is assumed to drain into the public sewage treatment plant (STP)

Table 2.6.2.1.2.2- 3 Storage phase in automated spraying process

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Parameter/variable | | Nomenclature | Value | Unit | Origin |
| Storage: automated spraying scenario | | | | | |
| **INPUTS** |  | |  |  |  |
| Effective surface area of treated wood, considered to be exposed to rain, per 1m² storage area (i.e. soil) | AREAwood-expo | | 11 | [m².m-2] | D |
| Surface area of the storage place | AREAstorage | | 79 | [m²] | D |
| Duration of the initial assessment period | TIME1 | | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | | 5475 | [d] | D |
| Duration of storage of treated wood prior to shipment | TIMEstorage | | 3 | [d] | D |
| Average daily flux i.e. the average quantity of an active ingredient that is  daily leached out of 1 m2 of treated wood during 3 days storage period [kg.m-2.d-1] | FLUXstorage,spray | | 2.5x10-8 | [kg.m-2 .d-1 ] | A |
| Volume of treated wood stacked per m2 of storage area (i.e. soil) | VOLUMEwood-stacked | | 2 | [m³.m-2] | D |
| Bulk density of wet soil | RHOsoil | | 1700 | [kg.m-3] | D |
| Soil depth | DEPTHsoil | | 0,50 | [m] | D |
| Volume of (wet) soil | Vsoil | | 39.5 | [m³] | D |
| Fraction of rainwater running off the storage site | Frunoff | | 0.5 | [-] | D |
| **OUTPUTS** |  | |  |  |  |
| Cumulative quantity of an active ingredient, leached due to rainfall from stored treated wood, over the initial assessment period | Qleach,storage,time1 | | 6.5x10-4 | [kg] | O |
| Cumulative quantity of an active ingredient, leached due to rainfall from stored treated wood, over a longer assessment period | Q leach,storage,time2 | | / | [kg] | O |
| Local concentration in soil at storage place at the end of the initial assessment period | Clocalsoil,time1 | | 4.8x10-9 | [kg.kgwwt-1] | O |
| Local concentration in soil at storage place at the end of a longer assessment period | Clocalsoil,time2 | | / | [kg.kgwwt-1] | O |
| Local emission rate in surface water resulting from leaching from stored treated wood due to rain run-off, over the initial assessment period | Elocalsurfacewater,time1 | | 1.08x10-5 | [kg.d-1 ] | O |
| Local emission rate in surface water resulting from leaching from stored treated  wood due to rain run-off, over a longer  assessment period | Elocalsurfacewater,time2 | | / | [kg.d-1] | O |
|  | PECwater | | 4.1x10-7 | mg/L | O |

D=default, A=based on information of applicant, O=output

**Calculations:**

• Volume of wet soil:

Vsoil= AREAstorage x DEPTHsoil

Vsoil=79x0.5 =39,5 m³

Storage: Emissions at storage:

• For an initial assessment period TIME1

Qleach,storage,time1= FLUXstorage,spray x AREAwood-expo x AREAstorage x TIME1

Qleach,storage,time1=2.5x10-8 x 11x 79 x 30 = 6.5x10-4 kg

Storage: Local concentration in soil

• For an initial assessment period TIME1

Clocalsoil,time1=(0.5x Qleach,storage,time1)/( Vsoil x RHOsoil)

Clocalsoil,time1=(0.5x6.5x10-4)/(39.5x1700) = 4.8x10-9 kg.kgwwt-1

Storage: Emission rate to surface water

• For an initial assessment period TIME1

Elocalsurfacewater,time1 = (Qleach,storage,time1 x Frunoff  )/ TIME1

Elocalsurfacewater,time1 = (6.5x10-4 x0.5) / 30 =1.08x10-5 [kg.d-1]

Clocalsurfacewater= Elocalsurfacewater/FLOWsurfacewater

The OECD ESD does not give a default value of FLOWsurfacewater. This can be assumed to be a small creek with a flow of 0.3 m3/s.

Clocalsurfacewater= 1.08x10-5 x106/(86400x0.3x103) = 4.1x10-7 mg/L

Clocalsed=Ksusp-water /RHOsusp \*PEClocalwater\*1000 = 25.7/1150\*4.1x10-7\*1000 = 9.16 x10-6mg/kg

b. Emission Scenario for Dipping/Immersion Processes

Table 2.6.2.1.2.2-4 Application phase in industrial Short dipping process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| Process: dipping/immersion scenario | | | | |
| INPUTS |  |  |  |  |
| Volume of wood treated per day | VOLUMEwood-treated | 100 | [m³.d-1] | D |
| Application rate: quantity of a.i. applied per 1 m³ wood | Qai | 1.71x10-3 | [kg.m-3] | A |
| Fraction released to facility drain solubility in water [mg/L] : 1 - <50 | Ffacilitydrain | 0.003 | [--] | D |
| Fraction released to air  vapour pressure at 20 °C [Pa] < 0,005 | Fair | 0 | [--] | D |
| OUTPUTS |  |  |  |  |
| Local emission rate to air | Elocalair | 0 | [kg.d-1] | O |
| Local emission rate to facility drain | Elocalfacilitydrain | 5.1x10-4 | [kg.d-1] | O |
|  | Clocalfacilitydrain | 1.96x10-5 | mg/L | O |

D=default, A=based on information of applicant, O=output

Calculations:

* Application rate

Application rate of a.i. (active ingredient) [kg.m-3]:

Qai= QproductxCaixDilution

Qai=120x0.75%x10%x10-3=4.5x10-5 kg.m-2

According to the information provided by the American Chemistry Council (ACC) [ Adrian Krygsman, pers. Commun, 2001] ; 2000 m2 of wood treated correspond to 52.5 m³ of wood treated. See OECD ESD, number 2, page 37.

Thereby: 1 m²= 0.02625 m³ ;

Qai=4.5x10-5/ 0.02625= 1.71x10-3 kg.m-3

* **Plant: Emission to local air [kg.d-1]**

Elocalair =VOLUMEwood-treated x Qai x Fair

Elocalair =100 x 1.71 x 10-3 x 0 = 0 kg.d-1

* **Plant: Emission to facility drain [kg.d-1]**

Elocalfacilitydrain= VOLUMEwood-treated x Qai x Ffacilitydrain

Elocalfacilitydrain= 100 x 1.71 x 10-3 x 0.003= 5.1x10-4 kg.d-1

* **PECSTP**

Clocalfacilitydrain= Elocalfacilitydrain /FLOWfacilitydrain

The OECD ESD does not give a default value of FLOWfacilitydrain. This can be assumed to be a small creek with a flow of 0.3 m3/s.

Clocalfacilitydrain= 5.1 x 10-3 x 106 / (86400 x 0.3 x 103) = 1.96x10-5 mg/L

Table 2.6.2.1.2.2-5 Storage phase in industrial dipping process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| Storage: dipping scenario | | | | |
| INPUTS |  |  |  |  |
| Effective surface area of treated wood, considered to be exposed to rain, per 1m² storage area (i.e. soil) | AREAwood-expo | 11 | [m2.m-2] | D |
| Surface area of the storage place | AREAstorage | 700 | [m2] | D |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | / | [d] | D |
| Duration of storage of treated wood prior to shipment | TIMEstorage | 14 | [d] | D |
| Average daily flux i.e. the average quantity of an active ingredient that is  daily leached out of 1 m2 of treated wood during 14 day storage period | FLUXstorage,dipp | 1.69x10-8 | [kg.m-2.d-1] | A |
| Volume of treated wood stacked per 1 m² of storage area (i.e. soil) | VOLUMEwood-stacked | 2 | [m3.m-2] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil depth | DEPTHsoil | 0.50 | [m] | D |
| Volume of (wet) soil | Vsoil | 350 | [m3] | D |
| Fraction of rainwater running off the storage site | Frunoff | 0.5 | [-] | D |
| OUTPUTS |  |  |  |  |
| Cumulative quantity of an active ingredient, leached due to rainfall from stored treated wood, over the initial assessment period | Qleach,storage,time1 | 3.9x10-3 | [kg] | O |
| Cumulative Quantity Of An Active Ingredient, Leached Due To Rainfall  From Stored Treated Wood, Over A Longer Assessment Period | Qleach,storage,time2 | / | [kg] | O |
| Local concentration in soil at storage place at the End of the initial assessment period | Clocalsoil,time1 | 3.28x10-9 | [kg.kgwwt-1] | O |
| Local concentration in soil at storage  place at the end of a longer assessment period | Clocalsoil,time2 | / | [kg.kgwwt-1] | O |
| Local emission rate in surface water  resulting from leaching from stored  treated wood due to rain run-off, over the initial assessment period | Elocalsurfacewater,time1 | 6.5x10-5 | [kg.d-1] | O |
| Local emission rate in surface water  resulting from leaching from stored treated wood due to rain run-off, over a longer assessment period | Elocalsurfacewater,time2 | / | [kg.d-1] | O |
|  | PECwater | 2.5x10-6 | [mg/L] | O |

D=default, A=based on information of applicant, O=output

**Calculations:**

* Volume of wet soil:

Vsoil= AREAstorage x DEPTHsoil

Vsoil=700 x 0.5=350 m3

Storage: Emissions at storage:

* For an initial assessment period TIME1

Qleach,storage,time1= FLUXstorage,dipp x AREAwood-expo x AREAstorage x TIME1

Qleach,storage,time1= 1.69 x10-8 x 11 x 700 x 30 = 3.9 x10-3 kg

Storage: Local concentration in soil

* Concentration in soil at storage place at the end of the initial assessment period TIME1

Clocalsoil,time1=(0.5x Qleach,storage,time1) / (Vsoilx RHOsoil )

Clocalsoil,time1=(0.5 x 3.9 x10-3) / (350 x1700) = 3.28 x 10-9 kg.kgwwt-1

Storage: Emission rate to (adjacent) surface water

* Emission rate from the storage place to an adjacent surface water body over an initial assessment period TIME1

Elocalsurfacewater,time1=( Qleach,storage,time1x Frunoff) / TIME1

Elocalsurfacewater,time1=(3.9 x10-3x 0.5) / 30 =6.5 x10-5 kg.d-1

Clocalsurfacewater= Elocalsurfacewater/FLOWsurfacewater

The OECD ESD does not give a default value of FLOWsurfacewater. This can be assumed to be a small creek with a flow of 0.3 m3/s.

Clocalsurfacewater= 6.5 x10-5 x106/ (86400 x 0.3x 103) = 2.5 x 10-6 mg/L

Clocalsed=Ksusp-water /RHOsusp \*PEClocalwater\*1000 = 25.7/1150\*2.5x10-6\*1000 = 5.58x10-5mg/kg

B. Scenario for the life stage of treated wood-in-service

a. Fence scenario

Table 2.6.2.1.2.2- 6 Fence scenario data

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| INPUTS |  |  |  |  |
| Emission of active ingredient during application (assumed to occur over 1 day) | Eapplic | / | [kg.d-1] | O |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | 5475 | [d] | D |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over the initial assessment period is determined based on the results of a leaching test. | Qxleach,time1 | 7.5x10-7 | [kg.m-2] | A |
| Cumulative quantity of an active ingredient leached out of 1m2 of  treated wood over the a longer assessment period | Qxleach,time2 | 7.5x10-5 | [kg.m-2] | A |
| Leachable treated wood area, proposed in the relevant scenarios (cf.Appendix 3) | AREAwood | 2 | [m2] | D |
| Volume of receiving soil, proposed in the relevant scenarios (cf. Appendix 3) | Vsoil | 0.25 | [m3] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil-water partitioning coefficient | Ksoil-water | 126 | [m3.m-3]  = mg/L | A |
| First order rate constant for removal from soil | k | 9x10-3 | [d-1] | A |
| OUTPUTS |  |  |  |  |
| Initial concentration in soil during application | Clocalsoil,applic | 0 | [kg.kgwwt-1] | O |
| Average daily emission of active ingredient due to leaching over the initial assessment period | Esoil,leach,time1 | 5x10-8 | [kg.d-1] | O |
| Average daily emission of active ingredient due to leaching over a  longer duration | Esoil,leach,time2 | 2.7x10-8 | [kg.d-1] | O |
| Time weighted concentration in local soil over the initial assessment period | Clocalsoil,time1 | 1.6x10-9 | [kg.kgwwt-1] | O |
| Time weighted concentration in local soil over a longer duration | Clocalsoil,time2 | 6.9x10-9 | [kg.kgwwt-1] | O |

D=default, A=based on information of applicant, O=output

Calculations:

• Volume of wet soil

Vsoil = FENCElength x DISTANCEhorizontal x DEPTH

Vsoil=1x 0.5 x 0.5= 0.25 m3

• Qxleach,time1 = FLUXTIME1xTIME1

Qxleach,time1=2.5x10-8x30= 7.5x10-7 kg.m-2

• Qxleach,time2= FLUXTIME2xTIME2

Qxleach,time2=1.37x10-8x5475= 7.5x10-5 kg.m-2

• k=Ln2/DT50

DT50=77d.

k=Ln2/77= 0.009d-1

• Esoil,leach,time1=( AREAwoodx Qxleach,time1)/ TIME1

Esoil,leach,time1=(2x7.5x10-7)/30 =5x10-8 [kg.d-1]

• Esoil,leach,time2=( AREAwoodx Qxleach,time2)/ TIME2

• Esoil,leach,time2=(2x7.5x10-5)/5475= 2.7x10-8 [kg.d-1]

Pre-treated wood is used for the construction of the fence; only the releases due to leaching from the wood are taken into consideration and Clocalsoil,applic=0

Clocalsoil,time1 = 5x10-8/(0.25 x1700 x 9x10-3) + (1/9x10-3x30) x(-5x10-8 /0.25x1700x9x10-3) x(1-e-30x9x10-3)

= 1.6x10-9 [kg.kgwwt-1]

=2.7x10-8/(0.25x1700x9x10-3)+(1/9x10-3x5475)x (-2.7x10-8/(0.25x1700x9x10-3)) x (1-e-5475x9x10-3)

=6.9x10-9 [kg.kgwwt-1]

b. Noise barrier scenario

Table 2.6.2.1.2.2- 7 Noise barrier scenario data

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| INPUTS |  |  |  |  |
| Emission of active ingredient during application (assumed to occur over 1 day) | Eapplic | / | [kg.d-1] | O |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | 5475 | [d] | D |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over  the initial assessment period is determined based on the results of a leaching test. | Qxleach,time1 | 7.5x10-7 | [kg.m-2] | A |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over the a longer assessment period | Qxleach,time2 | 7.5x10-5 | [kg.m-2] | A |
| Leachable treated wood area, proposed in the relevant scenarios (cf. Appendix 3) | AREAwood | 3000 | [m2] | D |
| Volume of receiving soil, proposed in the relevant scenarios (cf. Appendix 3) | Vsoil | 250 | [m3] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil-water partitioning coefficient | Ksoil-water | 126 | [m3.m-3]  =mg/L | A |
| Fraction released to STP | FSTP | 0.7 | [-] | D |
| Fraction released to soil | Fsoil | 0.3 | [-] | D |
| First order rate constant for removal from soil | k | 9x10-3 | [d-1] | A |
| OUTPUTS |  |  |  |  |
| Initial concentration in soil during application | Clocalsoil,applic | 0 | [kg.kgwwt-1] | O |
| Average daily emission of active ingredient due to leaching over the initial assessment period | Esoil,leach,time1 | 2.2x10-5 | [kg.d-1] | O |
| Average daily emission of active ingredient due to leaching over a longer duration | Esoil,leach,time2 | 1.2x10-5 | [kg.d-1] | O |
| Average emission rate of active ingredient to STP over the initial assessment period | ESTP,time1 | 5.2x10-5 | [kg.d-1] | O |
| Average emission rate of active ingredient to STP over a longer assessment period | ESTP,time2 | 2.8x10-5 | [kg.d-1] | O |
| Time weighted concentration in local soil over the initial assessment period | Clocalsoil,time1 | 7.1x10-10 | [kg.kgwwt-1] | O |
| Time weighted concentration in local soil over a longer duration | Clocalsoil,time2 | 3x10-9 | [kg.kgwwt-1] | O |

D=default, A=based on information of applicant, O=output

Calculations:

• Volume of wet soil

Vsoil =NOISEBARRIERlengthxDISTANCEhorizontalxDEPTH

Vsoil=1000 x0.5 x0.5= 250 m³

Based on information provided in in OECD ESD (number 2, part 2, page 72), during noise barrier scenario, it is assumed that 70% of leached product enters the STP and only 30% seeps into the adjacent soil:

STP

• ESTP,time1=( AREAnoise-barrier x FSTP x Qxleach,time1) / TIME1

ESTP,time1=3000x0.7x7.5x10-7/ 30 = 5.2x10-5 kg.d-1

• ESTP,time2=( AREAnoise-barrier x FSTP x Qxleach,time2) / TIME2

ESTP,time2=3000x0.7x7.5x10-5/ 5475= 2.8x10-5 kg.d-1

PECSTPtime1

ClocalSTP= ESTP/FLOWSTP

The OECD ESD does not give a default value of FLOWSTP. This can be assumed to be a small creek with a flow of 0.3 m³/s.

ClocalSTP= 5.2x10-5 x106/ (86400x0.3x103) = 2x10-6 mg/L

PECSTPtime2

ClocalSTP= ESTPtime2/FLOWSTP

The OECD ESD does not give a default value of FLOWSTP. This can be assumed to be a small creek with a flow of 0.3 m³/s.

ClocalSTP= 2.8x10-5 x106/ (86400 x0.3 x103) = 1x10-6 mg/L

Soil

• Esoil,leach,time1=( AREAwood x Qxleach,time1x Fsoil)/ TIME1

Esoil,leach,time1=(3000x7.5x10-7x0.3)/30 =2.2x10-5 [kg.d-1]

• Esoil,leach,time2=( AREAwoodx Qxleach,time2x Fsoil)/ TIME2

Esoil,leach,time2=(3000x7.5x10-5x0.3)/5475=1.2x10-5 [kg.d-1]

Pre-treated wood is used for the construction of the noise barrier; only the releases due to leaching from the wood are taken into consideration and Clocalsoil,applic=0

•

• Clocalsoil,time1=2.2x10-5/(250 x1700 x 9x10-3)+(1/9x10-3 x30)x (0-2.2x10-5/250 x1700 x9x10-3) x (1-e-30x0.009)

= 7.1x10-10 [kg.kgwwt-1]

• Clocalsoil,time2=1.2x10-5/(250 x1700 x9 x10-3) + (1/9x10-3x 5475)x(0 -1.2x10-5/(250 x1700 x9x10-3)) x (1-e-5475x0.009)

=3x10-9 [kg.kgwwt-1]

c. House scenario

Table 2.6.2.1.2.2- 8 House scenario data

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| INPUTS |  |  |  |  |
| Emission of active ingredient during application (assumed  to occur over 1 day) | Eapplic | / | [kg.d-1] | O |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | 5475 | [d] | D |
| Cumulative quantity of an active ingredient leached out of 1m2 of  treated wood over the initial assessment period is determined  based on the results of a leaching  test. | Qxleach,time1 | 7.5x10-7 | [kg.m-2] | A |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over the a longer assessment period | Qxleach,time2 | 7.5x10-5 | [kg.m-2] | A |
| Leachable treated wood area, proposed in the relevant scenarios  (cf. Appendix 3) | AREAwood | 125 | [m2] | D |
| Volume of receiving soil, proposed in the relevant scenarios (cf.  Appendix 3) | Vsoil | 12.5 | [m3] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil-water partitioning coefficient | Ksoil-water | 126 | [m3.m-3]  =mg/L | A |
| First order rate constant for removal from soil | k | 9x10-3 | [d-1] | A |
| OUTPUTS |  |  |  |  |
| Initial concentration in soil during application | Clocalsoil,applic | 0 | [kg.kgwwt-1] | O |
| Average daily emission of active ingredient due to leaching over the  initial assessment period | Esoil,leach,time1 | 3.1x10-6 | [kg.d-1] | O |
| Average daily emission of active ingredient due to leaching over a  longer duration | Esoil,leach,time2 | 1.7x10-6 | [kg.d-1] | O |
| Time weighted concentration in local soil over the initial  assessment period | Clocalsoil,time1 | 2x10-9 | [kg.kgwwt-1] | O |
| Time weighted concentration in local soil over a longer  duration | Clocalsoil,time2 | 8.7x10-9 | [kg.kgwwt-1] | O |

D=default, A=based on information of applicant, O=output

Calculations:

• Volume of wet soil

HOUSEcircumference = 2x(HOUSElength x HOUSE width) HOUSEcircumference = 2x(17.5+7.5) = 50 m

Vsoil = HOUSEcircumference x DISTANCEhorizontal x DEPTH

Vsoil =50x0.5x0.5= 12.5 m3

• Esoil,leach,time1 = (AREAwood x Qxleach,time1)/ TIME1

Esoil,leach,time1 = (125x7.5x10-7)/30 = 3.1x10-6  [kg.d-1]

• Esoil,leach,time2 = (AREAwood x Qxleach,time2)/ TIME2

Esoil,leach,time2 = (125x7.5x10-5)/5475=1.7x10-6 [kg.d-1]

Pre-treated wood is used for the construction of the house; only the releases due to leaching from the wood are taken into consideration and Clocalsoil,applic=0

Clocalsoil,time1 =3.1x10-6 /(12.5 x1700 x 9x10-3)+(1/9x10-3 x30) x (- 3.1x10-6 /12.5 x 1700 x 1.9x10-3) x (1-e-30x0.009)

= 2x10-9 [kg.kgwwt-1]

Clocalsoil,time2 =1.7x10-6/(12.5x1700x9x10-3) + (1/9x10-3x5475) x (-1.7x10-6/(12.5x1700x9x10-3)) x (1-e-5475x0.009)

=8.7x10-9 [kg.kgwwt-1]

###### Calculations of emissions for Propiconazole.

The environmental exposure assessment of Propiconazole from Axil 2000 has been determined with Emission Scenario Document (ESD) developed for product type 8 (wood preservatives) by OECD: OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Emission Scenario Document for Wood Preservatives. The emission scenarios estimate the emissions of wood preservatives from two stages of their life cycle:

• Application and storage of treated wood prior to shipment

• Treated wood in service

In the case of application and storage prior to shipment the emission scenarios used for Propiconazole cover: Automated spraying process and Dipping process.

The storage scenarios employed in this assessment assume that the storage area is uncovered and unpaved. However, according to the Annex I inclusion to directive 98/8/EC, in reality freshly treated timber must be stored on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.

In the case of treated wood in service, the following emission scenarios have been run for Propiconazole for use class 3: Fence, Noise barrier and House.

For the three emission scenarios of treated wood in service, calculations of emissions in soil have been done with Propiconazole removal processes in soil taken into account; according to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Part 3.

Axil 2000 is a water-based wood preservative containing 0.75% Tebuconazole, 0.75% Propiconazole and 0.75% IPBC. During tunnelling/ aspersion application 100g of the product diluted by 10% with water are applied per square meter of wood. So the application rate of each active ingredient is 0.075 g/m2. During short dipping application, 120g of the product diluted by 5% with water are applied per square meter of wood. So the application rate of Propiconazole is 0.045 g/m².

The leaching behaviour of Propiconazole from Axil 2000 has been determined with a semi-field testing on timber treated with Axil 2000. Please se the confidential version for more details.

A. Scenario for the life stage of product application

a. Emission scenario for automated spraying

Table 2.6.2.1.2.3-2 Application phase in automated spraying process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| Process: automated spraying scenario | | | | |
| INPUTS |  |  |  |  |
| Wood area treated per day | AREAwood-treated | 2000 | [m2.d-1] | D |
| Application rate: quantity of a.i. applied per 1 m2 of wood area | Qai | 7.5x10-5 | [kg.m-2] | A |
| Fraction released to facility drain solubility in water  [1g.l-1] >100 | Ffacilitydrain | 0.03 | [--] | D |
| Fraction released to air  vapour pressure at 20 °C  [Pa] < 0,005 | Fair | 0,001 | [--] | D |
| Fraction of spray drift deposition | Fdrift | 0,001 | [--] | D |
| OUTPUTS |  |  |  |  |
| Local emission rate to air | Elocalair | 3x10-4 | [kg.d-1] | O |
| Local emission rate to facility drain | Elocalfacilitydrain | 4.5x10-3 | [kg.d-1] | O |
| Local facility drain concentration | Clocalfacilitydrain | 1.74x10-4 | mg/L | O |

D=default, A=based on information of applicant, O=output

Calculations:

Application rate of a.i. (active ingredient) [kg.m-2]:

Qai= Qproduct xCai

Qai=100 x10% x0.75% x10-3=7.5x10-5 kg.m-2

**Plant: Emissions to local air [kg.d-1]**

Elocalair = AREAWood-Treated x Qai x (Fair +Fdrift)

Elocalair = 2000 x7.5x10-5 x (0.001+0.001) = 3x10-4 [kg.d-1]

**Plant: Emissions to facility drain [kg.d-1]**

Elocalfacilitydrain = AREAWood-Treated x Qai x Ffacilitydrain

Elocalfacilitydrain = 2000x7.5x10-5 x0.03 =4.5x10-3 [kg.d-1]

**PECSTP**

Clocalfacilitydrain = Elocalfacilitydrain /FLOWfacilitydrain

The OECD ESD does not give a default value of FLOWfacilitydrain. This can be assumed to be a small creek with a flow of 0.3 m3/s.

Clocalfacilitydrain = 4.5x10-3x106/ (86400 x0.3x103)= 1.74x10-4 mg/L

The facility drain is assumed to drain into the public sewage treatment plant (STP)

Table 2.6.2.1.2.3-3 Storage phase in automated spraying process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| Storage: automated spraying scenario | | | | |
| INPUTS |  |  |  |  |
| Effective surface area of treated wood, considered to be exposed to rain, per 1m2 storage area (i.e. soil) | AREAwood-expo | 11 | [m2.m-2] | D |
| Surface area of the storage place | AREAstorage | 79 | [m2] | D |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | 5475 | [d] | D |
| Duration of storage of treated wood prior to shipment | TIMEstorage | 3 | [d] | D |
| Average daily flux i.e. the average quantity of an active ingredient that is  daily leached out of 1 m2 of treated wood during 3 days storage period [kg.m-2.d-1] | FLUXstorage,spray | 2.6x10-8 | [kg.m-2  .d-1] | A |
| Volume of treated wood stacked per m2 of storage area (i.e. soil) | VOLUMEwood-stacked | 2 | [m3.m-2] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil depth | DEPTHsoil | 0,50 | [m] | D |
| Volume of (wet) soil | Vsoil | 39.5 | [m3] | D |
| Fraction of rainwater running off the storage site | Frunoff | 0.5 | [-] | D |
| OUTPUTS |  |  |  |  |
| Cumulative quantity of an active ingredient, leached due to rainfall from stored treated wood, over the initial assessment period | Qleach,storage,time1 | 6.7x10-4 | [kg] | O |
| Cumulative quantity of an active  ingredient, leached due to rainfall from stored treated wood, over a longer assessment period | Q leach,storage,time2 | / | [kg] | O |
| Local concentration in soil at storage place at the end of the initial assessment period | Clocalsoil,time1 | 5x10-9 | [kg.kgwwt-1] | O |
| Local concentration in soil at storage place at the end of a longer  assessment period | Clocalsoil,time2 | / | [kg.kgwwt-1] | O |
| Local emission rate in surface water resulting from leaching from stored  treated wood due to rain run-off, over the initial assessment period | Elocalsurfacewater,time1 | 1.1x10-5 | [kg.d-1] | O |
| Local emission rate in surface water resulting from leaching from stored  treated wood due to rain run-off, over a  longer assessment period | Elocalsurfacewater,time2 | / | [kg.d-1] | O |
|  | PECwater | 4.2x10-7 | mg/L | O |

D=default, A=based on information of applicant, O=output

**Calculations**:

• Volume of wet soil:

Vsoil = AREAstorage x DEPTHsoil

Vsoil = 79x0.5 =39,5 m3

Storage: Emissions at storage:

• For an initial assessment period TIME1

Qleach,storage,time1 = FLUXstorage,spray x AREAwood-expo x AREAstorage x TIME1

Qleach,storage,time1 = 2.6x10-8x11 x79 x 30 = 6.7x10-4 kg

Storage: Local concentration in soil

• For an initial assessment period TIME1

Clocalsoil,time1 = (0.5 x Qleach,storage,time1)/(Vsoil x RHOsoil)

Clocalsoil,time1 = (0.5 x 6.7 x10-4)/(39.5 x1700) = 5x10-9 kg.kgwwt-1

Storage: Emission rate to surface water

• For an initial assessment period TIME1

Elocalsurfacewater,time1 = (Qleach,storage,time1x Frunoff )/ TIME1

Elocalsurfacewater,time1 =(6.7x10-4 x 0.5) / 30 =1.1x10-5 [kg.d-1]

Clocalsurfacewater= Elocalsurfacewater/FLOWsurfacewater

The OECD ESD does not give a default value of FLOWsurfacewater. This can be assumed to be a small creek with a flow of 0.3 m3/s.

Clocalsurfacewater= 1.1x10-5 x106/ (86400 x 0.3x103) = 4.2x10-7 mg/L

Clocalsed=Ksusp-water /RHOsusp \*PEClocalwater\*1000 = 25.7 5/1150\*4.2x10-7\*1000 = 9.40 x10-6mg/kg

b. Emission Scenario for Dipping/Immersion Processes

Table 2.6.2.1.2.3-4 Application phase in industrial dipping process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| Process: dipping/immersion scenario | | | | |
| INPUTS |  |  |  |  |
| Volume of wood treated per day | VOLUMEwood-treated | 100 | [m² .d-1] | D |
| Application rate: quantity of a.i. applied per 1 m³ wood | Qai | 1.71 x 10-3 | [kg.m-3] | A |
| Fraction released to facility drain solubility in water [1g.l-1] =100 | Ffacilitydrain | 0.015 | [--] | D |
| Fraction released to air  vapour pressure at 20 °C  [Pa] < 0,005 | Fair | 0 | [--] | D |
| OUTPUTS |  |  |  |  |
| Local emission rate to air | Elocalair | 0 | [kg.d-1] | O |
| Local emission rate to facility drain | Elocalfacilitydrain | 2.56x10-3 | [kg.d-1] | O |
|  | Clocalfacilitydrain | 9.87x10-5 | mg/L | O |

D=default, A=based on information of applicant, O=output

Calculations:

• Application rate

Application rate of a.i. (active ingredient) [kg.m-3]:

Qai= Qproduct x Cai x Dilution

Qai=120 x 0.75% x 10%x10-3= 4.5x10-5 kg.m-2

According to the information provided by the American Chemistry Council (ACC) [ Adrian Krygsman, pers. Commun, 2001] ; 2000 m2 of wood treated correspond to 52.5 m3 of wood treated. See OECD ESD, number 2, page 37.

Thereby: 1 m²= 0.02625 m3 ;

Qai=4.5 x10-5/ 0.02625 = 1.71x10-3 kg.m-3

• **Plant: Emission to local air [kg.d-1]**

Elocalair =VOLUMEwood-treated xQai x Fair

Elocalair =100 x 1.71x10-3 x 0= 0 kg.d-1

• **Plant: Emission to facility drain [kg.d-1]**

Elocalfacilitydrain= VOLUMEwood-treated x Qai x Ffacilitydrain

Elocalfacilitydrain = 100 x 1.71 x10-3 x 0.015= 2.56 x 10-3 kg.d-1

• **PECSTP**

Clocalfacilitydrain = Elocalfacilitydrain /FLOWfacilitydrain

The OECD ESD does not give a default value of FLOWfacilitydrain. This can be assumed to be a small

creek with a flow of 0.3 m3/s.

Clocalfacilitydrain= 2.56 x10-3 x 106/ (86400 x0.3x103) = 9.87 x 10-5 mg/L

Table 2.6.2.1.2.3-5 Storage phase in industrial dipping process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| Storage: Storage: dipping scenario | | | | |
| INPUTS |  |  |  |  |
| Effective surface area of treated wood, considered to be exposed to rain, per 1m2 storage area (i.e. soil) | AREAwood-expo | 11 | [m2.m-2] | D |
| Surface area of the storage place | AREAstorage | 700 | [m2] | D |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | / | [d] | D |
| Duration of storage of treated wood prior to shipment | TIMEstorage | 14 | [d] | D |
| Average daily flux i.e. the average quantity of an active ingredient that is daily leached out of 1 m2 of treated wood during 14 day storage period | FLUXstorage,dipp | 1.69 x10-8 | [kg.m-2.d-1] | A |
| Volume of treated wood stacked per 1 m2 of storage area (i.e. soil) | VOLUMEwood-stacked | 2 | [m3.m-2] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil depth | DEPTHsoil | 0.50 | [m] | D |
| Volume of (wet) soil | Vsoil | 350 | [m3] | D |
| Fraction of rainwater running off the storage site | Frunoff | 0.5 | [-] | D |
| OUTPUTS |  |  |  |  |
| Cumulative quantity of an active ingredient, leached due to rainfall from stored treated wood, over the initial assessment period | Qleach,storage,time1 | 3.9x10-3 | [kg] | O |
| Cumulative quantity of an active ingredient, leached due to rainfall from stored treated wood, over a longer assessment period | Qleach,storage,time2 | / | [kg] | O |
| Local concentration in soil at storage place at the End of the initial assessment period | Clocalsoil,time1 | 3.28x10-9 | [kg.kgwwt-1] | O |
| Local concentration in soil at storage place at the end of a longer assessment period | Clocalsoil,time2 | / | [kg.kgwwt-1] | O |
| Local emission rate in surface water resulting from leaching from stored treated wood due to rain run-off, over the initial assessment period | Elocalsurfacewater,time1 | 6.5x10-5 | [kg.d-1] | O |
| Local emission rate in surface water resulting from leaching from stored treated wood due to rain run-off, over a longer assessment period | Elocalsurfacewater,time2 | / | [kg.d-1] | O |
|  | PECwater | 2.5x10-6 | [mg/L] | O |

D=default, A=based on information of applicant, O=output

**Calculations**:

• Volume of wet soil:

Vsoil= AREAstorage x DEPTHsoil

Vsoil= 700 x 0.5 = 350 m3

Storage: Emissions at storage:

• For an initial assessment period TIME1

Qleach,storage,time1= FLUXstorage,dipp x AREAwood-expo x AREAstorage x TIME1

Qleach,storage,time1= 1.69 x10-8x 11x 700x 30 = 3.9 x10-3 kg

Storage: Local concentration in soil

• Concentration in soil at storage place at the end of the initial assessment period TIME1

Clocalsoil,time1=(0.5x Qleach,storage,time1) / (Vsoil x RHOsoil)

Clocalsoil,time1=(0.5x 3.9 x10-3) / (350 x1700) = 3.28 x10-9 kg.kgwwt-1

Storage: Emission rate to (adjacent) surface water

• Emission rate from the storage place to an adjacent surface water body over an initial assessment period TIME1

Elocalsurfacewater,time1=( Qleach,storage,time1x Frunoff) / TIME1

Elocalsurfacewater,time1= (3.9 x 10-3 x0.5)/ 30 =6.5 x10-5 kg.d-1

Clocalsurfacewater = Elocalsurfacewater/FLOWsurfacewater

The OECD ESD does not give a default value of FLOWsurfacewater. This can be assumed to be a small creek with a flow of 0.3 m3/s.

Clocalsurfacewater = 6.5x10-5 x106/ (86400 x0.3 x103) = 2.5 x10-6 mg/L

Clocalsed=Ksusp-water /RHOsusp \*PEClocalwater\*1000 = 25.75/1150\*2.5x10-6\*1000 = 5.59x10-5mg/kg

B. Scenario for the life stage of treated wood-in-service a. Fence scenario

Table 2.6.2.1.2.3-6 Fence scenario data:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| INPUTS |  |  |  |  |
| Emission of active ingredient during application (assumed to occur over 1 day) | Eapplic | / | [kg.d-1] | O |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | 5475 | [d] | D |
| Cumulative quantity of an active ingredient leached out of 1m² of treated wood over the initial assessment period is  determined based on the results of a leaching test. | Qxleach,time1 | 7.8x10-7 | [kg.m-2] | A |
| Cumulative quantity of an active ingredient leached out of 1m²  of treated wood over the a longer assessment period | Qxleach,time2 | 7.5x10-5 | [kg.m-2] | A |
| Leachable treated wood area, proposed in the relevant scenarios (cf. Appendix 3) | AREAwood | 2 | [m2] | D |
| Volume of receiving soil, proposed in the relevant  scenarios (cf. Appendix 3) | Vsoil | 0.25 | [m3] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil-water partitioning coefficient | Ksoil-water | 126 | [m3.m-3]  =mg/L | A |
| First order rate constant for removal from soil | k | 5x10-3 | [d-1] | A |
| OUTPUTS |  |  |  |  |
| Initial concentration in soil during application | Clocalsoil,applic | 0 | [kg.kgwwt-1] | O |
| Average daily emission of active ingredient due to leaching over the initial assessment period | Esoil,leach,time1 | 5.2x10-8 | [kg.d-1] | O |
| Average daily emission of active ingredient due to leaching over  a longer duration | Esoil,leach,time2 | 2.7x10-8 | [kg.d-1] | O |
| Time weighted concentration in local soil over the initial assessment period | Clocalsoil,time1 | 1.7x10-9 | [kg.kgwwt-1] | O |
| Time weighted concentration in local soil over a longer duration | Clocalsoil,time2 | 1.2x10-8 | [kg.kgwwt-1] | O |

D=default, A=based on information of applicant, O=output

**Calculations:**

• Volume of wet soil

Vsoil =FENCElength x DISTANCEhorizontal xDEPTH

Vsoil=1x 0.5 x 0.5= 0.25 m3

• Qxleach,time1= FLUXTIME1xTIME1

Qxleach,time1=2.6x10-8x30= 7.8x10-7 kg.m-2

• Qxleach,time2= FLUXTIME2xTIME2

Qxleach,time2=1.37x10-8 x5475= 7.5x10-5 kg.m-2

• k=Ln2/DT50

DT50=129d.

k=Ln2/129=0.005d-1

• Esoil,leach,time1=(AREAwood x Qxleach,time1)/TIME1

Esoil,leach,time1=(2 x 7.8x10-7)/30=5.2x10-8[kg.d-1]

*•* Esoil,leach,time2= (AREAwoodx Qxleach,time2)/ TIME2

• Esoil,leach,time2= (2x7.5x10-5)/5475=2.7x10-8[kg.d-1]

Pre-treated wood is used for the construction of the fence; only the releases due to leaching from the wood are taken into consideration and Clocalsoil,applic=0

Clocalsoil,time1= 5.2x10-8/(0.25x1700x5x10-3)+(1/5x10-3x30)x(-5.2x10-8/0.25x 1700x 5x10-3) x (1-e-30x0.005)

= 1.7x10-9 [kg.kgwwt-1]

• Clocalsoil,time2 = 2.7x10-8/(0.25 x1700 x 5x10-3)+(1/5x10-3x 5475) x (-2.7x10-8/(0.25x 1700 x 5x10-3)) x (1-e-5475x5x10-3)

=1.2x10-8 [kg.kgwwt-1]

b. Noise barrier scenario

Table 2.6.2.1.2.3-7 Noise barrier scenario data

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| INPUTS |  |  |  |  |
| Emission of active ingredient during application (assumed  to occur over 1 day) | Eapplic | / | [kg.d-1] | O |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | 5475 | [d] | D |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over the initial assessment period is determined based on the results of a leaching test. | Qxleach,time1 | 7.8x10-7 | [kg.m-2] | A |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over the a longer assessment period | Qxleach,time2 | 7.5x10-5 | [kg.m-2] | A |
| Leachable treated wood area, proposed in the relevant scenarios (cf. Appendix 3) | AREAwood | 3000 | [m2] | D |
| Volume of receiving soil, proposed in the relevant scenarios (cf. Appendix 3) | Vsoil | 250 | [m3] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil-water partitioning coefficient | Ksoil-water | 126 | [m3.m-3]  =mg/L | A |
| Fraction released to STP | FSTP | 0.7 | [-] | D |
| Fraction released to soil | Fsoil | 0.3 | [-] | D |
| First order rate constant for removal from soil | k | 5x10-3 | [d-1] | A |
| OUTPUTS |  |  |  |  |
| Average emission rate of active ingredient to STP over the initial assessment period | ESTP,time1 | 5.4x10-5 | [kg.d-1] | O |
| Average emission rate of active ingredient to STP over a longer assessment period | ESTP,time2 | 2.8x10-5 | [kg.d-1] | O |
| Initial concentration in soil during application | Clocalsoil,applic | 0 | [kg.kgwwt-1] | O |
| Average daily emission of active ingredient due to leaching over the initial assessment period | Esoil,leach,time1 | 2.3x10-5 | [kg.d-1] | O |
| Average daily emission of active ingredient due to leaching over a longer duration | Esoil,leach,time2 | 1.2x10-5 | [kg.d-1] | O |
| Time weighted concentration in local soil over the initial assessment period | Clocalsoil,time1 | 7.7x10-10 | [kg.kgwwt-1] | O |
| Time weighted concentration in local soil over a longer duration | Clocalsoil,time2 | 5.4x10-9 | [kg.kgwwt-1] | O |

D=default, A=based on information of applicant, O=output

Calculations:

• Volume of wet soil

Vsoil =NOISE BARRIERlength xDISTANCEhorizontalxDEPTH

Vsoil=1000 x0.5x 0.5= 250 m3

Based on information provided in in OECD ESD (number 2, part 2, page 72), during noise barrier scenario, it is assumed that 70% of leached product enters the STP and only 30% seeps into the adjacent soil:

STP

• ESTP,time1= (AREAnoise-barrier x FSTP x Qxleach,time1)/TIME1

ESTP,time1=3000x0.7x7.8x10-7/ 30 = 5.4x10-5 kg.d-1

• ESTP,time2= (AREAnoise-barrier x FSTP x Qxleach,time2)/TIME2

ESTP,time2= 3000x 0.7x 7.5x10-5/5475= 2.8x10-5 kg.d-1

PECSTPtime1

ClocalSTP= ESTP/FLOWSTP

The OECD ESD does not give a default value of FLOWSTP. This can be assumed to be a small creek with a flow of 0.3 m3/s.

ClocalSTP= 5.4x10-5 x106/ (86400x0.3x103) = 2.1x10-6 mg/L

PECSTPtime2

ClocalSTP = ESTPtime2/FLOWSTP

The OECD ESD does not give a default value of FLOWSTP. This can be assumed to be a small creek with a flow of 0.3 m3/s.

ClocalSTP= 2.8x10-5 x106/ (86400x0.3x103) = 1x10-6 mg/L

Soil

• Esoil,leach,time1= (AREAwood x Qxleach,time1x Fsoil)/ TIME1

Esoil,leach,time1=(3000x7.8x10-7x0.3)/30 =2.3x10-5 [kg.d-1]

• Esoil,leach,time2= (AREAwood x Qxleach,time2x Fsoil)/TIME2

Esoil,leach,time2 = (3000x7.5x10-5x0.3)/5475=1.2x10-5 [kg.d-1]

Pre-treated wood is used for the construction of the noise barrier; only the releases due to leaching from the wood are taken into consideration and Clocalsoil,applic=0

• Clocalsoil,time1=2.3x10-5/(250 x1700x 5x 10-3)+(1/5x10-3x30)x (-2.3x10-5/250x1700x5x10-3)

x (1-e-30x0.005)

= 7.7x10-10 [kg.kgwwt-1]

• Clocalsoil,time2= 1.2x10-5/ (250x1700x5x10-3) + (1/5x10-3x5475) x (-1.2x10-5/(250x1700x5x10-3))

x (1-e-5475x0.005)

= 5.4x10-9 [kg.kgwwt-1]

c. House scenario

Table 2.6.2.1.2.3-8 House scenario data:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| INPUTS |  |  |  |  |
| Emission of active ingredient during application (assumed to occur over 1 day) | Eapplic | / | [kg.d-1] | O |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | 5475 | [d] | D |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over the initial assessment period is determined based on the results of a leaching test. | Qxleach,time1 | 7.8x10-7 | [kg.m-2] | A |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over the a longer assessment period | Qxleach,time2 | 7.5x10-5 | [kg.m-2] | A |
| Leachable treated wood area, proposed in the relevant scenarios (cf. Appendix 3) | AREAwood | 125 | [m2] | D |
| Volume of receiving soil, proposed in the relevant  scenarios (cf. Appendix 3) | Vsoil | 12.5 | [m3] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil-water partitioning coefficient | Ksoil-water | 126 | [m3.m-3]  =mg/L | A |
| First order rate constant for removal from soil | k | 5x10-3 | [d-1] | A |
| OUTPUTS |  |  |  |  |
| Initial concentration in soil during application | Clocalsoil,applic | 0 | [kg.kgwwt-1] | O |
| Average daily emission of active ingredient due to leaching over the initial assessment period | Esoil,leach,time1 | 3.2x10-6 | [kg.d-1] | O |
| Average daily emission of active ingredient due to leaching over a longer duration | Esoil,leach,time2 | 1.7x10-6 | [kg.d-1] | O |
| Time weighted concentration in local soil over the initial  assessment period | Clocalsoil,time1 | 2.1x10-9 | [kg.kgwwt-1] | O |
| Time weighted concentration in local soil over a longer  duration | Clocalsoil,time2 | 1.5x10-8 | [kg.kgwwt-1] | O |

D=default, A=based on information of applicant, O=output

Calculations:

• Volume of wet soil

HOUSEcircumference=2x(HOUSElengthxHOUSEwidth) HOUSEcircumference=2x(17.5+7.5) = 50 m

Vsoil =HOUSEcircumferencexDISTANCEhorizontalxDEPTH

Vsoil=50x0.5x0.5= 12.5 m3

• Esoil,leach,time1=( AREAwoodx Qxleach,time1)/ TIME1

Esoil,leach,time1=(125x7.8x10-7)/30 =3.2x10-6 [kg.d-1]

• Esoil,leach,time2=( AREAwood x Qxleach,time2)/ TIME2

Esoil,leach,time2=(125x7.5x10-5)/5475=1.7x10-6 [kg.d-1]

Pre-treated wood is used for the construction of the house; only the releases due to leaching from the wood are taken into consideration and Clocalsoil,applic=0

* Clocalsoil,time1=3.2x10-6 /(12.5x1700x5x10-3)+(1/5x10-3x30) x (-3.2x10-6 /12.5x1700x5x10-3) x (1-e-30x0.005)

= 2.1x10-9 [kg.kgwwt-1]

* Clocalsoil,time2 =1.7x10-6 / (12.5x1700x5x10-3) + (1/5x10-3x5475)x (-1.7x10-6 /(12.5x1700x5x

10-3)) x (1-e-5475x0.005)

=1.5x10-8 [kg.kgwwt-1]

###### Calculations of emissions for IPBC.

The environmental exposure assessment of IPBC from Axil 2000 has been determined with Emission Scenario Document (ESD) developed for product type 8 (wood preservatives) by OECD: OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Emission Scenario Document for Wood Preservatives. The emission scenarios estimate the emissions of wood preservatives from two stages of their life cycle:

• Application and storage of treated wood prior to shipment;

• Treated wood in service.

In the case of application and storage prior to shipment the emission scenarios used for IPBC cover: Automated spraying process and Short Dipping process.

The storage scenarios employed in this assessment assume that the storage area is uncovered and unpaved. However, according to the Annex I inclusion to directive 98/8/EC, in reality freshly treated timber must be stored on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.

In the case of treated wood in service, the following emission scenarios have been run for IPBC for use class 3: Fence, Noise barrier and House.

For the three emission scenarios of treated wood in service, calculations of emissions in soil have been done with IPBC removal processes in soil taken into account; according to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Part 3.

Axil 2000 is a water-based wood preservative containing 0.75% Tebuconazole, 0.75% Propiconazole and 0.75% IPBC. During application by tunnelling/aspersion 100g of the product diluted by 10% with water are applied per square meter of wood. So the application rate of each active ingredient is 0.075 g/m2. During application by short dipping, 120g of the product diluted by 5% with water are applied per square meter of wood. So the application rate of IPBC is 0.045 g/m².

The leaching behaviour of IPBC from Axil 2000 has been determined with a semi-field testing on timber treated with Axil 2000. Please se the confidential version for more details.

A. Scenario for the product application

a. Emission scenario for automated spraying

Table 2.6.2.1.2.4-2 Application phase in automated spraying process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| Process: automated spraying scenario | | | | |
| INPUTS |  |  |  |  |
| Wood area treated per day | AREAwood-treated | 2000 | [m2.d-1] | D |
| Application rate: quantity of a.i. applied per 1 m2 of wood area | Qai | 7.5x10-5 | [kg.m-2] | A |
| Fraction released to facility drain solubility in water  [1g.l-1] >100 | Ffacilitydrain | 0.03 | [--] | D |
| Fraction released to air  vapour pressure at 20 °C  [Pa] < 0,005 | Fair | 0,001 | [--] | D |
| Fraction of spray drift deposition | Fdrift | 0,001 | [--] | D |
| OUTPUTS |  |  |  |  |
| Local emission rate to air | Elocalair | 3x10-4 | [kg.d-1] | O |
| Local emission rate to facility drain | Elocalfacilitydrain | 4.5x10-3 | [kg.d-1] | O |
| Local facility drain concentration | Clocalfacilitydrain | 1.74x10-4 | [mg/L] | O |

D=default, A=based on information of applicant, O=output

Calculations:

Application rate of a.i. (active ingredient) [kg.m-2]:

Qai = Qproduct xCai

Qai =100 x 0.75% x 10% x 10-3=7.5x10-5 [kg.m-2]

**Plant: Emissions to local air [kg.d-1]**

Elocalair = AREAWood-Treated x Qai x (Fair +Fdrift)

Elocalair = 2000 x7.5x10-5x (0.001+0.001) = 3x10-4 [kg.d-1]

**Plant: Emissions to facility drain [kg.d-1]**

Elocalfacilitydrain = AREAWood-Treated x Qai x Ffacilitydrain

Elocalfacilitydrain= 2000x7.5x10-5x0.03 =4.5x10-3 [kg.d-1]

**PECSTP**

Clocalfacilitydrain= Elocalfacilitydrain /FLOWfacilitydrain

The OECD ESD does not give a default value of FLOWfacilitydrain. This can be assumed to be a small creek with a flow of 0.3 m3/s.

Clocalfacilitydrain= 4.5x10-3x106/ (86400x 0.3 x 103) = 1.74x10-4 mg/L

The facility drain is assumed to drain into the public sewage treatment plant (STP).

Table 2.6.2.1.2.4-3 Storage phase in automated spraying process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| Storage: automated spraying scenario | | | | |
| INPUTS |  |  |  |  |
| Effective surface area of treated wood, considered to be exposed to rain, per 1m2 storage area (i.e. soil) | AREAwood-expo | 11 | [m2.m-2] | D |
| Surface area of the storage place | AREAstorage | 79 | [m2] | D |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | 5475 | [d] | D |
| Duration of storage of treated wood prior to shipment | TIMEstorage | 3 | [d] | D |
| Average daily flux i.e. the average quantity of an active ingredient that is  daily leached out of 1 m2 of treated wood during 3 days storage period [kg.m-2.d-1] | FLUXstorage,spray | 1.1x10-8 | [kg.m-2.d-1 ] | A |
| Volume of treated wood stacked per m2 of storage area (i.e. soil) | VOLUMEwood-stacked | 2 | [m3.m-2] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil depth | DEPTHsoil | 0,50 | [m] | D |
| Volume of (wet) soil | Vsoil | 39.5 | [m3] | D |
| Fraction of rainwater running off the storage site | Frunoff | 0.5 | [-] | D |
| OUTPUTS |  |  |  |  |
| Cumulative quantity of an active ingredient, leached due to rainfall from stored treated wood, over the initial  assessment period | Qleach,storage,time1 | 3.1x10-3 | [kg] | O |
| Cumulative quantity of an active  ingredient, leached due to rainfall from stored treated wood, over a longer assessment period | Qleach,storage,time2 | / | [kg] | O |
| Local concentration in soil at storage place at the end of the initial assessment period | Clocalsoil,time1 | 2.1x10-9 | [kg.kgwwt-1] | O |
| Local concentration in soil at storage place at the end of a longer  assessment period | Clocalsoil,time2 | / | [kg.kgwwt-1] | O |
| Local emission rate in surface water resulting from leaching from stored  treated wood due to rain run-off, over the initial assessment period | Elocalsurfacewater,time1 | 4.6x10-6 | [kg.d-1] | O |
| Local emission rate in surface water resulting from leaching from stored treated  wood due to rain run-off, over a longer  assessment period | Elocalsurfacewater,time2 | / | [kg.d-1] | O |
|  | PECwater | 1.8x10-7 | [mg/L] | O |

D=default, A=based on information of applicant, O=output

Calculations:

• Volume of wet soil:

Vsoil= AREAstorage x DEPTHsoil

Vsoil=79x0.5 =39,5 m3

Storage: Emissions at storage:

• For an initial assessment period TIME1

Qleach,storage,time1 = FLUXstorage,spray x AREAwood-expo x AREAstorage x TIME1

Qleach,storage,time1 =1.1x10-8 x 11x 79x30 = 2.8x10-4 kg

Storage: Local concentration in soil

• For an initial assessment period TIME1

Clocalsoil,time1 =(0.5x Qleach,storage,time1)/( Vsoil x RHOsoil)

Clocalsoil,time1 =(0.5x2.8x10-4)/(39.5x1700)=2.1x10-9 kg.kgwwt-1

Storage: Emission rate to surface water

• For an initial assessment period TIME1

Elocalsurfacewater,time1 = (Qleach,storage,time1x Frunoff )/ TIME1

Elocalsurfacewater,time1 =(2.8x10-4 x0.5) / 30 =4.6x10-6 [kg.d-1]

Clocalsurfacewater = Elocalsurfacewater/FLOWsurfacewater

The OECD ESD does not give a default value of FLOWsurfacewater. This can be assumed to be a small creek with a flow of 0.3 m3/s.

Clocalsurfacewater = 4.6x10-6 x106/ (86400x0.3x103) = 1.8x10-7 mg/L

Clocalsed=Ksusp-water /RHOsusp \*PEClocalwater\*1000 = 4.05 /1150\*1.8x10-7\*1000 = 6.34x10-7 mg/kg

b. Emission Scenario for Dipping/Immersion Processes

Table 2.6.2.1.2.4-4 Application phase in industrial dipping process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| Process: dipping/immersion scenario | | | | |
| INPUTS |  |  |  |  |
| Volume of wood treated per day | VOLUMEwood-treated | 100 | [m3 .d-1 ] | D |
| Application rate: quantity of a.i. applied per 1 m3 wood | Qai | 1.71x10-3 | [kg.m-3] | A |
| Fraction released to facility drain solubility in water [1g.l-1] >100 | Ffacilitydrain | 0.03 | [--] | D |
| Fraction released to air  vapour pressure at 20 °C [Pa]  < 0,005 | Fair | 0 | [--] | D |
| OUTPUTS |  |  |  |  |
| Local emission rate to air | Elocalair | 0 | [kg.d-1] | O |
| Local emission rate to facility drain | Elocalfacilitydrain | 5.1x10-3 | [kg.d-1] | O |
|  | Clocalfacilitydrain | 1.97 x 10-4 | [mg/L] | O |

D=default, A=based on information of applicant, O=output

Calculations:

• Application rate

Application rate of a.i. (active ingredient) [kg.m-3]:

Qai= Qproduct x Cai x Dilution

Qai=120 x 0.75% x10% x10-3=7.5x10-5 kg.m-2

According to the information provided by the American Chemistry Council (ACC) [ Adrian Krygsman, pers. Commun, 2001] ; 2000 m2 of wood treated correspond to 52.5 m3 of wood treated. See OECD ESD, number 2, page 37.

Thereby: 1 m2= 0.02625 m3 ;

Qai=4.5x10-5/ 0.02625= 1.71x10-3 kg.m-3

• **Plant: Emission to local air [kg.d-1]**

Elocalair =VOLUMEwood-treated x Qai x Fair

Elocalair =100 x2.86 x10-3x 0 = 0 kg.d-1

• **Plant: Emission to facility drain [kg.d-1]**

Elocalfacilitydrain = VOLUMEwood-treated x Qai x Ffacilitydrain

Elocalfacilitydrain= 100 x 1.71 x10-3 x 0.03= 5.1x10-3 kg.d-1

• **PECSTP**

Clocalfacilitydrain = Elocalfacilitydrain /FLOWfacilitydrain

The OECD ESD does not give a default value of FLOWfacilitydrain. This can be assumed to be a small creek with a flow of 0.3 m3/s.

Clocalfacilitydrain= 5.1x10-3 x106/ (86400x0.3x103) = 1.97 x 10-4 mg/L

Table 2.6.2.1.2.4-5 Storage phase in industrial dipping process

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| Storage: Storage: dipping scenario | | | | |
| INPUTS |  |  |  |  |
| Effective surface area of treated wood, considered to be exposed to rain, per 1m2 storage area (i.e. soil) | AREAwood-expo | 11 | [m2.m-2] | D |
| Surface area of the storage place | AREAstorage | 700 | [m2] | D |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | / | [d] | D |
| Duration of storage of treated wood prior to shipment | TIMEstorage | 14 | [d] | D |
| Average daily flux i.e. the average quantity of an active ingredient that is daily leached out of 1 m2 of treated wood during 14 day storage period | FLUXstorage,dipp | 8.6x10-9 | [kg.m-2 .d-1] | A |
| Volume of treated wood stacked per 1 m2 of storage area (i.e. soil) | VOLUMEwood-stacked | 2 | [m3.m-2] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil depth | DEPTHsoil | 0.50 | [m] | D |
| Volume of (wet) soil | Vsoil | 350 | [m3] | D |
| Fraction of rainwater running off the storage site | Frunoff | 0.5 | [-] | D |
| OUTPUTS |  |  |  |  |
| Cumulative quantity of an active ingredient, leached due to rainfall from stored treated wood, over the initial assessment period | Qleach,storage,time1 | 1.9x10-3 | [kg] | O |
| Cumulative quantity of an active Ingredient, leached due to rainfall  from stored treated wood, over a longer  assessment period | Qleach,storage,time2 | / | [kg] | O |
| Local concentration in soil at storage place at the End of the initial assessment period | Clocalsoil,time1 | 1.6x10-9 | [kg.kgwwt-1] | O |
| Local concentration in soil at storage  place at the end of a longer assessment period | Clocalsoil,time2 | / | [kg.kgwwt-1] | O |
| Local emission rate in surface water  resulting from leaching from stored  treated wood due to rain run-off, over the initial assessment period | Elocalsurfacewater,time1 | 3.2x10-5 | [kg.d-1] | O |
| Local emission rate in surface water resulting from leaching from stored treated wood due to rain run-off, over a longer assessment period | Elocalsurfacewater,time2 | / | [kg.d-1] | O |
|  | PECwater | 1.2x10-6 | [mg/L] | O |

D=default, A=based on information of applicant, O=output

**Calculations**:

• Volume of wet soil:

Vsoil = AREAstorage x DEPTHsoil

Vsoil = 700 x 0.5 = 350 m3

Storage: Emissions at storage:

• For an initial assessment period TIME1

Qleach,storage,time1= FLUXstorage,dipp x AREAwood-expo x AREAstorage x TIME1

Qleach,storage,time1= 8.6 x 10-9 x 11 x 700 x 30 = 1.9 x10-3 kg

Storage: Local concentration in soil

• Concentration in soil at storage place at the end of the initial assessment period TIME1

Clocalsoil,time1 = (0.5x Qleach,storage,time1) / (Vsoil x RHOsoil)

Clocalsoil,time1 =(0.5x 1.9 x10-3) / (350x1700) = 1.6 x10-9 kg.kgwwt-1

Storage: Emission rate to (adjacent) surface water

• Emission rate from the storage place to an adjacent surface water body over an initial assessment period TIME1

Elocalsurfacewater,time1 = (Qleach,storage,time1 x Frunoff) / TIME1

Elocalsurfacewater,time1 = (1.9 x10-3 x0.5)/ 30 = 3.2 x10-5 kg.d-1

Clocalsurfacewater= Elocalsurfacewater/FLOWsurfacewater

The OECD ESD does not give a default value of FLOWsurfacewater. This can be assumed to be a small creek with a flow of 0.3 m3/s.

Clocalsurfacewater = 3.2 x10-5 x106/ (86400 x 0.3 x103) = 1.2 x10-6 mg/L

Clocalsed=Ksusp-water /RHOsusp \*PEClocalwater\*1000 = 4.05 /1150\*1.2x10-6\*1000 = 4.22 x10-6 mg/kg

B. Scenario for the life stage of treated wood-in-service

a. Fence scenario

Table 2.6.2.1.2.4-6 Fence scenario data

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| INPUTS |  |  |  |  |
| Emission of active ingredient during application (assumed  to occur over 1 day) | Eapplic | / | [kg.d-1] | O |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | 5475 | [d] | D |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over the initial assessment period is determined based on the results of a leaching test. | Qxleach,time1 | 3.3x10-7 | [kg.m-2] | A |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over the a longer assessment period | Qxleach,time2 | 7.5x10-5 | [kg.m-2] | A |
| Leachable treated wood area, proposed in the relevant  scenarios (cf. Appendix 3) | AREAwood | 2 | [m2] | D |
| Volume of receiving soil, proposed in the relevant  scenarios (cf. Appendix 3) | Vsoil | 0.25 | [m3] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil-water partitioning coefficient | Ksoil-water | 126 | [m3.m-3]  =mg/L | A |
| First order rate constant for removal from soil | k | 7.7 | [d-1] | A |
| OUTPUTS |  |  |  |  |
| Initial concentration in soil during application | Clocalsoil,applic | 0 | [kg.kgwwt-1] | O |
| Average daily emission of active ingredient due to leaching over the initial assessment period | Esoil,leach,time1 | 2.2x10-8 | [kg.d-1] | O |
| Average daily emission of active ingredient due to leaching over a longer duration | Esoil,leach,time2 | 2.7x10-8 | [kg.d-1] | O |
| Time weighted concentration in local soil over the initial  assessment period | Clocalsoil,time1 | 1x10-11 | [kg.kgwwt-1] | O |
| Time weighted concentration in local soil over a longer  duration | Clocalsoil,time2 | 1x10-11 | [kg.kgwwt-1] | O |

D=default, A=based on information of applicant, O=output

Calculations:

• Volume of wet soil

Vsoil =FENCElength x DISTANCEhorizontal xDEPTH

Vsoil=1x0.5x0.5= 0.25 m3

• Qxleach,time1= FLUXTIME1 x TIME1

Qxleach,time1=1.1x10-8 x30= 3.3x10-7 kg.m-2

• Qxleach,time2 = FLUXTIME2 x TIME2

Qxleach,time2 = 1.37x10-8 x 5475= 7.5x10-5 kg.m-2

• k=Ln2/DT50

DT50=2.1h=2.1/24 = 0.09 d

k=Ln2/0.09=7.7 d-1

• Esoil,leach,time1=( AREAwood x Qxleach,time1)/ TIME1

Esoil,leach,time1=(2x3.3x10-7)/30 =2.2 x10-8 [kg.d-1]

• Esoil,leach,time2 = (AREAwood x Qxleach,time2)/ TIME2

• Esoil,leach,time2 = (2x7.5x10-5)/5475=2.7x10-8 [kg.d-1]

Pre-treated wood is used for the construction of the fence; only the releases due to leaching from the wood are taken into consideration and Clocalsoil,applic=0

Clocalsoil,time1 =2.2x10-8/(0.25x1700x7.7)+(1/7.7x30)x(-2.2x10-8/0.25x1700x7.7) x (1-e-30x7.7)

= 1x10-11 [kg.kgwwt-1]

Clocalsoil,time2=2.7x10-8/ (0.25x1700x7.7)+(1/7.7x5475) x (- 2.7x10-8/(0.25x1700x7.7)) x

(1-e-5475x7.7)

=1x10-11 [kg.kgwwt-1]

b. Noise barrier scenario

Table 2.6.2.1.2.4-7 Noise barrier scenario data

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| INPUTS |  |  |  |  |
| Emission of active ingredient during application (assumed to occur over 1 day) | Eapplic | / | [kg.d-1] | O |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | 5475 | [d] | D |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over the initial assessment period is determined  based on the results of a leaching test. | Qxleach,time1 | 3.3x10-7 | [kg.m-2] | A |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over the a longer assessment period | Qxleach,time2 | 7.5x10-5 | [kg.m-2] | A |
| Leachable treated wood area, proposed in the relevant scenarios (cf. Appendix 3) | AREAwood | 3000 | [m2] | D |
| Volume of receiving soil, proposed in the relevant scenarios (cf. Appendix 3) | Vsoil | 250 | [m3] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil-water partitioning coefficient | Ksoil-water | 126 | [m3.m-3]  =mg/L | A |
| Fraction released to STP | FSTP | 0.7 | [-] | D |
| Fraction released to soil | Fsoil | 0.3 | [-] | D |
| First order rate constant for removal from soil | k | 7.7 | [d-1] | A |
| OUTPUTS |  |  |  |  |
| Initial concentrationin soil during application | Clocalsoil,applic | 0 | [kg.kgwwt-1] | O |
| Average emission rate of active ingredient to STP over the initial assessment period | ESTP,time1 | 2.3x10-5 | [kg.d-1] | O |
| Average emission rate of active ingredient to STP over a longer assessment period | ESTP,time2 | 2.8x10-5 | [kg.d-1] | O |
| Average daily emission of active ingredient due to leaching over the initial assessment  period | Esoil,leach,time1 | 9.9x10-6 | [kg.d-1] | O |
| Average daily emission of active ingredient due to leaching over a longer duration | Esoil,leach,time2 | 1.2x10-5 | [kg.d-1] | O |
| Time weighted concentration in local soil over the initial assessment period | Clocalsoil,time1 | 3x10-12 | [kg.kgwwt-1] | O |
| Time weighted concentration in local soil over a longer duration | Clocalsoil,time2 | 3.6x10-12 | [kg.kgwwt-1]] | O |

D=default, A=based on information of applicant, O=output

Calculations:

• Volume of wet soil

Vsoil =NOISE BARRIERlength xDISTANCEhorizontal xDEPTH

Vsoil=1000x0.5x0.5= 250 m3

Based on information provided in in OECD ESD (number 2, part 2, page 72), during noise barrier scenario, it is assumed that 70% of leached product enters the STP and only 30% seeps into the adjacent soil:

STP

• ESTP,time1 = (AREAnoise-barrier x FSTP x Qxleach,time1) / TIME1

ESTP,time1 = 3000x0.7x3.3x10-7/ 30 = 2.3x10-5 kg.d-1

• ESTP,time2= (AREAnoise-barrier x FSTP x Qxleach,time2) / TIME2

ESTP,time2=3000x0.7x7.5x10-5/ 5475= 2.8x10-5 kg.d-1

PECSTPtime1

ClocalSTP= ESTP/FLOWSTP

The OECD ESD does not give a default value of FLOWSTP. This can be assumed to be a small creek with a flow of 0.3 m3/s.

ClocalSTP = 2.3x10-5 x106/ (86400x0.3x103) = 8.8x10-7 mg/L

PECSTPtime2

ClocalSTP= ESTPtime2/FLOWSTP

The OECD ESD does not give a default value of FLOWSTP. This can be assumed to be a small creek with a flow of 0.3 m3/s.

ClocalSTP= 2.8x10-5 x106/ (86400x0.3x103) = 1x10-6 mg/L

Soil

• Esoil,leach,time1 =(AREAwoodx Qxleach,time1x Fsoil)/ TIME1

Esoil,leach,time1 =(3000x3.3x10-7x0.3)/30 =9.9x10-6 [kg.d-1]

• Esoil,leach,time2 = (AREAwood x Qxleach,time2x Fsoil)/ TIME2

Esoil,leach,time2 = (3000x7.5x10-5x0.3)/5475=1.2x10-5 [kg.d-1]

Pre-treated wood is used for the construction of the noise barrier; only the releases due to leaching from the wood are taken into consideration and Clocalsoil,applic=0

* Clocalsoil,time1=9.9x10-6 /(250x1700x7.7)+(1/7.7x30) x (- 9.9x10-6 /250x1700x7.7) x (1-e-30x7.7)

= 3x10-12 [kg.kgwwt-1]

* Clocalsoil,time2=1.2x10-5 / (250x1700x7.7) + (1/7.7x5475)x(- 1.2x10-5 /(250x1700x7.7)) x (1-e-5475x7.7)

=3.6x10-12 [kg.kgwwt-1]

c. House scenario

Table 2.6.2.1.2.4-8 House scenario data

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| INPUTS |  |  |  |  |
| Emission of active ingredient during application (assumed to occur over 1 day) | Eapplic | / | [kg.d-1] | O |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of a longer assessment period | TIME2 | 5475 | [d] | D |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over the initial assessment period is determined based on the results of a leaching test. | Qxleach,time1 | 3.3x10-7 | [kg.m-2] | A |
| Cumulative quantity of an active ingredient leached out of 1m2 of treated wood over the a longer assessment period | Qxleach,time2 | 7.5x10-5 | [kg.m-2] | A |
| Leachable treated wood area, proposed in the relevant scenarios (cf. Appendix 3) | AREAwood | 125 | [m2] | D |
| Volume of receiving soil, proposed in the relevant  scenarios (cf. Appendix 3) | Vsoil | 12.5 | [m3] | D |
| Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | D |
| Soil-water partitioning coefficient | Ksoil-water | 126 | [m3.m-3]  =mg/L | A |
| First order rate constant for removal from soil | k | 7.7 | [d-1] | A |
| OUTPUTS |  |  |  |  |
| Initial concentration in soil during application | Clocalsoil,applic | 0 | [kg.kgwwt-1] | O |
| Average daily emission of active ingredient due to leaching over the initial assessment period | Esoil,leach,time1 | 1.4x10-6 | [kg.d-1] | O |
| Average daily emission of active ingredient due to leaching over  a longer duration | Esoil,leach,time2 | 1.7x10-6 | [kg.d-1] | O |
| Time weighted concentration in local soil over the initial  assessment period | Clocalsoil,time1 | 1x10-11 | [kg.kgwwt-1] | O |
| Time weighted concentration in local soil over a longer  duration | Clocalsoil,time2 | 1x10-11 | [kg.kgwwt-1] | O |

D=default, A=based on information of applicant, O=output

Calculations:

• Volume of wet soil

HOUSEcircumference = 2 x (HOUSElength xHOUSEwidth)

HOUSEcircumference = 2 x (17.5+7.5) = 50 m

Vsoil = HOUSEcircumference x DISTANCEhorizontal x DEPTH

Vsoil = 50x0.5x0.5 = 12.5 m3

• Esoil,leach,time1 = (AREAwood x Qxleach,time1)/ TIME1

Esoil,leach,time1 = (125x3.3x10-7)/30 =1.4x10-6 [kg.d-1]

• Esoil,leach,time2 = (AREAwoodx Qxleach,time2)/ TIME2

Esoil,leach,time2 = (125x7.5x10-5)/5475=1.7x10-6 [kg.d-1]

Pre-treated wood is used for the construction of the house; only the releases due to leaching from the wood are taken into consideration and Clocalsoil,applic=0

* Clocalsoil,time1 =1.4x10-6 /(12.5x1700x7.7)+(1/7.7x30)x(- 1.4x10-6 /12.5x1700x7.7)x

(1-e-30x7.7)

= 1x10-11 [kg.kgwwt-1]

* Clocalsoil,time2 =1.7x10-6/ (12.5x1700x7.7) + (1/7.7x5475)x(- 1.7x10-6/(12.5x1700x7.7))x

(1-e-5475x7.7)

=1x10-11 [kg.kgwwt-1]

##### Relevant metabolites.

**TEBUCONAZOLE**

1,2,4-triazole was identified as a relevant metabolite of Tebuconazole in soil, because it was found in soil degradation studies at concentrations up to 9%, what is close to the limit value of 10%. Due to the considerably shorter half-life of 1,2,4-triazole in soil compared to that of Tebuconazole (DT50 soil = 77 days), 1,2,4-triazole can be regarded as a transient metabolite.

**PROPICONAZOLE**

The two main degradation products of Propiconazole in soil (CGA 118245 and 1,2,4-triazole) are biodegraded in soil faster than Propiconazole (DT50 soil of 1 and 9.3 days at 20°C respectively). The concentrations of these two compounds are not assumed to exceed the one of Propiconazole in soil. Therefore, concentrations of Propiconazole in soil can be used as the worst-case assumption in the risk assessment of these degradation products. Furthermore, both degradation products are found to be less toxic to earthworms than Propiconazole.

**IPBC**

PBC was identified as a relevant metabolite of IPBC in water, sediment and soil, because it was found in degradation studies at above the limit value of 10%. Due to a relative short half-life of PBC (DT50 of 31.2, 31.4 and 9.5 days at 12°C in water, sediment and soil, respectively) PBC can be regarded as a transient metabolite.

Metabolites of IPBC, Propiconazole and Tebuconazole are considered to be transient or less persistent than their respective parent, and are not more toxic. Therefore as presented inthe risk assessment chapter, the environmental risk assessment for metabolites is considered to be covered by the risk assessment for parents, and emissions and PEC values were calculated for parents only.

#### Human exposure assessment

The biocidal product Axil 2000 contains the active substances Propiconazole 0.75% (purity 930 g/kg), Tebuconazole 0.75% (purity 950 g/kg), and IPBC 0.75% (purity 980 g/kg).

It is a water-based concentrated micro-emulsion product that is diluted in water (dilution rate: 10%).

The preparation is intended for industrial use, using tunneling aspersion: automated flow coating (deluge) or automated dipping.

For flow coating the product the dilution rate is 10%, for dipping 5%.

The product is not for amateur use.

The product will be packaged 1000L containers.

The preparation is intended for industrial use only using automated spraying, like automated flow coating (deluge) and short dipping. The product is not for amateur use.

In a worst case scenario, Axil 2000 is used diluted. Human exposure assessment is based on the diluted Axil 2000 containing 0.075% (w/w) propiconazole, 0.075% (w/w) tebuconazole, and 0.075% (w/w) IPBC.

BE CA has re-evaluated the exposure to the diluted biocidal solution using a dermal absorption of 2% for propiconazole, 75% for tebuconazole, 75% for IPBC and a human adult bodyweight of 60 kg.

The main routes of exposure are summarized in table 2.6.2.2-1

**Table 2.6.2.2-1: Summary of human exposure paths to Axil 2000**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure path** | **Industrial use** | **Professional use** | **General public** | **Secondary exposure** |
| Inhalation | Yes | Not relevant (\*) | Not relevant (\*) | Yes |
| Dermal | Yes | Not relevant (\*) | Not relevant (\*) | Yes |
| Oral | No | Not relevant (\*) | Not relevant (\*) | Yes |

\* only industrial use is intended

##### Exposure of industrial users

**Industrial use by automated spraying, like flow coating (deluge)**

Mixing and Loading

The mixing and loading is a fully automated process (pumping process) in a closed system. The product Axil 2000 is delivered in 1000L containers. There is no manual interaction needed. It is considered that the Mixing and Loading process is not associated with significant exposure to the operator. No exposure calculation is needed.

Application

Automated spraying, flow coating is an industrial automated process. The wood is moved through one or more longitudinal or transversal boxes on a continuously moving conveyor system. The product is applied as a spray which is usually as a coarse spray using a particle spray size to ensure the wetting of the wood with the correct amount of wood preservative. The spray boxes are relatively contained and splasguards surround the spraying boxes to eliminate any droplets of spray from entering the rest of the area and may have local exhaust ventilation. After the treatment of the wood, before removing treated wood from the system, excessive treatment solution is allowed to drain off. A potential source of exposure might be via evaporation of the product from opening the system after treatment. However, the active substances contained in Axil 2000 have very low volability (IPBC Vp 2.36 10-3 Pa at 25°C, Tebuconazole Vp 1.7 10-6 Pa at 20°C, Propiconazole Vp 5.6 10-5 Pa at 25°C) and the process occurs at ambient temperature.

No separate exposure calculation is made for this activity. However, the model applied for post-application handling may cover potential exposure during the treatment process itself. The exposure calculation for the application stage is covered by post application.

Post-application: Handling of treated (wet) articles

Post-application exposure to the product may occur during the manual handling of treated (wet) wood. The handling phase includes a cycle of loading, waiting, unloading and removal of treated timber to storage. Dermal contamination can occur through direct contact with the surface of treated wood and through contact with ancillary equipment and the contaminated process system.

For the estimation of the exposure during the application/post-application exposure scenario the BEAT pre-worked example for timber pre-treatment was found the most suitable model (TNsG 2007, BEAT computing database). The model describes treatment of timber in sealed vessels. Dermal exposure is possible through contact with treated wet wood when it is removed from the vessel. This model considers 30% of the time of the task for handling and 70% of the time of the task as incidental exposure. The default values from the industrial wood treatment “water-based vacuum timber pre-treatment” are used (75th percentiles).

The duration default value of exposure for automated dipping according to in the HEEG opinion 2009 (Defaults and appropriate models to assess human exposure for dipping processes PT8) is used: 4 cycles of 60 minutes/day. This duration has also been considered as a reasonable value for the flow coating process.

Professionals working in the industrial plants are expected to wear coated coveralls. Therefore, according to the HEEG opinion “Default protection factors for protective clothing and gloves”,

2010, a clothing penetration factor of 10% has been assumed in a Tier 1 calculation. In a Tier 2 approach, exposure of the industrial workers was calculated using other PPE, namely the use of impermeable coveralls. According to the HEEG opinion, 2010 “Default protection factors for protective clothing and gloves”, a clothing penetration factor of 5% can be used.

Maintenance / Cleaning of the system

Any sort of maintenance/repair work on the system (hoses, valves etc.) may potentially lead to exposure. One cycle for the cleaning phase is added in the models above. The use of PPE is recommended during these tasks.

Exposure assessment – Handling of treated wed wood

See table below for applied model, parameters and default values.

**Table 2.6.2.2.1.-1 Relevant parameters and default values**

|  |  |  |
| --- | --- | --- |
| Model | Professional automated dipping/immersion of wooden articles  Handling Model 1 | Biocides Human Health Exposure Methodology p.117 |
| Indicative exposure values | Hands (inside gloves): 1080 mg/cycle  Body: 8570 mg/cycle | Water-based formulations |
| Glove penetration | Not applicable | Hand exposure: actual exposure inside gloves |
| Clothing penetration | Tier 1: coated coverall 10%  Tier 2: impermeable coverall 5% | HEEG opinion 9, 2010 |
| RPE | No RPE |  |
| Duration | 5 cycles |  |
| BW adult | 60 kg | default |

The summary of primary systemic exposure for industrial users is given in **2.6.2.2.1.-2** .

**Table 2.6.2.2.1.-2 Summary primary exposure for industrial use – automated flow coating**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **PPE** | **Systemic dose (mg/kg bw/d)** | | |
| **Propiconazole** | **Tebuconazole** | **IPBC** |
| **Tier 1 approach** | | | | |
| Automated dipping, handling wet articles | Coated coverall  gloves | Dermal: 0.0012 | Dermal: 0.0454 | Dermal: 0.0454 |
| **Tier 2 approach** | | | | |
| Automated dipping, handling wet articles | Impermeable coverall  gloves | Dermal: 0.00094 | Dermal: 0.03535 | Dermal: 0.03535 |

**Industrial use by automated dipping**

Mixing and Loading

The mixing and loading is a fully automated process (pumping process) in a closed system. The product Axil 2000 is delivered in 1000L containers. There is no manual interaction needed. It is considered that the Mixing and Loading process is not associated with significant exposure to the operator. No exposure calculation is needed.

Application

Automated dipping is an industrial automated process. Loading and unloading with wood occurs mechanically by forklift trucks. For the actual dipping process timber stacks are loaded onto a forklift integrated in the dipping system. Before removing treated wood from the dipping system, excessive treatment solution is allowed to drain off above the tank. Afterwards it is transported mechanically to the storage place. A potential source of exposure might be via evaporation of the product from opening the system after treatment. However, the active substances contained in Axil 2000 have very low volability (IPBC Vp 2.36 10-3 Pa at 25°C, Tebuconazole Vp 1.7 10-6 Pa at 20°C, Propiconazole Vp 5.6 10-5 Pa at 25°C) and the process occurs at ambient temperature.

No separate exposure calculation is made for this activity. However, the model applied for post-application handling may cover potential exposure during the treatment process itself. The exposure calculation for the application stage is covered by post application.

Post-application: Handling of treated (wet) articles

Post-application exposure to the product may occur during the manual handling of treated (wet) wood. The handling phase includes a cycle of loading, waiting, unloading and removal of treated timber to storage. Dermal contamination can occur through direct contact with the surface of treated wood and through contact with ancillary equipment and the contaminated process system.

For the estimation of the exposure during the application/post-application exposure scenario

the Handling model 1 was used (recommended in Biocides Human Health Exposure Methodology p. 117). The default values from the water-based products are used.

Professionals working in the industrial plants are expected to wear coated coveralls. Therefore,

according to the HEEG opinion “Default protection factors for protective clothing and gloves”,

2010, a clothing penetration factor of 10% has been assumed in a Tier 1 calculation. In a Tier 2 approach, exposure of the industrial workers was calculated using other PPE, namely the use of impermeable coveralls. According to the HEEG opinion, 2010 “Default protection factors for protective clothing and gloves”, a clothing penetration factor of 5% can be used.

Maintenance / Cleaning of the system

Any sort of maintenance/repair work on the system may potentially lead to exposure. However, such activities are of short duration (few minutes to few hours) and occur only occasionally (once to a few times a year or even less). Cleaning of the system is a potential source of exposure and varies between industries. This activity may never or very rarely occur. Unfortunately, there is no adequate model to estimate this type of exposure. The use of PPE is recommended during these tasks.

Exposure assessment – Handling of treated wet wood

See table below for applied model, parameters and default values.

**Table 2.6.2.2.1.-3 Relevant parameters and default values**

|  |  |  |
| --- | --- | --- |
| Model | Professional automated dipping/immersion of wooden articles  Handling Model 1 | Biocides Human Health Exposure Methodology p.117 |
| Indicative exposure values | Hands (inside gloves): 1080 mg/cycle  Body: 8570 mg/cycle | Water-based formulations |
| Glove penetration | Not applicable | Hand exposure: actual exposure inside gloves |
| Clothing penetration | Tier 1: coated coverall 10%  Tier 2: impermeable coverall 5% | HEEG opinion 9, 2010 |
| RPE | No RPE |  |
| Duration | 4 cycles |  |
| BW adult | 60 kg | default |

The summary of primary systemic exposure for industrial users is given in **2.6.2.2.1.-4** .

**Table 2.6.2.2.1.-4 Summary primary exposure for industrial use – automated dipping**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **PPE** | **Systemic dose (mg/kg bw/d)** | | |
| **Propiconazole** | **Tebuconazole** | **IPBC** |
| **Tier 1 approach** | | | | |
| Automated dipping, handling wet articles | Coated coverall  gloves | Dermal: 0.0012 | Dermal: 0.0454 | Dermal: 0.0454 |
| **Tier 2 approach** | | | | |
| Automated dipping, handling wet articles | Impermeable coverall  gloves | Dermal: 0.0009 | Dermal: 0.003535 | Dermal: 0.03535 |

Detailed calculations are presented in Annex 6.

In Annex 7„Safety for professional operators“, the results of the exposure calculations for the active substance and the substance of concern for the professional user are laid out.

##### Exposure of professional users (other than industrial users) and non-professional users

Exposure to professional users (other than industrial users) and non-professional users is not considered relevant as the biocidal product Axil 2000 is only made available for industrial use.

##### Indirect exposure of the general public (secondary exposure)

Secondary exposure in the residential environment may result from professional and non-professional applications. These exposures include: dermal contact of contaminated surfaces of handling contaminated subjects. Oral contact by mouthing contaminated objects or hand-mouth contact is related to toddlers and infants playing.

**Acute Phase Secondary Exposure**

**Adult – Sanding treated wooden posts - Amateur**

Exposure of adults towards dust during sanding of treated wood was estimated using the example calculation provided in the TNsG, 2002, part 3: User Guidance (worked examples, page 50).

Inhalation exposure

**Table 2.6.2.2.3-1 Inhalation exposure – Amateur sanding treated wooden posts**

|  |  |  |
| --- | --- | --- |
| Size of the treated wood | Volume wooden post: 4 cm x 4 cm x 250 cm = 4000 cm3  Surface area wooden post: 4032 cm2, if the surface area of the 2 ends of the post is included  Volume of treated wood in the post: 393 cm3 (superficial treatment, only penetration in the 1 mm outermost layer: volume of the post – volume of the untreated inner core of the post = 4x4x250 -3.8x3.8x249.8 = 393 cm3). | TNsG 2002, User Guidance version 1, p51 |
| Active substance concentration in in-use solution | 0.075% propiconazole  0.075% tebuconazole  0.075% IPBC |  |
| Active substance concentration in the outer 1 mm layer\* | 0.092 mg/cm3 | Superficial treatment: wood preservative is assumed to penetrate only the outermost layer of the wood |
| Inhalation rate | 1.25 m3/h | TNsG 2002, User Guidance version 1, p52 |
| Exposure for wood dust during sanding for 60 min | 5 mg/m3 | TNsG 2002, User Guidance version 1, p52 |
| Inhaled wood dust amount | 1.25 x 5 = 6.25 mg |  |
| Density of wood | 0.4 g/cm3 | MOTA, TM08III |
| Volume of wood dust | 6.25.10-3/0.4= 0.015625 cm3 |  |
| Concentration of active substance in the wood dust | 0.015625 x 0.092 = 0,0014375 mg |  |
| Inhalatory uptake | 100% |  |
| Systemic exposure by inhalation adult | Propiconazole: 0.000024 mg/kg bw/d  Tebuconazole: 0.000024 mg/kg bw/d  IPBC: 0.000024 mg/kg bw/d | 60 kg default |

\* Active substance concentration in the 1 mm outermost layer:

- Product specific information (table 2.6.2.1-1): application rate Axil 2000 = 80-120 g/m². Worst case = 120 g/m²

- The active substance concentration in the dilution is 0.075% (w/w).

- The density of Axil 2000 is 1 kg/L

- The active substance per square meter is 120 g x 0.075/100 = 90 mg/m2 correspond to 0.009 mg/cm2

- The default values of the surface of treated wood is 4032 cm2

- The active substance concentration on a 4032 cm2 layer is 0.009 mg/cm2 x 4032 cm2 = 36,3 mg per 4032 cm2

- We have the default values of the size of treated wood: 4032 cm2 which corresponds to 393 cm3 (superficial treatment), thus the concentration active substance per volume unit is 36,3 mg/ 393 cm3= 0.092 mg/cm3

Dermal exposure

**Table 2.6.2.2.3-2 Dermal exposure – Amateur sanding treated wooden posts – no gloves**

|  |  |  |
| --- | --- | --- |
| Hand surface area | 420 cm2 | TNsG 2002, User Guidance version 1, p52 |
| % of hand contaminated during sanding | 20% | TNsG 2002, User Guidance version 1, p52 |
| Active substance concentration on wood surface \* | 0.009 mg/cm2 | Product specific information (tabel 2.6.2.1-1) |
| Transfer efficiency | 3% | TNsG 2007 and 2013, Annex 6 |
| Dermal uptake | Propiconazole: 2%  Tebuconazole: 75%  IPBC: 75% |  |
| Active substance concentration on hand | 0.009 mg/cm2 x 420 cm2 x 20/100 x 3/100 = 0.02268 mg |  |
| Systemic dose | Propiconazole: 0.02268 x 2% = 0.0004536 mg  Tebuconazole: 0.02268 x 75% = 0.01701 mg  IPBC: 0.02268 x 75% = 0.01701 mg |  |
| Systemic dermal exposure adult | Propiconazole: 0.0000076 mg/kg bw/d  Tebuconazole: 0.0002835 mg/kg bw/d  IPBC: 0.0002835 mg/kg bw/d | 60 kg default |

\* Product specific information (table 2.6.2.1-1): application rate: 80-120 g/m2. Worst case = 120 g/m2.

The active substance per square meter is 120 g x 0.075/100 = 90 mg/m2, corresponds to 0.009 mg/cm2.

Total exposure

**Table 2.6.2.2.3-3 Total systemic exposure – Amateur sanding treated wooden posts**

|  |  |  |  |
| --- | --- | --- | --- |
| Active substance | Inhalation exposure  (mg/kg bw/d) | Dermal exposure  (mg/kg bw/d) | Total systemic exposure  (mg/kg bw/d) |
| **Propiconazole** | 0.000024 | 0.0000076 | **0.0000316** |
| **Tebuconazole** | 0.000024 | 0.0002835 | **0.0003075** |
| **IPBC** | 0.000024 | 0.0002835 | **0.0003075** |

**Infant – Chewing wood off-cut**

The relevant exposure route is oral. This is an incidental event and the exposure duration is therefore best described as acute. This scenario is considered to represent the worst case for secondary oral exposure

**Table 2.6.2.2.3-4 Infants – Chewing wood off-cut – Ingestion exposure**

|  |  |  |
| --- | --- | --- |
| Size of wood chip | 4 cm x 4 cm x 1 cm = 16 cm3  Surface area: 48 cm2 | TNsG 2002, User Guidance version 1, p52 |
| Maximum absorption of product | 120 g/m2 | Product specific information (table 2.6.2.1-1): application rate: 80-120 g/m2. Worst case = 120 g/m2. |
| Maximum content of a.s. in in-use product solution | 0.075% propiconazole  0.075% tebuconazole  0.075% IPBC |  |
| Maximum absorption of a.s. \* | 0.009 mg/cm2 |  |
| Extraction of a.s. when chewing | 50% | DocIIB – Risk assessment Propiconazole (PT8), p53, 2006 |
| Extraction from wood | 0.009 mg/cm2 x 48 cm2 = 0.435 mg |  |
| Exposure through ingestion of infant | Propiconazole: 0.022 mg/kg bw/d  Tebuconazole: 0.022 mg/kg bw/d  IPBC: 0.022 mg/kg bw/d | Default: 10 kg |

\*Product specific information (table 2.6.2.1-1): application rate: 80-120 g/m2. Worst case = 120 g/m2.

The active substance per square meter is 120 g x 0.075/100 = 90 mg/m2, corresponds to 0.009 mg/cm2.

**Chronic Phase Secondary Exposure**

**Adult – Sanding treated wooden posts - Professional**

The acute sanding scenario is extrapolated to the chronic situation (inhalation and dermal exposure) by assuming an exposure time of 6 hours per day.

Inhalation exposure

**Table 2.6.2.2.3-5 Inhalation exposure – Professional sanding**

|  |  |  |
| --- | --- | --- |
| Size of the treated wood | Volume wooden post: 4 cm x 4 cm x 250 cm = 4000 cm3  Surface area wooden post: 4032 cm2, if the surface area of the 2 ends of the post is included  Volume of treated wood in the post: 393 cm3 (superficial treatment, only penetration in the 1 mm outermost layer: volume of the post – volume of the untreated inner core of the post = 4x4x250 -3.8x3.8x249.8 = 393 cm3). | TNsG 2002, User Guidance version 1, p51 |
| Active substance concentration in in-use solution | 0.075% propiconazole  0.075% tebuconazole  0.075% IPBC |  |
| Active substance concentration on the outer 1 cm3 layer  Dipping\* | 0.092 mg/cm3 | Superficial treatment: wood preservative is assumed to penetrate only the outermost layer of the wood |
| Inhalation rate | 1.25 m3/h | TNsG 2002, User Guidance version 1, p52 |
| Exposure for wood dust during sanding for 60 min | 5 mg/m3 | TNsG 2002, User Guidance version 1, p52 |
| Duration of the work | 6 hours |  |
| Inhaled wood dust amount | 1.25 x 5 x 6= 37.5 mg |  |
| Density of wood | 0.4 g/cm3 | MOTA, TM08III |
| Volume of wood dust | 37.5.10-3/0.4= 0.09375 cm3 |  |
| Concentration of active substance in the wood dust | 0.09375 x 0.092 = 0.008625 mg |  |
| Inhalatory uptake | 100% |  |
| Systemic exposure by inhalation adult | Propiconazole: 0.0001438 mg/kg bw/d  Tebuconazole: 0.0001438 mg/kg bw/d  IPBC: 0.0001438 mg/kg bw/d | 60 kg default |

\* Active substance concentration in the 1 mm outermost layer:

- Product specific information (tabel 2.6.2.1-1): application rate Axil 2000= 80-120 g/m2. Worst case = 120 g/m2.

- The active substance concentration in the dilution is 0.075% (w/w).

- The density of Axil 2000 is 1 kg/L

- The active substance per square meter is 120 g x 0.075/100 = 90 mg/m2 correspond to 0.009 mg/cm2

- The default values of the surface of treated wood is 4032 cm2

- The active substance concentration on a 4032 cm2 layer is 0.009 mg/cm2 x 4032 cm2 = 36.3 mg per 4032 cm2

- We have the default values of the size of treated wood: 4032 cm2 which corresponds to 393 cm3 (superficial treatment), thus the concentration active substance per volume unit is 36.3/393 cm3 = 0.092 mg/cm3

Dermal exposure

**Table 2.6.2.2.3-6 Dermal exposure – Professional sanding – no gloves**

|  |  |  |
| --- | --- | --- |
| Hand surface area | 420 cm2 | TNsG 2002, User Guidance version 1, p52 |
| % of hand contaminated during sanding | 20% | TNsG 2002, User Guidance version 1, p52 |
| Active substance concentration on wood surface \* | 0.009 mg/cm2 | Product specific information (tabel 2.6.2.1-1) |
| Transfer efficiency | 3% | TNsG 2007 and 2013, Annex 6 |
| Dermal uptake | Propiconazole: 2%  Tebuconazole: 75%  IPBC: 75% |  |
| Active substance concentration on hand | 0.009 mg/cm2 x 420 cm2 x 20/100 x 3/100 = 0.02268 mg |  |
| Systemic dose | Propiconazole: 0.02268 x 2% = 0.0004536 mg  Tebuconazole: 0.02268 x 75% = 0.01701 mg  IPBC: 0.02268 x 75% = 0.01701 mg |  |
| Systemic dermal exposure adult | Propiconazole: 0.0000076 mg/kg bw/d  Tebuconazole: 0.0002835 mg/kg bw/d  IPBC: 0.0002835 mg/kg bw/d | 60 kg default |

\*Product specific information (table 2.6.2.1-1): application rate: 80-120 g/m2. Worst case = 120 g/m2.

The active substance per square meter is 120 g x 0.075/100 = 90 mg/m2, corresponds to 0.009 mg/cm2

Total exposure

**Table 2.6.2.2.3-7 Total systemic exposure – Professional sanding**

|  |  |  |  |
| --- | --- | --- | --- |
| Active substance | Inhalation exposure  (mg/kg bw/d) | Dermal exposure  (mg/kg bw/d) | Total systemic exposure  (mg/kg bw/d) |
| **Propiconazole** | 0.0001438 | 0.0000076 | **0.0001514** |
| **Tebuconazole** | 0.0001438 | 0.0002835 | **0.0004273** |
| **IPBC** | 0.0001438 | 0.0002835 | **0.0004273** |

**Aduld, child, infant – Inhalation of volatised residues indoors**

Chronic inhalation exposure to wood preservatives may arise from indoor remedial treatment. However Axil 2000 is not made available for remedial treatment. In addition, exposure through preserved window frames or joists is not considered to be relevant, because the frame or other wood generally is coated and the wood preservative is sealed and cannot evaporate. Furthermore, propiconazole, tebuconazole, and IPBC have a low vapour pressure. Nevertheless, exposure by volatilised residues indoors was calculated.

A model for inhalation of volatilized residues from treated wood indoors is worked out in the TNsG 2002, User Guidance version 1 p52. The model assumes a moderately ventilated room and residence time of 18 h/day. As a worst-case an inhalation exposure is taken as 1% of the saturated vapour pressure of the active substance.

Saturated vapour concentration = vapour pressure x moleculair weight

Gas constant x temperature in degrees Kelvin

**Table 2.6.2.2.3-8 Chronic exposure from inhalation of volatized residues indoors**

|  |  |  |
| --- | --- | --- |
| Vapour pressure | Propiconazole: 5.6x10-5 Pa (25°C)  Tebuconazole: 1.7x10-6 Pa (20°C)  IPBC: 2.36x10-3 Pa (20°C) |  |
| Molecular weight | Propiconazole: 342.2 g/mol  Tebuconazole: 307.8 g/mol  IPBC:281 g/mol |  |
| Bodyweight | Adult: 60 kg  Child: 15 kg  Infant: 10 kg |  |
| Inhalation rate | Adult: 1.25 m3 air/h  Child: 0.35 m3 air/h  Infant: 0.24 m3 air/h | TNsG, 2007, 61  TGD p274  TGD p274 |
| 1 bar equivalent | 101.325 Pa |  |
| Molar volume of gas at roomtemperature | 24.1 L |  |
| Airborne concentration | Propiconazole  5.6x10-5 Pa x 1% / 101325x106 =  5.53x10-6 ppm (ml/m3)  Tebuconazole  1.7x10-6 Pa x 1% / 101325x106 =  1.68x10-6 ppm (ml/m3)  IPBC  2.36x10-3 Pa x 1% / 101325x106 =  2.33x10-4 ppm (ml/m3) |  |
| Saturated vapour concentration  (SVC) | Propiconazole  5.53x10-6 ppm x 342.2 g/mol / 24.1 L =  7.85x10-5 mg/m3  Tebuconazole  1.68x10-6 ppm x307.8 g/mol / 24.1 L =  2.14x10-5 mg/m3  IPBC  2.33x10-4 ppm x 342. g/mol / 24.1 L =  2.72x10-3 mg/m3 |  |
| Systemic dose | = SVC x inhalation rate x duration / BW  **Propiconazole**  Adult: 2.94x10-5 mg/kg bw/d  Child: 3.30x10-5 mg/kg bw/d  Infant: 3.39x10-5 mg/kg bw/d  **Tebuconazole**  Adult: 8.03x10-6 mg/kg bw/d  Child: 8.99x10-6 mg/kg bw/d  Infant: 9.24x10-6 mg/kg bw/d  **IPBC**  Adult: 1.02x10-3 mg/kg bw/d  Child: 1.14x10-3 mg/kg bw/d  Infant: 1.18x10-3 mg/kg bw/d |  |

According to the exposure calculations is the chronic exposure to propiconazole, tebuconazole, and IPBC during residence time negligible.

**Child - playing on playground structure outdoors**

**Table 2.6.2.2.3-9 Child – chronic dermal exposure- playing on playground structure**

|  |  |  |
| --- | --- | --- |
| Hand surface area | 200 cm2 | TNsG 2002, User Guidance version 1, p53 |
| % of hand contaminad | 20% | TNsG 2002, User Guidance version 1, p53 |
| Active substance concentration on wood surface \* | 0.009 mg/cm2 | Product specific information (tabel 2.6.2.1-1) |
| Transfer efficiency | 3% | TNsG 2007 and 2013, Annex 6 |
| Dermal uptake | Propiconazole: 2%  Tebuconazole: 75%  IPBC: 75% |  |
| Active substance concentration on hand | 0.009 mg/cm2 x 200 cm2 x 20/100 x 3/100 = 0,0108 mg |  |
| Systemic dose | Propiconazole: 0,0108 x 2% = 0.000216 mg  Tebuconazole: 0,0108 x 75% = 0.0081 mg  IPBC: 0,0108 x 75% = 0.0081 mg |  |
| **Systemic dermal exposure child** | **Propiconazole: 0.0000144 mg/kg bw/d**  **Tebuconazole: 0.00054 mg/kg bw/d**  **IPBC: 0.00054 mg/kg bw/d** | 15 kg default |

\*Product specific information (table 2.6.2.1-1): application rate: 80-120 g/m2. Worst case = 120 g/m2.

The active substance per square meter is 120 g x 0.075/100 = 90 mg/m2, corresponds to 0.009 mg/cm2

**Infant – playing on and mouthing weathered structure outdoors**

**Table 2.6.2.2.3-10 Infant – chronic exposure- playing on and mouthing weathered structure**

|  |  |  |
| --- | --- | --- |
| Hand surface area | 200 cm2 | TNsG 2002, User Guidance version 1, p53 |
| % of hand contaminated | 20% | TNsG 2002, User Guidance version 1, p53 |
| Active substance concentration on wood surface \* | 0.009 mg/cm2 | Product specific information (tabel 2.6.2.1-1) |
| Transfer efficiency | 3% | TNsG 2007 and 2013, Annex 6 |
| Dermal uptake | Propiconazole: 2%  Tebuconazole: 75%  IPBC: 75% |  |
| Active substance concentration on hand | 0.009 mg/cm2 x 200 cm2 x 20/100 x 3/100 = 0.0108 mg |  |
| Systemic dermal dose | Propiconazole: 0.0108 x 2% = 0.000216 mg  Tebuconazole: 0.0108 x 75% = 0.0081 mg  IPBC: 0.0108 x 75% = 0.0081 mg |  |
| Systemic dermal exposure infant | Propiconazole: 0.000022 mg/kg bw/d  Tebuconazole: 0.00081 mg/kg bw/d  IPBC: 0.00081 mg/kg bw/d | 10 kg default |
| Oral uptake | 100% | TNsG 2002, User Guidance version 1, p53 |
| Systemic oral dose | Propiconazole: 0.0108 mg  Tebuconazole0.0108 mg  IPBC: 0.0108 mg |  |
| Systemic oral exposure infant | Propiconazole: 0.0108 mg/kg bw/d  Tebuconazole: 0.0108 mg/kg bw/d  IPBC: 0.0108 mg/kg bw/d | 10 kg default |
| **Total systemic exposure infant** | **Propiconazole: 0.00110 mg/kg bw/d**  **Tebuconazole: 0.00189 mg/kg bw/d**  **IPBC: 0.00189 mg/kg bw/d** |  |

\*Product specific information (table 2.6.2.1-1): application rate: 80-120 g/m2. Worst case = 120 g/m2.

The active substance per square meter is 120 g x 0.075/100 = 90 mg/m2, corresponds to 0.009 mg/cm2

The overall summary of secondary systemic exposure is given in Table **2.6.2.2.3-11**

**Table 2.6.2.2.3-11 Summary of secondary systemic exposure**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario** | **Systemic dose (mg/kg bw/d)** | | |
| **Propiconazole** | **Tebuconazole** | **IPBC** |
| Acute:  Sanding of treated wood, amateur | Inhalation: 0.000024  Dermal: 0.0000076  **Total: 0.0000316** | Inhalation: 0.000024  Dermal: 0.0002835  **Total: 0.0003075** | Inhalation: 0.000024  Dermal: 0.0002835  **Total: 0.0003075** |
| Acute:  Chewing treated wood off-cut, infant | **Oral: 0.022** | **Oral: 0.022** | **Oral: 0.022** |
| Chronic:  Sanding of treated wood, professional | Inhalation: 0.0001438  Dermal: 0.0000076  **Total: 0.0001514** | Inhalation: 0.0001438  Dermal: 0.0002835  **Total: 0.0004273** | Inhalation: 0.0001438  Dermal: 0.0002835  **Total: 0.0004273** |
| Chronic:  Playing on playground structure outdoors, child | **Dermal: 0.00001444** | **Dermal: 0.00054** | **Dermal: 0.00054** |
| Chronic:  Playing on and mouthing weathered structure outdoors, infant | Dermal: 0.000022  Oral: 0.00108  **Total: 0.00110** | Dermal: 0.00081  Oral: 0.00108  **Total: 0.00189** | Dermal: 0.00081  Oral: 0.00108  **Total: 0.00189** |
| Chronic:  Inhalation volatile residues, adult/child/infant | **Inhalation**  Adult: 2.94x10-5  Child: 3.30x10-5  Infant: 3.39x10-5 | **Inhalation**  Adult: 8.03x10-6  Child: 8.99x10-6  Infant: 9.24x10-6 | **Inhalation**  Adult: 1.02x10-3  Child: 1.14x10-3  Infant: 1.18x10-3 |

##### Exposure to residues in food

Axil 2000 can be used on wood which is in indirect contact with food and/or feeding stuff: pallets used for storage of food and feeding stuff.

An estimation of the transfer of biocidal active substances into foods/feeds (professional uses) is relevant.

The applicant submitted a study concerning the emission transfer of the active substances IPBC, propiconazole and tebuconazole to foodstuffs stacked on Axil 2000 treated pallet planks. Please se the confidential version for more details.

The foodstuffs were placed in direct contact with the pallet planks, i.e. without intermediate protecting paper or cardboard layer. Test period: 3 months. Test conditions: ± 15°C, relative air humidity ± 65% RH.

## Risk assessment for human health

### Hazard potential

#### Toxicology of the active substance

The toxicology of the active substances IPBC, Propiconazole and Tebuconazole was examined extensively according to standard requirements in the context of their inclusion in Annex I to Directive 98/8/EC. The results of these toxicological assessments can be found in the CARs.

The following section contains a synthesis of the most relevant toxicological information. More detailed descriptions and references to the different studies can be found in the aforementioned reports

##### Iodopropynylbutylcarbamate (IPBC)

The active substance, IPBC, was evaluated and approved for annex I inclusion according to the procedures of Directive 98/8/EC for use as a wood preservative by the Danish Competent Authority in 2008. No new studies on toxicology for human health have been submitted.

**Acute systemic toxicity:**

LD50-oral-rat = 300-500 mg/kg bw

LD50-dermal-rat > 2000 mg/kg bw

LC50-inh-rat > 6.89 mg/l/4h for technical IPBC (not-respirable dust)  
> 0.67 mg/l/4h for respirable dust  
> 0.76 mg/l/4h for respirable liquid aerosol

IPBC is considered of moderate acute toxicity by the oral route and of low toxicity by the dermal route. It is classified as toxic by inhalation.

**Local toxicity:**

IPBC showed to be non-irritant to the rabbit skin and severely irritating to the eyes. The substance showed to be a skin sensitiser in several guinea pig assays (GPMTs).

**Oral and dermal absorption data:**

IPBC was completely and readily absorbed via the oral route (90%).

An *in vitro* study with human skin gave dermal absorption values (including skin residues) of 30, 10, and 1.6% for solvent-based formulations containing 0.6, 2.3, and 17.1% IPBC, respectively.

IPBC has an octanol/water partition coefficient of 2.81 at 25°C.

**Repeated dose toxicity:**

Subchronic and chronic oral toxicity studies with the rat revealed the following NOAEL-values:

* NOAEL (90d-oral-rat) = 35 mg/kg bw/day
* NOAEL (2y-oral-rat) = 20 mg/kg bw/day

The main adverse effects noted consisted of reduced body weight and body weight gain, increased liver and kidney weights and increased iron concentration. Some histopathological changes in the stomach were also reported.

A 90-day inhalation toxicity study in the rat generated a NOAEC value of 1.16 mg/m³.

**Specific toxicological effects:**

* In experimental animal teratogenicity studies, IPBC did not affect fertility and did not cause developmental toxicity:

- NOAEL (maternal toxicity, rabbit) = 10 mg/kg bw/day  
- NOAEL (developmental toxicity, rabbit) = 40 mg/kg bw/day

* The evidence suggests that this substance does not possess significant potential with respect to toxicity to reproduction.   
  - NOAEL (parental toxicity, rat) = 10 mg/kg bw/day  
  - NOAEL (developmental toxicity, rat) = 10 mg/kg bw/day  
  - NOAEL (reproductive toxicity, rat) = 30 mg/kg bw/day
* The weight of evidence from the available well-conducted *in vitro* and *in vivo* genotoxicity studies indicates that IPBC is not a genotoxic substance.
* IPBC was not carcinogenic in rats and mice up to and including the highest dose levels tested (80 and 150 mg/kg bw/day for rats and mice, respectively).
* IPBC was not neurotoxic when administered via the oral route.

**Classification/labeling for IPBC in accordance with Regulation (EC) N° 1272/2008:**

|  |  |  |
| --- | --- | --- |
| Danger Category | Acute Tox. 3, Acute Tox 4, Skin Sens. 1, STOT RE 1, Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1 | |
| Pictogram(s)  Signal word(s) | GHS05,GHS06, GHS08, GHS09  Danger | |
| H statements | H302  H331  H317  H318  H372  H400  H410 | Harmful if swallowed  Toxic if inhaled  May cause an allergic skin reaction  Causes serious eye damage  Causes damage to organs through prolonged or repeated exposure (larynx)  Very toxic to aquatic life  Very toxic to aquatic life with long lasting effects |

**Classification and labelling for IPBC in accordance with Directive 67/548/EEC[[3]](#footnote-3):**

|  |  |  |
| --- | --- | --- |
| Danger class  Symbol(s) | N  T | Dangerous for the environment  Toxic |
| R phrases | R22  R23  R37  R41  R43  R50 | Harmful if swallowed  Toxic by inhalation  Irritating to respiratory system  Risk of serious damage to the eye  May cause sensitization by skin contact  Very toxic to aquatic organisms |
| S phrases | S1  S2  S22  S24  S26  S37/39  S38  S45  S46  S61 | Keep locked up  Keep out the reach of children  Do not breathe dust  Avoid contact with skin  In case of contact with eyes, rinse immediately with plenty of water and seek medical advice  Wear suitable gloves and eye/face protection  In case of insufficient ventilation, wear suitable respiratory equipment  In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)  If swallowed, seek medical advice immediately and show this container or label  Avoid release to the environment. Refer to special instructions/safety data sheets |

For further information on the toxicology of IPBC, please see the CAR (Assessment Report on IPBC, European Commission, 2008)

##### Propiconazole

The active substance, propiconazole, was evaluated and approved for annex I inclusion according to the procedures of Directive 98/8/EC for use as a wood preservative by the Finnish Competent Authority in 2007. No new studies on toxicology for human health have been submitted.

**Acute systemic toxicity:**

LD50-oral-rat = 1500 mg/kg bw

LD50-dermal-rat > 4000 mg/kg bw

LC50-inh-rat > 5.8 mg/l/4h

Propiconazole is considered of moderate acute toxicity by the oral route and of low toxicity by the dermal and inhalation routes.

**Local toxicity:**

Propiconazole showed to be non-irritant to the rabbit skin and eyes. The substance showed to be a skin sensitiser in the guinea pig maximisation test.

**Oral and dermal absorption data:**

The oral absorption of Propiconazole showed to be 86% within 48 hours. The dermal absorption is reported to be 2% for a solvent-based 1.5% solution.

Propiconazole has an octanol/water partition coefficient of 3.7 at 25°C.

**Repeated dose toxicity:**

Chronic, subchronic and subacute toxicity studies with rats and mice revealed the following NOAEL/NOAEC-values for Propiconazole:

* NOAEL (2y-oral-rat) = 3.6 mg/kg bw/day
* NOAEL (3m-oral-mice) = 2.7 mg/kg bw/day
* NOAEL (28d-dermal-rat) = 100 mg/kg bw/day
* NOAEC (90d-inh-rat) = 21 mg/m³

The main adverse effects noted consisted of increased liver weights and histopathological changes in the liver.

**Specific toxicological effects:**

* In experimental animal teratogenicity studies, Propiconazole did not affect fertility and did not cause developmental toxicity. A NOAEL of 30 mg/kg bw/day was obtained in a teratogenicity study with the rat, based on a slight increase in cleft palate and increased visceral and skeletal variations.
* The evidence suggests that this substance does not possess significant potential with respect to toxicity to reproduction. A NOAEL of 8 mg/kg bw/day was obtained in a 2-generation reproduction study with the rat, based on liver toxicity in parental animals.
* The weight of evidence from the available *in vitro* and *in vivo* genotoxicity studies indicates that Propiconazole does not display genotoxic properties.
* Propiconazole is a strong inducer of xenobiotic metabolism and a tumor promoter in rodents which explains the induction of tumors in male mice. It may be presumed that rodents are more susceptible than humans to the hepatotoxicity of propiconazole. The lowest dose with tumors (mainly hepatocellular adenomas) was 344 mg/kg bw/day. The NOAEL value in this chronic toxicity/carcinogenicity study was 3.6 mg/kg bw/day.

**Classification/labelling for propiconazole in accordance with Regulation (EC) N° 1272/2008:**

|  |  |  |
| --- | --- | --- |
| Danger Category | Acute Tox. 4, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1 | |
| Pictogram(s)  Signal word(s) | GHS07, GHS09  Warning | |
| H statements | H302  H317  H400  H410 | Harmful if swallowed  May cause an allergic skin reaction  Very toxic to aquatic life  Very toxic to aquatic life with long lasting effects |

**Classification/labelling for propiconazole in accordance with Directive 67/548/EEC[[4]](#footnote-4):**

|  |  |  |
| --- | --- | --- |
| Danger class  Symbol(s) | N  Xn | Dangerous for the environment  Harmful |
| R phrases | R22  R43  R50/53 | Harmful if swallowed  May cause sensitization by skin contact  Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment |
| S phrases | S2  S36/37  S46  S60  S61 | Keep out the reach of children  Wear suitable protective clothing and gloves  If swallowed seek medical advice immediately and show this container of label  This material and its container must be disposed of as hazardous waste  Avoid release to the environment. Refer to special instructions/safety data sheet |

For further information on the toxicology of Propiconazole, please see the CAR (Assessment Report on Propiconazole, European Commission, 2007)

##### Tebuconazole

The active substance, tebuconazole, was evaluated and approved for annex I inclusion according to the procedures of Directive 98/8/EC for use as a wood preservative by the Danish Competent Authority in 2007. No new studies on toxicology for human health have been submitted.

**Acute systemic toxicity:**

LD50-oral-rat = 1700 mg/kg bw

LD50-dermal-rat > 2000 mg/kg bw

LC50-inh-rat > 0.37 mg/l/4h (aerosol)  
> 5.09 mg/l/4h (dust)

Tebuconazole is of low acute toxicity by the oral, dermal and inhalation route.

**Local toxicity:**

Tebuconazole has no potential for skin or eye irritation and is not sensitising to the skin in the Magnusson-Kligmann Maximisation Test or in the Buehler Patch test.

**Oral and dermal absorption data:**

The ADME-studies show that oral administration of Tebuconazole is followed by a rapid and extensive absorption in the rat. Thus no correction for incomplete oral absorption is necessary in the risk assessment. A dermal absorption study in that same species revealed that about 50% of the test substance was absorbed within 8 hours.

An *in vitro* dermal absorption study with human skin showed that the absorbed percentage of [14C]-Tebuconazole was 14.4% for the solvent-based formulation and 3.3% for a water-based formulation. Both formulations contained 0.63-0.65% of active substance.

Tebuconazole has an octanol/water partition coefficient of 3.5 at 20°C.

**Repeated dose toxicity:**

Subacute, subchronic and chronic oral, dermal and inhalation toxicity studies with different species revealed the following critical NOAEL/NOAEC-values:

* NOAEL (1y-oral-dog) = 3 mg/kg bw/day
* NOAEL (28d-dermal-rabbit) = 1000 mg/kg bw/day
* NOAEC (28d-inhalation-rat) = 10.6 mg/m³

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.

**Specific toxicological effects:**

* In an experimental teratogenicity study in mice, rats and rabbits, Tebuconazole did not affect fertility, but developmental toxicity could not be excluded. Therefore Tebuconazole is considered a teratogenic substance:

- NOAEL (maternal toxicity, rabbit) = 10 mg/kg bw/day  
- NOAEL (developmental toxicity, rabbit) = 10 mg/kg bw/day

* Tebuconazole did not show any reproduction toxic potential in a 2‑generation study with the rat. The NOAEL value was 27 mg/kg bw/day.
* No evidence for genotoxic potential was observed in an adequate battery of *in vitro* tests with various endpoints including both prokaryotes and eukaryotes.
* Mouse/liver tumours were only detected in a sensitive mouse strain and at very high dose levels above the maximum tolerated dose. Rat/spontaneous tumours typically for old rats were detected (C-cell tumours of the thyroid in males and endometrial adenocarcinomas in females). They are not considered of relevance for humans. The lowest dosage at which tumors were detected was 280 mg/kg bw/day in the mouse.
* No signs of neurotoxicity were observed after acute and subchronic oral treatment with Tebuconazole:

- NOAEL (acute neurotoxicity) = 50 mg/kg bw/day  
- NOAEL (subchronic neurotoxicity) = 29 mg/kg bw/day  
- NOAEL (developmental neurotoxicity) = 20 mg/kg bw/day

**Classification/labelling for Tebuconazole in accordance with Regulation (EC) N° 1272/2008:**

|  |  |  |
| --- | --- | --- |
| Danger Category | Repr. 2, Acute Tox. 4, Aquatic Chronic 2 | |
| Pictogram(s)  Signal word(s) | GHS07, GHS08, GHS09  Warning | |
| H statements | H302  H361d  H411 | Harmful if swallowed. Suspected of damaging the unborn child.  Toxic to aquatic life with long lasting effects |

**Classification/labelling for Tebuconazole in accordance with Directive 67/548/EEC[[5]](#footnote-5):**

|  |  |  |
| --- | --- | --- |
| Danger class |  | Repr. Cat. 3 |
| Symbol(s) | Xn  N | Harmful  Dangerous for the environment |
| R phrases | R22  R63  R51/53 | Harmful if swallowed  Possible risk of harm to unborn child  Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment |
| S phrases | S2  S22  S36/37  S61 | Keep out the reach of children  Do not breathe dust  Wear suitable protective clothing and gloves  Avoid release to the environment. Refer to special instructions/safety data sheet |

For further information on the toxicology of Tebuconazole, please see the CAR (Assessment Report on Tebuconazole, European Commission, 2007)

#### Toxicology of the substance(s) of concern

The biocidal product contains no substances of concern for human health.

#### Toxicology of the biocidal product

##### Introduction

The dossier was submitted by Berkem SA (Gardonne, FR) and relates to the biocidal product Axil 2000, a biocidal product with Propiconazole, Tebuconazole and IPBC as active substances, each present at 0.75%. For the full composition, reference is made to R4BP and the confidential annex.

No toxicity studies have been performed with Axil 2000. However, the applicant submitted toxicity studies performed with a similar biocidal product (Please se the confidential version for more details). According to article 6.4 of Directive 1999/45/EC the permitted variation of the constituents is 30% if the initial concentration range of the 3 active substances is ≤ 2.5%. The BE CA agrees that the studies can be used in the evaluation.

##### Percutaneous absorption

Dermal absorption studies with the biocidal product have not been performed.

1. **Dermal absorption of propiconazole**

For dilute solutions of propiconazole (0.006% – 1.4%), a dermal absorption values of app. 2% has been set in the CAR (RMS FI, 2007).

The BE CA agrees to use the proposed value for the risk assessment for both exposure to propiconazole via the biocidal product Axil 2000 water-based concentrate containing 0.75% propiconazole as for exposure to the in-use dilution containing 0.075% propiconazole.

1. **Dermal absorption of Tebuconazole**

For a water-based formulation (0.6% tebuconazole) a dermal absorption value of 3.3% has been set on the CAR (RMS DK, 2007).

The BE CA does not agree to use this value in the risk assessment for exposure to the in-use dilution containing 0.075% tebuconazole. Given the assumption that dermal absorption increases with decreasing concentration of the active substance, the use of 3.3% absorption is not considered appropriate. According to the EFSA guidance document on dermal absorption (EFSA Journal 2012; 10(4):2665) a default value of 75% is considered appropriate for diluted products and in use dilutions that do not meet the criteria for use of the 10% default (Log Pow<-1 or >4 and MW<500). The BE CA proposes a default dermal absorption of 75% for the risk assessment of tebuconazole (0.075%) in the in-use dilution of Axil 2000.

1. **Dermal absorption of IPBC**

For solvent-based solutions containing 0.6% IPBC, a dermal absorption value of 30% has been set in the CAR (RMS Denmark, 2008).

The BE CA does not agree to use this value in the risk assessment for exposure to the in-use dilution containing 0.075% IPBC. Given the assumption that dermal absorption increases with decreasing concentration of the active substance, the use of 30% absorption is not considered appropriate. According to the EFSA guidance document on dermal absorption (EFSA Journal 2012; 10(4):2665) a default value of 75% is considered appropriate for diluted products and in use dilutions that do not meet the criteria for use of the 10% default (Log Pow<-1 or >4 and MW<500). The BE CA proposes a default dermal absorption of 75% for the risk assessment of IPBC (0.075%) in the in-use dilution of Axil 2000.

##### Acute toxicity

The acute toxicity of the product has been evaluated on the basis of the main ingredients and the submitted studies with the similar product (Please se the confidential version for more details). According to the submitted information, Axil 2000 should not be classified for acute toxicity.

* + - * 1. ***Irritation and corrosivity***

According to the submitted studies on the similar product (Please se the confidential version for more details), Axil 2000 should not be classified for irritation or corrosivity.

##### Skin sensitsation

According to the submitted studies on the similar product (Please se the confidential version for more details), Axil 2000 should be classified for skin sensitisation.

##### Other toxicological endpoints and conclusion

No other studies regarding the testing of additional toxicological endpoints for the product have been submitted.

Tebuconazole is classified as a Repr.Cat.3 with R63 (DPD) and Repr. 2 with H361d (CLP). This classification does not pertain to the classification of Axil 2000 because the tebuconazole content is only 0.75%.

IPBC is classified as a STOT RE 1 (larynx) with H372 (larynx) (CLP). This classification does not pertain to the classification of Axil 2000 because the IPBC content is only 0.75%.

Table 2.7.1.3.6-1: Classification for acute health effects of Axil 2000

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Endpoint | Guideline | Species | Dose level | Result | DPD | CLP |
| Acute tox oral | OECD 423 | Rat | 2000 mg/kg bw | LD50 > 5000 mg/kg bw | none | None |
| Acute tox dermal | OECD 402 | Rat | 2000 mg/kg bw | LD50 > 2000 mg/kg bw | none | none |
| Acute tox inhalation | - | - | - | No test submitted | No relevant route of exposure | |
| Dermal irritation | OECD 404 | Rabbit | undiluted | Not irritant | none | none |
| Eye irritation | OECD 405 | Rabbit | undiluted | Slightly irritant | none | none |
| Skin sensitisation | OECD 406 | Guinea pig | MNNC = 3.125%  MNIC = 100% | May cause sensitisation by skin contact | R43 | Skin Sens. 1  H317 |
| Dermal absorption | OECD 428 | - | - | No test submitted | - | - |

### Exposure

#### Exposure of professional users

See 2.6.2.2.1

#### Exposure of non-professional users and the general public

See 2.6.2.2.2 and 2.6.2.2.3

#### Exposure to residues in food

Please see 2.6.2.2.4.

### Risk Characterisation

The biocidal product Axil 2000 is a water-based concentrated micro-emulsion product that is diluted in water (dilution rate: 5-10%).

The preparation is intended for industrial use, using tunneling aspersion: automated flow coating (deluge) or automated dipping.

For flow coating the product the dilution rate is 10%, for dipping 5%.

There are different population groups that may be exposed to Axil 2000: primary exposure for industrial users, secondary exposure for professionals and the general public via indirect exposure as a result of use. The risk characterisation will therefore focus on these populations.

The human health risk assessment is taking into account the following situations:

• Industrials applying by automated processes and handling.

• Professionals and General public secondarily exposed to Axil 2000 via the oral, dermal and inhalation routes.

* Exposure to residues in food.

**Choice of toxicological reference doses**

For each of the active substances, two reference doses for their systemic toxicity are defined, one for short-term exposure and one for long-term expsoure. Both scenarios will be encountered when assessing the potential risks associated with exposure to the wood preservative product under study. The risks are related to the length of exposure and take into account the most relevant adverse health effects expected on the basis of animal studies. The reference values are applicable both to primary (direct) exposure in professional and non-professional use, as well as secondary (indirect) exposure with intentional or unintentional exposure to the treated products. The reference values are based on systemic NOAELs from oral dosage studies in experimental animals.

IPBC

Out of the animal studies described in the European assessment report for IPBC, the 2-year chronic toxicity/carcinogenicity study with rats revealed the lowest NOAEL value of 20 mg/kg bw/day based on reduced mean body weight and body weight gain in both sexes and increased incidence of histopathological changes in stomach, forestomach and salivary glands. This NOAEL value will be used as the basis for the long-term AOEL level, taking into consideration an uncertainty factor of 100. As absorption by the oral route was found to be close to 100%, no correction for absorption from the gastrointestinal tract has been made in the AOEL setting.

As IPBC showed to be non-toxic to reproduction and no developmental toxicant, the most relevant study to be chosen as a basis for setting the short-term AOEL is claimed to be the 3 months gavage study in rats, revealing a NOAEL of 35 mg/kg bw/day based on reduced body weight and body weight gain, increased absolute and relative kidney and liver weight and increased iron concentration. The CAR mentions that this AOEL can be used as a conservative approach in risk assessments covering acute exposures.

This brings us to the following long-term and acute AOEL values for risk assessment related to repeated and acute exposure, respectively:

Table 2.7.3-1 Toxicological reference doses for IPBC

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference dose** | **Value**  (mg/kg bw/day) | **Study** | **NOAEL**  (mg/kg bw/day) | **Uncertainty Factor** | **Relevance for risk assessment** |
| AOELlong term | 0.20 | 2-year chronic toxicity/ carcino-genicity study rat | 20 | 100 | Repeated exposure  (few weeks per year or frequent exposure)  Exposure to residues in food |
| AOELshort term | 0.35 | 90-days oral (gavage) study rat | 35 | 100 | Acute exposure  (single dose or a few days of exposure) |

No Maximum Residue Level (MRL) is available for IPBC. According to CA-March17-Doc.7.6.c-final the general default MRL (0.01 mg/kg) or the LOQ should be used.

Propiconazole

Out of the animal studies described in the European assessment report for propiconazole, liver toxicity appeared to be the most critical effect of the active substance. Increased liver weights and slight histopathological hepatic changes were seen already in short term studies. The overall chronic NOAEL in mice, based on hepatoxicity, was 10 mg/kg bw/day. The NOEL for hepatotoxicity in the 2-year rat study was 18 mg/kg bw/day, and the NOAEL was 3.6 mg/kg bw/day, based on changes in body weight and food conversion, changes in haematology and blood glucose, and adrenal weight changes. The overall NOAEL for chronic effects, 3.6 mg/kg bw/day in the 2-year rat study, covers liver toxicity in both rats and mice. A rat teratogenicity study revealed the lowest relevant NOAEL for developmental effects to be 30 mg/kg bw/day, based on a slight increase in cleft palate and increased visceral and skeletal variations. Results of a two-generation study in rats included, in addition to hepatotoxicity in parental animals at low dose levels, slight reproductive effects at a high dose (reduced litter sizes and pup weights, reductions in testes/epididymides weights). The lowest relevant NOAEL in the 2-generation study was 8 mg/kg bw/day, based on liver toxicity in parental animals.

Toxicokinetic studies in rat shows that 86% is absorbed within 48h after oral administration. Correction for bioavailability is therefore not considered necessary.

Based upon the raw data of the above studies, the CAR proposes to use the following long-term and acute AOEL values for risk assessment related to repeated and acute exposure, respectively:

Table 2.7.3-2 Toxicological reference doses for propiconazole

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference dose** | **Value**  (mg/kg bw/day) | **Study** | **NOAEL**  (mg/kg bw/day) | **Uncertainty Factor** | **Relevance for risk assessment** |
| AOELlong term | 0.04 | 2-year rat study | 3.6 | 100 | Repeated exposure  (few weeks per year or frequent exposure)  Exposure to residues in food |
| AOELshort term | 0.3 | developmental toxicity study in rat | 30 | 100 | Acute exposure  (single dose or a few days of exposure) |

The most stringent MRL-value for Propiconazole (EU 2016/567) is 0.05 mg/kg.

Tebuconazole

Based upon the available animal studies, the European assessment report for tebuconazole identifies the NOAEL of 3 mg/kg bw/day as the basis for the long-term AOEL determination. This NOAEL value originated from a one-year study in dogs where unspecific effects like histopathological alterations in the adrenal cortex were found..

Therefore the following AOEL value for risk assessment related to repeated and acute exposure, respectively, is proposed:

**Table 2.7.3-3 Toxicological reference doses for tebuconazole**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference dose** | **Value**  (mg/kg bw/day) | **Study** | **NOAEL**  (mg/kg bw/day) | **Uncertainty Factor** | **Relevance for risk assessment** |
| AOELshort/long term | 0.03 | 1-year chronic toxicity study dog | 3 | 100 | Repeated exposure  (few weeks per year or frequent exposure)  Exposure to residues in food  Acute exposure (a single or a few days of exposure) |

The most stringent MRL-value for Tebuconazole (EU 2016/1003, EU 2017/626) is 0.02 mg/kg.

#### Risk for Professional Users

Axil 2000 is a wood preservative product for industrial use only. Industrial wood preservation usually takes place in specialised facilities, under primarily automated conditions.

The estimated exposures for industrial users involved in the wood treatment by flow-coating (deluge) and automated dipping are presented in Table 2.7.3-1. Industrial workers are expected to be in a risk controlled area and follow a minimum of instructions. In a Tier 1 approach, it is assumed that industrial users wear coated coveralls (as stated by the applicant) and gloves on a daily basis. Therefore, exposure was only estimated with protective coated coveralls for professional use and gloves. In a tier 2 approach, the use of impermeable coveralls and gloves was taken in consideration. The exposures are compared to the respective long-term systemic AELs.

**Table 2.7.3.1-1.1 Risk characterisation for primary exposure for flow coating**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Systemic dose**  **(mg/kg bw/d)** | **AEL**  **(mg/kg bw/d)** | **% AEL** | **NOAEL**  **(mg/kg bw/d)** | **MOE** |
| **TIER 1 – PPE: coated coverall and gloves** | | | | | |
| **Propiconazole** | | | | | |
| Flow coating (deluge) handling | 0.0012 | 0.04 | 3 | 3.6 | 3000 |
| **Tebuconazole** | | | | | |
| Flow coating (deluge) handling | 0.0454 | 0.03 | 151 | 3 | 66 |
| **IPBC** | | | | | |
| Flow coating (deluge) handling | 0.0454 | 0.20 | 22 | 20 | 440 |
| **Tier 2 – PPE: impermeable coverall and gloves** | | | | | |
| **Propiconazole** | | | | | |
| Flow coating (deluge) handling | 0.00094 | 0.04 | 2.35 | 3.6 | 3829 |
| **Tebuconazole** | | | | | |
| Flow coating (deluge) handling | 0.03535 | 0.03 | 117 | 3 | 85 |
| **IPBC** | | | | | |
| Flow coating (deluge) handling | 0.03535 | 0.20 | 18 | 20 | 566 |

**Table 2.7.3.1-1.2 Risk characterisation for primary exposure for automated dipping**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Systemic dose**  **(mg/kg bw/d)** | **AEL**  **(mg/kg bw/d)** | **% AEL** | **NOAEL**  **(mg/kg bw/d)** | **MOE** |
| **TIER 1 – PPE: coated coverall and gloves** | | | | | |
| **Propiconazole** | | | | | |
| Automated dipping | 0.0012 | 0.04 | 3 | 3.6 | 3000 |
| **Tebuconazole** | | | | | |
| Automated dipping | 0.0454 | 0.03 | 151 | 3 | 66 |
| **IPBC** | | | | | |
| Automated dipping | 0.0454 | 0.20 | 22 | 20 | 440 |
| **Tier 2 – PPE: impermeable coverall and gloves** | | | | | |
| **Propiconazole** | | | | | |
| Automated dipping | 0.00094 | 0.04 | 2.35 | 3.6 | 3829 |
| **Tebuconazole** | | | | | |
| Automated dipping | 0.03535 | 0.03 | 117 | 3 | 85 |
| **IPBC** | | | | | |
| Automated dipping | 0.0.03535 | 0.20 | 18 | 20 | 566 |

*Tier 1 approach*

For an industrial worker wearing a coated coverall and appropriate gloves, the exposure estimate for tebuconazole during flow coating and automated dipping exceeds the long-term AEL.-However, a conservative dermal absorption default value of 75% had to be used for the estimation of the systemic dose because no dermal absorption data is made available for such a low water-based dilution of 0.075% or 0.0375% tebuconazole. It is expected that in a water-based formulation the dermal absorption will be much lower. If the actual dermal absorption of tebuconazole is < 50% for the in-use Axil 2000 formulation, there would be no objections against the intended use. Nevertheless, this should be documented with a reliable dermal penetration study.

*Tier 2 approach*

For an industrial worker wearing an impermeable coverall and appropriate gloves, and taking into account a conservative default dermal absorption value of 75%, the exposure estimate for tebuconazole during flow coating is very close to the long-term AEL. We are convinced that the actual dermal absorption of tebuconazole for the in-use water-based Axil 2000 formulation is less than the used default value. Therefore, a risk for professional users resulting from the intended use is unlikely when using appropriate PPE: appropriate gloves and impermeable coverall.

Based on the risk assessment of the other active substance, propiconazole and IPBC, a risk for professional users resulting from the intended use is unlikely.

In conclusion,

***Tier 1***: Regarding industrial worker health protection, there are objections against the intended use when the industrial worker is wearing a coated coverall and gloves. To be able to make a more refined risk characterisation, the dermal absorption for a 0.075%/0.0375% water-based tebuconazole in-use dilution should be provided or tested.

**Tier 2**: Regarding industrial worker health protection, there are no objections against the intended use when the industrial worker is wearing an impermeable coverall and gloves.

Based on the risk assessment of the active substances Propiconazole, Tebuconazle, and IPBC, a risk for professional users resulting from the intended use is unlikely when the appropriate PPE is used. Nevertheless, to be able to make a more refined risk characterisation and oppose less restrictive measures (impermeable coverall versus coated coverall), it is advisable to provide the dermal absorption for a 0.075%/0.0375% water-based tebuconazole in-use dilution.

Regarding occupational safety, there are no objections against the intended use.

#### Risk for professional users (other than industrial users) and non-professional users

Exposure to professional users (other than industrial users) and non-professional users is not considered relevant as the biocidal product Axil 2000 is only made available for industrial use.

#### Risk for the general public- secondary exposure

The estimated secondary systemic exposures for professionals and the general public are presented in Table 2.7.3.3-1.

Secondary exposure in the residential environment may result from professional and non-professional applications. These exposures include: dermal contact of contaminated surfaces of handling contaminated subjects. Oral contact by mouthing contaminated objects or hand-mouth contact is related to toddlers and infants playing.

Exposure was estimated without the use of personal protective equipment. The exposures are compared to the respective short-term and long-term systemic AELs.

**Table 2.7.3.3-1 Risk characterisation for secondary exposure**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Systemic dose**  **(mg/kg bw/d)** | **AEL**  **(mg/kg bw/d)** | **% AEL** | **NOAEL**  **(mg/kg bw/d)** | **MOE** |
| **Propiconazole** | | | | | |
| Acute: amateur sanding | 0.0000316 | 0.30 | 0.011 | 30 | 949367 |
| Acute: infant chewing wood | 0.022 | 0.30 | 7.333 | 30 | 1364 |
| Chronic: professional sanding | 0.0001514 | 0.08 | 0.189 | 8 | 52840 |
| Chronic: child on playground structure | 0.00001444 | 0.08 | 0.018 | 8 | 69444 |
| Chronic: infant on playground structure | 0.00110 | 0.08 | 1.375 | 8 | 7273 |
| Chronic: Inhalation volatile residues indoors: adult | 2.94x10-5 | 0.08 | 0.0368 | 8 | 272109 |
| child | 3.30x10-5 | 0.08 | 0.0413 | 8 | 242424 |
| infant | 3.39x10-5 | 0.08 | 0.0424 | 8 | 235988 |
| **Tebuconazole** | | | | | |
| Acute: amateur sanding | 0.0003075 | 0.03 | 1.025 | 3 | 9756 |
| Acute: infant chewing wood | 0.022 | 0.03 | 73 | 3 | 136 |
| Chronic: professional sanding | 0.0004273 | 0.03 | 1.424 | 3 | 7021 |
| Chronic: child on playground structure | 0.00054 | 0.03 | 1.800 | 3 | 5556 |
| Chronic: infant on playground structure | 0.00189 | 0.03 | 6.300 | 3 | 1587 |
| Chronic: Inhalation volatile residues indoors: adult | 8.03x10-6 | 0.03 | 0.027 | 3 | 375000 |
| child | 8.99x10-6 | 0.03 | 0.030 | 3 | 333333 |
| infant | 9.24x10-6 | 0.03 | 0.031 | 3 | 326087 |
| **IPBC** | | | | | |
| Acute: amateur sanding | 0.0003075 | 0.35 | 0.088 | 35 | 113821 |
| Acute: infant chewing wood | 0.022 | 0.35 | 6.286 | 35 | 1591 |
| Chronic: professional sanding | 0.0004273 | 0.20 | 0.214 | 20 | 46806 |
| Chronic: child on playground structure | 0.00054 | 0.20 | 0.270 | 20 | 37037 |
| Chronic: infant on playground structure | 0.00189 | 0.20 | 0.945 | 20 | 10582 |
| Chronic: Inhalation volatile residues indoors: adult | 1.02x10-3 | 0.20 | 0.51 | 20 | 19608 |
| child | 1.14x10-3 | 0.20 | 0.70 | 20 | 17544 |
| infant | 1.18x10-3 | 0.20 | 0.59 | 20 | 16949 |

The indirect exposure 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 use.

#### Risk from combined exposure to the three substances

The combined toxicological effects of the three active subsances have not been investigated with regard to repeated exposure.

We believe that a combined exposure assessment according to chapter 4.4.1. of Guidance for human health risk assessment, volume III, part b. can only be made if we can use the appropriate dermal absorption values for the three active substances while calculating the internal exposure values.

For dilute solutions of propiconazole (0.006% – 1.4%), a dermal absorption values of app. 2% was set in the CAR (RMS FI, 2007). We proposed the use this dermal absorption value of 2% for the risk assessement of Axil 2000.

However, for the other 2 active substances we proposed the use of a default dermal absorption value of 75 % for the risk assessment of IPBC and tebuconazole in the in-use dilution of Axil 2000.

We consider this approach already conservative. The assessment of combined exposure to mixture by concentration (dose) addition would never lead to an acceptable risk when using the same dermal absorption values (for IPBC and tebuconazole) as for the risk assessment of substance by substance.

Therefore we proposed very restrictive measures (impermeable coverall) to exclude any risk from exposure to the three active substances while using the product.

We do not expect that combined exposure to the 3 active substances will result in an additional risk above the estimated risks based on the individual substances.

#### Risk for consumers via residues

Axil 2000 can be used on wood which is in indirect contact with food and/or feeding stuff: pallets used for storage of food and feeding stuff.

Transfer of biocidal active substances into foods/feeds (professional uses): Please se the confidential version for more details.

In conclusion: For the scenario that Axil 2000 is used on wood which is in indirect contact with food and/or feeding stuff - pallets used for storage of food and feeding stuff, the intake of propiconazole, tebuconazole and IPBC will be lower than 10% of the AEL long-term / ADI and therefore this foodstuff will not cause a consumer concern in adults or toddlers.

The applicant study concerning the emission transfer of the active substances IPBC, propiconazole and tebuconazole to foodstuffs stacked on Axil 2000 treated pallet planks. Please se the confidential version for more details.

In conclusion: For the scenario that Axil 2000 is used on wood which is in indirect contact with food and/or feeding stuff - pallets used for storage of food and feeding stuff, the intake of propiconazole, tebuconazole and IPBC will be lower than 10% of the AEL long-term / ADI and therefore this foodstuff will not cause a consumer concern in adults or toddlers.

### Summary of the Human Health Risk Assessment

As presented in tables above, the assessment carried out by BE CA indicates that risks posed by the product can be considered acceptable.

Based on the available exposure data and assuming the use of appropriate PPE (impermeable coverall, gloves) the estimated exposure to professional uses applying Axil 2000 is below the established threshold limits for all three active substances. The risk for professional users (industrial application) is unlikely when PPE is used (gloves, impermeable coverall). Please se the confidential version for more details concerning possible less restrictive measures. Other user categories are not concerned since the product is only available for industrial application.

Furterhmore the use of wood treated with Axil 2000 does not pose an unacceptable risk for human health through secondary exposure.

The overall outcome of the risk assessment for humans is that proper use, i.e. in compliance with the conditions on the label/SDS of Axil 2000 and wood treated with this product, is considered safe for all subpopulations.

## Risk assessment for the environment

### Effects Assessment

Axil 2000 is a wood preservative product containing 0,75 % w/w IPBC, 0,75 % w/w tebuconazole and 0,75 % w/w propiconazole. Since none of the non-active components is reported to carry an environmental hazard warning, there are no substances of concern for the environment. Therefore we can conclude that the risk for the environment is exclusively driven by the active substances in the formulation.

The environmental effects of IPBC, tebuconazole and propiconazole in the biocidal product can be derived from the information provided in Document I and IIA of the Annex I CARs for those active substances.

For all the active substances, information on fate and effects from the BPD 98/8/EC Assessment Reports is used, to which BERKEM SAS has a letter of acces.

See also 2.6.2.1.1

### Exposure Assessment.

Detailed information can be found in section See 2.6.2.1 Environmental Exposure Assessment

### 

### Risk Characterisation for the environment

According to the experimental data, the biocidal product is less toxic than the sum of the three active substances. Therefore the risk assessment is based on individual data on each active substance.

The PECs were calculated thanks to OECD Emission Scenario Document. See detailed calculations in Document II-B-2.

The PNEC values used in the risk assessment are the following:

Table 2.8.3-1 PNEC used for risk assessment

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Active substance | PNECwater | PNECsed | PNEC soil | PNECSTP |
| Tebuconazole | 1,0E-03 mg/L | 0.55 mg/kg | 1,0E-01 mg/kgwwt | 3,2E-01 mg/L |
| Propiconazole | 1,6E-03 mg/L | 0.054 mg/kg | 1,0E-01 mg/kgwwt | 1,0E+00 mg/L |
| IPBC | 5,0E-04 mg/L | 0.545 mg/kg | 5,0E-03 mg/kgwwt | 4,4E-01 mg/L |

Values found from Assessment Report of each active ingredient.

Inclusion of active substances in Annex I.

#### Risk characterisation for surface water

Table 2.8.3.1-1 OECD PEC/PNEC ratios for surface water

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Phase | Scenario | Active ing. | Time | PECwater  (mg/L) | PENCwater  (mg/L) | PEC/PNEC |
| Application & Storage | Auto. Spraying | Tebuconazole | 1 | 4,1E-07 | 1,0E-03 | 4,1E-04 |
| 2 | / | 1,0E-03 | / |
| Propiconazole | 1 | 4,2E-07 | 1,6E-03 | 2,6E-04 |
| 2 | / | 1,6E-03 | / |
| IPBC | 1 | 1,8E-07 | 5,0E-04 | 3,6E-04 |
| 2 | / | 5,0E-04 | / |
| Short  Dipping | Tebuconazole | 1 | 2.5E-06 | 1,0E-03 | 2.5E-03 |
| 2 | / | 1,0E-03 | / |
| Propiconazole | 1 | 2.5E-06 | 1,6E-03 | 1.56E-03 |
| 2 | / | 1,6E-03 | / |
| IPBC | 1 | 1,2E-06 | 5,0E-04 | 2.4E-03 |
| 2 | / | 5,0E-04 | / |
| Service life | Fence | Tebuconazole | 1 | 0 | 1,0E-03 | 0 |
| 2 | 0 | 1,0E-03 | 0 |
| Propiconazole | 1 | 0 | 1,6E-03 | 0 |
| 2 | 0 | 1,6E-03 | 0 |
| IPBC | 1 | 0 | 5,0E-04 | 0 |
| 2 | 0 | 5,0E-04 | 0 |
| Noise barrier | Tebuconazole | 1 | 0 | 1,0E-03 | 0 |
| 2 | 0 | 1,0E-03 | 0 |
| Propiconazole | 1 | 0 | 1,6E-03 | 0 |
| 2 | 0 | 1,6E-03 | 0 |
| IPBC | 1 | 0 | 5,0E-04 | 0 |
| 2 | 0 | 5,0E-04 | 0 |
| House | Tebuconazole | 1 | 0 | 1,0E-03 | 0 |
| 2 | 0 | 1,0E-03 | 0 |
| Propiconazole | 1 | 0 | 1,6E-03 | 0 |
| 2 | 0 | 1,6E-03 | 0 |
| IPBC | 1 | 0 | 5,0E-04 | 0 |
| 2 | 0 | 5,0E-04 | 0 |

Table 2.8.3.1-2 OECD PEC/PNEC ratios for sediment

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Phase | Scenario | Active ing. | Time | PECsed  (mg/kg) | PENCsed  (mg/kg) | PEC/PNEC |
| Application & Storage | Auto. Spraying | Tebuconazole | 1 | 9.16E-06 | 0.55 | 1.6E-05 |
| Propiconazole | 1 | 9.40E-06 | 0.054 | 1.7E-04 |
| IPBC | 1 | 6.34E-07 | 0.545 | 1.16E-06 |
| Short Dipping | Tebuconazole | 1 | 5.58E-05 | 0.55 | 1.01E-04 |
| Propiconazole | 1 | 5.59E-05 | 0.054 | 1.03E-03 |
| IPBC | 1 | 4.22E-06 | 0.545 | 7.74E-06 |

During application & storage and service life phases, for the 3 active ingredients, there is no unacceptable risk for surface water compartment.

#### Risk characterisation for soil

Table 2.8.3.2-1 OECD PEC/PNEC ratios for soil

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Phase | Scenario | Active ing. | Time | PECSOIL  (mg/kg wet soil) | PNECSOIL  (mg/kg wet soil) | PEC/PNEC |
| Application & Storage | Auto. Spraying | Tebuconazole | 1 | 4,8E-03 | 1,0E-01 | 4,8E-02 |
| 2 | / | 1,0E-01 | / |
| Propiconazole | 1 | 5,0E-03 | 2,0E-01 | 2,5E-01 |
| 2 | / | 2,0E-01 | / |
| IPBC | 1 | 2,1E-03 | 5,0E-03 | 4,2E-01 |
| 2 | / | 5,0E-03 | / |
| Short Dipping | Tebuconazole | 1 | 3,28E-03 | 1,0E-01 | 3,8E-02 |
| 2 | / | 1,0E-01 | / |
| Propiconazole | 1 | 3,28E-03 | 2,0E-02 | 1,64E-01 |
| 2 | / | 2,0E-02 | / |
| IPBC | 1 | 1,6E-03 | 5,0E-03 | 3,2E-01 |
| 2 | / | 5,0E-03 | / |
| Service life | Fence | Tebuconazole | 1 | 1,6E-03 | 1,0E-01 | 1,6E-02 |
| 2 | 6,9E-03 | 1,0E-01 | 6,9E-02 |
| Propiconazole | 1 | 1,7E-03 | 2,0E-02 | 8,5E-02 |
| 2 | 1,2E-02 | 2,0E-02 | 6,0E-01 |
| IPBC | 1 | 1,0E-05 | 5,0E-03 | 2,0E-03 |
| 2 | 1,0E-05 | 5,0E-03 | 2,0E-03 |
| Noise barrier | Tebuconazole | 1 | 7,1E-04 | 1,0E-01 | 7,1E-03 |
| 2 | 3,0E-03 | 1,0E-01 | 3,0E-02 |
| Propiconazole | 1 | 7,7E-04 | 2,0E-02 | 3,8E-02 |
| 2 | 5,4E-03 | 2,0E-02 | 2,7E-01 |
| IPBC | 1 | 3,0E-06 | 5,0E-03 | 6,0E-04 |
| 2 | 3,6E-06 | 5,0E-03 | 7,2E-04 |
| House | Tebuconazole | 1 | 2,0E-03 | 1,0E-01 | 2,0E-02 |
| 2 | 8,7E-03 | 1,0E-01 | 8,7E-02 |
| Propiconazole | 1 | 2,1E-03 | 2,0E-02 | 1,051E-01 |
| 2 | 1,5E-02 | 2,0E-02 | 7,5E-01 |
| IPBC | 1 | 1,0E-05 | 5,0E-03 | 2,0E-03 |
| 2 | 1,0E-05 | 5,0E-03 | 2,0E-03 |

During application & storage and service life phases, for the 3 active ingredients, there is no unacceptable risk for soil.

#### Risk characterisation for sewage treatment plant (STP)

Table 2.8.3.3-1 OECD PEC/PNEC ratios for STP

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Phase | Scenario | Active ing. | Time | PECSTP  (mg/L) | PNECSTP  (mg/L) | PEC/PNEC |
| Application & Storage | Auto. Spraying | Tebuconazole | 1 | 1,7E-04 | 3,2E-01 | 5,4E-04 |
| 2 | / | 3,2E-01 | / |
| Propiconazole | 1 | 1,7E-04 | 1,0E+00 | 1,7E-04 |
| 2 | / | 1,0E+00 | / |
| IPBC | 1 | 1,7E-04 | 4,4E-01 | 4,0E-04 |
| 2 | / | 4,4E-01 | / |
| Short Dipping | Tebuconazole | 1 | 1,96E-05 | 3,2E-01 | 0,6E-04 |
| 2 | / | 3,2E-01 | / |
| Propiconazole | 1 | 9,87E-05 | 1,0E+00 | 1,0E-04 |
| 2 | / | 1,0E+00 | / |
| IPBC | 1 | 1,97E-04 | 4,4E-01 | 4,5E-04 |
| 2 | / | 4,4E-01 | / |
| Service life | Fence | Tebuconazole | 1 | 0 | 3,2E-01 | 0 |
| 2 | 0 | 3,2E-01 | 0 |
| Propiconazole | 1 | 0 | 1,0E+00 | 0 |
| 2 | 0 | 1,0E+00 | 0 |
| IPBC | 1 | 0 | 4,4E-01 | 0 |
| 2 | 0 | 4,4E-01 | 0 |
| Noise barrier | Tebuconazole | 1 | 2,0E-06 | 3,2E-01 | 6,3E-06 |
| 2 | 1,0E-06 | 3,2E-01 | 3,1E-06 |
| Propiconazole | 1 | 2,1E-06 | 1,0E+00 | 2,1E-06 |
| 2 | 1,0E-06 | 1,0E+00 | 1,0E-06 |
| IPBC | 1 | 8,8E-07 | 4,4E-01 | 2,0E-06 |
| 2 | 1,0E-06 | 4,4E-01 | 2,3E-06 |
| House | Tebuconazole | 1 | 0 | 3,2E-01 | 0 |
| 2 | 0 | 3,2E-01 | 0 |
| Propiconazole | 1 | 0 | 1,0E+00 | 0 |
| 2 | 0 | 1,0E+00 | 0 |
| IPBC | 1 | 0 | 4,4E-01 | 0 |
| 2 | 0 | 4,4E-01 | 0 |

During application & storage and service life phases, for the 3 active ingredients, there is no unacceptable risk for STP.

### Summary of the Environmental Risk Assessment

As presented in tables above, the assessment carried out by BE CA indicates that risks posed by the product can be considered acceptable. During application of the product Axil 2000, during the storage period of treated wood prior to shipment and during the service life of treated wood, there are no unacceptable risks for surface water, sediment, STP and for soil. All the PEC/PNECs ratios are lower than 1.

Therefore, the product Axil 2000 represents no unacceptable risk for the environment according to this environmental risk assessment conducted with OECD Emission Scenario Documents.

## Substitution/Exclusion criteria and Comparative assessment

The Belgian CA for biocides has been processing an application for the biocidal product Axil 2000 which contains an active substance which meets the criteria for substitution under Article 10 of the Biocidal Products Regulations (528/2012) (tebuconazole). Therefore in line with Article 23(2) of the Regulations the Belgian CA has to conduct a comparative assessment for the product.

### Active substances in the biocidal product and criteria for substitution and exclusion

The biocidal product Axil 2000 is a wood preservative product containing three active substances;, tebuconazole, propiconazole and IPBC.

According to the most recent scientific information available, of the three active substances in the biocidal product, the fungicide tebuconazole shall be considered a candidate for substitution using the criteria in Article 10(1). Tebuconazole is not considered as meeting the exclusion criteria according to Article 5(1). This conclusion is based on the Annex I Assessment Report for tebuconazole under PT10 from 2013, which states that tebuconazole is considered to be very persistent (vP) and toxic (T) but not bioaccumulative. Therefore tebuconazole can be considered to meet the criteria in Article 10(1)d, notably it meets two of the criteria for being PBT in accordance with Annex XIII to regulation (EC) No 1907/2006.

Under Article 23(1) of Regulation 528/2012 Member States are required to perform a comparative assessment for biocidal products containing an active substance that is a candidate for substitution in accordance with Article 10(1) . The Belgian CA has therefore used the approach in the EU guidance[[6]](#footnote-6) on the comparative assessment of the biocidal product. In line with this Note for Guidance, the Belgian CA began the comparative assessment with the screening phase to identify whether the diversity of the active substances - mode of action combination in authorised biocidal products is adequate.

### Screening phase of comparative assessment

#### Intended use of the biocidal product and properties of active substances

Article 23(3) and the Note for Guidance focus the comparative assessment on the uses specified in the application of the biocidal product, as the requirement for a comparative assessment is product specific.

**Table 2.9.2.1.-1 Intended uses of the biocidal product**

|  |  |
| --- | --- |
| Product Type | 8 Wood preservatives |
| Where relevant, an exact description of the authorised use | Preventative |
| Target organism (including, where relevant) development stage) | Brown rot fungi |
| Field(s) of use | Outdoor use – use class 3 |
| Application method(s) | Surface application (industrial application): deluging like flow coating and automated spraying |
| Category(ies) of users | Professionals (industrial use) |

IPBC is a carbamate fungicide. The target sites of carbamates in fungi are cell membrane permeability and fatty acids.

Tebuconazole and Propiconazole are azole fungicides intended for use against wood rotting fungi (basidiomycota). The actives act by interfering with the basic metabolism of the fungal cell wall and contents.

Of the three fungicidal active substances in the biocidal product tebuconazole is highly effective against the wood rotting fungi *Coniophora puteana* and *Gloeophyllum trabeum,* butis less effective against the wood rotting fungus *Poria placenta*.

Propiconazole is effective against the wood rotting fungus *P. placenta*, but isless effective against the wood rotting fungi *C. puteana* or *G. trabeum*.

IPBC has some activity against brown wood-rotting fungi but its efficacy largely lies with its activity against bluestain (wood staining) fungi. IPBC is usually not used stand-alone but in combination with propiconazole to achieve efficacy against wood decay. Propiconazole is effective against wood decay.

In combination products, especially well-balanced efficacy against a broad range of wood rotting fungi can be achieved with minimising the amounts of each active.

The big advantage of tebuconazole/propiconazole with respect to the single actives, is that the mixture offers advantages in efficiency as much less triazole is necessary for the long term protection of wood against decay fungi. The very high efficacy of tebuconazole towards the brown rot fungi *C. puteana*. and *G. trabeum* is well compensating the moderate effectiveness of propiconazole towards these fungi, and in case of the fungi *P.placenta* and *C. versicolor*. the 1:1 mixture of tebuconazole and propiconazole is showing even high effectiveness compared to the individual effectiveness of each single triazole.



(Source: Berkem SAS)

#### Chemical diversity of the active substances – mode of action combination in authorised biocidal products

According to the information available (Souce: R4BP3 and ECHA website information on chemicals/biocidal active substances) to the Belgian CA, there are in the region of 1400 biocidal products authorised under Product Type 8 (Wood Preservatives) of the Biocidal Products Directive and Biocidal Products Regulations (including Mutual Recognitions and same product authorisations). Thirty seven active substances (insecticides and fungicides) are approved for PT8 applications. Of these are twenty five fungicides. Of these fungicides are currently ten active substance used in authorised products. There are approximately 660 PT 8 products on the EU market having fungicidal properties. Most of these authorized products are based op propiconazole, tebuconazole, and IPBC or a mixture of these active substances.

The Fungicide Resistance Action Committee (FRAC), an international scientific committee with an overview of the global position, has provided the following information on the potential for resistance; this has been derived from experience with plant protection products rather than wood preservative products.

**Table 2.9.2.2-1 Mode of action and risk of resistance formation for PT8 fungicidal substances in authorised biocidal products**

|  |  |  |  |
| --- | --- | --- | --- |
| Active substance | Tebuconazole | Propiconazole | IPBC |
| Mode of action | G: sterol biosynthesis in membranes  G1: C14- demethylase in sterol biosynthesis | G: sterol biosynthesis in membranes  G1: C14- demethylase in sterol biosynthesis | F: lipid synthesis and membrane integrity  F4: cell membrane permeability, fatty acids (proposed) |
| FRAC code | 3 | 3 | 28 |
| Risk of resistance formation | Medium  (resistance management required) | Medium  (resistance management required) | Low to medium (resistance management required) |

**Occurrence of resistance**

IPBC

According to the Annex I CAR for IPBC and the Fungicide Resistance Action Committee (FRAC) Code List (http://www.frac.info/publication/publication.htm) the risk of resistance formation against carbamate fungicides is regarded to be low to medium.

Tebuconazole and Propiconazole

Tebuconazole and Propiconazole are DeMethylation Inhibitor (DMI) fungicides within Sterol Biosynthesis Inhibitor (SBI) Class I. According to the FRAC Code List, DMI fungicides show no cross resistance to other SBI classes. There are big differences in the activity spectra of DMI fungicides. Resistance to DMI fungicides is known in various fungal species. Several resistance mechanisms are known incl. target site mutations in cyp51 (erg 11) gene, e.g. V136A, Y137F, A379G, I381V; cyp51 promotor; ABC transporters and others. It is considered generally wise to accept that cross resistance is present between DMI fungicides active against the same fungus, and the risk of resistance formation against DMI fungicides is regarded to be medium

According to the Annex I CARs for tebuconazole and propiconazole, for wood preservation with tebuconazole-and propiconazole-containing products, cases of resistances are not reported or known up to the time being.

#### Effects of removal or substitution of tebuconazole in biocidal product

On the basis of the information provided it can be assumed that removal of tebuconazole from the biocidal product would leave a gap in the activity of the biocidal product against certain target pests where the remaining fungicidal active substances in the biocidal product have only weak activity.(see also 2.9.2.1 – properties of active substances)

Regarding substitution by other PT 8 fungicidal active substances in biocidal products (i.e. listed in table 2.9.2.2-1, two of these active substances are already included in the biocidal product, and on the basis of the information on their activity profiles are not considered viable substitutes for tebuconazole. Regarding substitution by the remaining PT8 fungicidal active substance, dichlofluanid, according to the Annex I CAR for dichlofluanid this fungicide is targeted against wood-staining fungi (blue-staining fungi). However, it would not be expected to be able to substitute for tebuconazole regarding activity against wood rotting fungi such as *C. puteana* or *G. trabeum.*

### Conclusion on comparative assessment

According to section 4 of the Note for Guidance, if the outcome of the comparative assessment is not sufficiently conclusive to conclude that the criteria of Article 23(3) of BPR are met, the product could be authorised for a period not exceeding 5 years in accordance with Article 23(6).

Taking into account:

* assuming that substitution of tebuconazole by one of the remaining available fungicidal active substances would reduce the activity of the biocidal product to control certain target organisms and
* the available information on the risk of resistance formation for the PT8 remaining fungicides

the Belgian CA considers that if tebuconazole were substituted in the biocidal product the chemical diversity would be inadequate for the given PT/use/target organism combination, and there would be an increased potential for fungicide resistance where activity gaps are left. Therefore, the Belgian CA concludes that there is not an adequate chemical diversity and in line with Article 23(3)(b) and the Note for Guidance, and since tebuconazole does not meet the exclusion criteria as outlined in Article 5(1), consider it valid to conduct no further investigation at this point. As such, the comparative assessment for Axil 2000 can be finalised at the screening stage and the application taken forward to product authorisation in accordance with Article 23(6) of BPR.

## Measures to protect man, animals and the environment

### Applicant’s proposal

**Recommended methods and precautions concerning handling and use**

Handling and use:

Good standards of hygiene should be maintained at all the times. Avoid contact with skin, eyes and clothes. Avoid inhalation of fog and vapors. Do not eat, drink, smoke while working. In addition to the measures taken usually in the chemical works like splashproof filling and measuring equipment (including vaporstripping) further personal protection measures may have to be implemented to avoid possible contact with the product.

*Hand protection*: The types of gloves recommended are Latex, Neoprene, Nitrile.

*Skin protection*: Working clothing in heavy duty cotton or in synthetic fabric with heavy duty shoes or boots is recommended. You should change working clothes every day.

*Eye and face protection*: You should avoid contact with eyes and wear safety glasses.

*Respiratory protection*: In case of high nuisance exposure, or high temperatures, use gas mask.

Storage:

Keep the product in well closed original package in a dry and well ventilated place, away from food and stimulants. Protect from light and humidity. Keep the product on tight surface and store it on retention area.

Exposure controls and personal protection: Ventilation measures

In the event of dust formed by mechanical action (sanding, sawing, etc…), this dust may cause irritation by inhalation and contact with eyes. Adequate ventilation can be possible with extractor fans at work posts and appropriate general extraction. If this ventilation is insufficient to maintain the concentration of particles and dust below the exposure limits, wear breathing apparatus. Avoid inhaling dust.

Fire-Fighting measures:

Suitable extinguishing media: dry chemical powder, C02, foam or water spray. Direct jet of water must not be used for safety reasons.

*Special protective equipment for fire-fighters*. Due to the toxicity of the gas emitted on thermal decomposition of the products, fire-fighting personnel are to be equipped with autonomous insulationg breathing apparatus. Gloves, protective clothing and respirator are necessary to protect from fumes.

Materials to avoid:

Powerful oxidant and reducers

Transport:

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO.IATA for air transport (ADR 2009 – IMDG 2008 – ICAO/IATA 2009)

Methods and precautions concerning placing on the market:

The biocidal product is concentrated and will be generally used for making dilutions. Thus, there is less emission of VOCs than with solvents.

Then, workers must have formation to learn how to use the products in security in order to be aware of the exposition hazards.

Nowadays, there is more and more security since many product applications are automated. So thers is less hazards for the operator.

**Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available**

First aid in general:

Remove the affected person from the danger zone to a well-ventilated room or to fresh air, and protect from undercooling. In case of suspected poisoning, you must call a physician immediately. Tell the doctor that no specific antidote is known, a symptomatic treatment is necessary. NEVER induce swallowing in an unconscious person.

General safety and hygiene measures:

Observe the precautions generally taken with chemicals.

In the event of exposure by inhalation:

In the event of dust formed by mechanical action (sanding, sawing, etc…), this dust may cause irritation by inhalation and contact with eyes. If a large quantity is inhaled, move the patient into the fresh air and keep him/her warm and still. If breathing is irregular or has stopped, effect mouth-to-mouth resuscitation and call a doctor. Do not give the patient anything orally.

In the event of splashes or contact with eyes:

Wash thoroughly with soft, clean water for 15 minutes holding the eyelids open. Refer the patient to an ophthalmologist, in particular if there is any redness, pain or visual impairment. In the event of splashes or contact with skin, remove contaminated clothes and shoes, and wash with soap and water all affected parts of the body including hair. Destroy or wash entirely all contaminated clothes and shoes before each re-use.

In the event of ingestion:

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor. Call a doctor immediately and show him the label. Tell the doctor that no specific antidote is known, a symptomatic treatment is necessary.

Note to physician:

No specific antidote known. Symptomatic treatment

**Emergency measures to protect the environment**

Environmental precautions:

Do not discharge the product into drains or environment.

Contain and control the leaks or spills with non-combustable absorbent materials suchs as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal. Prevent any material from entering drains or waterways. Use drums to dispose of waste recovered in accordance with applicable regulations.

If the product contaminates waterways, rivers of drains, alert the relevant authorities in accordance with statutory procedures.

Do not contaminated the ground of water with waste. That kind of waste must be disposed of as hazardous waste.

**Procedures, if any, for cleaning application equipment**

Methods for cleaning up

Clean with water, do not use solvents.

Prevent entry into drains, waters or soil. Dam up with absorbing material, e.g. sand. Fill into labelled, sealable containers. Use the necessary personal protective equipment when handling.

After contaminations with product change the gloves immediately and remove them according to relevant national and local regulations.

**Identity of relevant combustion products in cases of fire.**

Combustion products:

Combustion products are toxic. Measures have to be taken to prevent the contaminated extinguishing agent from seeping into the ground or from spreading uncontrollably.

Active substances (propiconazole, tebuconazole, IPBC) contain the elements carbon, hydrogen, oxygen, nitrogen and chlorine. Thus, in the event of fire, the formation of oxides of carbon and nitrogen, or hydrogen chloride, or hydrogen cyanide must be anticipated.

**Procedures for waste management of the biocidal product and its packaging and where relevant treated waste material, e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration.**

Waste:

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company. Do not contaminate the ground or water with waste; do not dispose of waste into the environment.

Dispose of empty containers in an incinerator approved for chemicals by the competent authorities. Damaged containers should be placed in specially marked larger ones. Check possibilities of recycling large empty containers.

Codes of wastes (Decision 2001/573/EC; Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste): 030205 other wood preservatives containing dangerous substances.

Soiled packaging:

Empty container completely. Keep label(s) on container. Give to a certified disposal contractor.

Soak up spilled material with absorptive material such as sand, soil, … Prevevnt product from spreading e.g. by damming in with absorptive material. Clean contaminated area. Collect spillage and washing waters in specially marked, tightly closing containers. Dispose of in a manner approved by local authority.

When uncleanded empty containers are passed on, the recipient must be warned of any possible hazard that my be caused by residues.

**Possibility of destruction or decontamination following release in or on the following: air, water including drinking water, soil.**

If the product contaminates waterways, rivers or drains, alert the relevant authorities in accordance with statutory procedures.

No specific information is available on the product. Reference is made to the recommandations given for the three active substances.

Neither the product nor the active substances are volatile. As a wood preservative, the material is not intentionally aerosolized. Therefore, destruction in aire is not a concern.

The formulation is an aqueous microemulsion and, therefore, it can be expected that introduction into water systems will not be different than the active substance.

In the event of a significant accidental release, contaminated soil should be disposed of according to local regulations.

### Comments and conclusion

The instructions for use must contain the following indications:

* For industrial use only
* Skin protection: Use of impermeable coverall
* As precautionary measure RMM during application/storage/post application such as bunding and recycling / collection of waste should be applied to prevent losses to the environment.

The Belgian CA can agree with the version of the applicant except for skin protection

It needs to be emphasized that contact with the skin is to be avoided due to the product’s skin sensitising potential. As only professional use is envisaged, the risks can be managed by the use of appropriate protective clothing and face protection. Therefore the measures to protect the workers mentioned may be more stringent than currently formulated. The protective equipment and clothing is now ‘recommended’, but should be ‘required’ and the term ‘should’ needs to be replaced by ‘needs to’. Otherwise, the safety of the operator cannot be guaranteed. Working clothing required: impermeable coverall.

Personal protection equipment:

*Skin and body:* Personnel needs wear impermeable coveralls which provide a high degree of protection against heavy contamination by being relatively resistant to the penetration of the biocide through the material of which the coverall is made, and wear heavy duty shoes or boots. Change working clothes every day.

*Hands:* For prolonged or repeated handling, use the following type of gloves: Recommended: latex, neoprene, nitrile. Barrier creams may help to protect the exposed areas of the skin but should not be applied once exposure has occurred. The user must check that the final choice of type of glove selected for handling this product is the most appropriate and takes into account the particular conditions of use, as included in the user's risk assessment.

# Proposal for decision

The evaluation has shown that sufficient data have been provided concerning the evaluation of the application for product authorisation for the product Axil 2000. The authorisation of the product Axil 2000 as wood preservative is therefore granted with the use conditions and restrictions outlined in section 3.1.

## Summary of use conditions and restrictions for Axil 2000

Axil 2000 shall be authorised with the following use conditions and restrictions.:

* The maximum levels of the active ingredients in the product are:

Tebuconazole 0,75 % w/w (purity min. 95 %)

Propiconazole 0,75 % w/w (purity min. 93 %)

IPBC 0,75 % w/w (purity min. 98 %)

* Authorised for industrial use only
* Only to be used for the preventive treatment of construction wood (UC3) to protect against brown rot fungi. White rot fungi claim is not part of this. It acts against sapstain and moulds on fresh-cut wood.
* Application method: the intended ways of application: automated spraying , flow-coating (deluge) and dipping.
* Application rate for surface application: Axil 2000 is used at a 10 % dilution. The product is intended to be used by automated spraying and flow coating (deluge) at an application rate of 120 g/m² (15L/m³) RTU product (at 1/10 dilution).
* Application rate for dipping: Axil 2000 is used at a 5 % dilution. The product is intended to be used by immersion during 20 sec minimum.
* The use of Axil 2000 for treatment of wood inside housing areas (with the exeption of window frames and external doors) is not recommended (see CAR for inclusion on to Annex I doc. 1- p.6)
* Not to be used on materials which are in direct contact with food and feeding stuff
* Appropriate and suitable PPE has to be used by professionals. Risk for professional users is unlikely when appropriate PPE is used (gloves, impermeable coverall).
* It needs to be emphasized that contact with the skin is to be avoided due to the product’s skin sensitising potential. As only professional use is envisaged, the risks can be managed by the use of appropriate protective clothing and face protection. Therefore the measures to protect the workers mentioned may be more stringent than currently formulated by the applicant. The protective equipment and clothing is now ‘recommended’, but should be ‘required’ and the term ‘should’ needs to be replaced by ‘needs to’ (see 2.10 Measures to protect man - Handling and use). Otherwise, the safety of the operator cannot be guaranteed. Working clothing required: impermeable coverall.

Personal protection equipment:

*Skin and body:* Personnel needs wear impermeable coveralls which provide a high degree of protection against heavy contamination by being relatively resistant to the penetration of the biocide through the material of which the coverall is made, and wear heavy duty shoes or boots. Change working clothes every day.

*Hands:* For prolonged or repeated handling, use the following type of gloves: Recommended: latex, neoprene, nitrile. Barrier creams may help to protect the exposed areas of the skin but should not be applied once exposure has occurred. The user must check that the final choice of type of glove selected for handling this product is the most appropriate and takes into account the particular conditions of use, as included in the user's risk assessment

* No risks associated with industrial application and storage have been considered and it is assumed that RMM such as bunding and recycling / collection of waste will ensure small losses.

As a precautionary measure the application processes and storage of freshly treated wood at industrial sites and joineries must be carried out within a contained area:

• Situated on impermeable hard standing,

• With bunding to prevent run-off and

• A recovery system in place

Such measures to ensure collection of leachate for recycling or appropriate disposal as hazardous waste will prevent losses to soil, STP and surface water.

Material and/or container must be disposed of as hazardous waste.

* A top coat is required after treatment with Axil 2000. This coat should be a top-coat which does not contain biocides. This top-coat has to be stable under the standard EN 927-2 in order to limit biocide leaching all along the service-life of wood.
* Stable at least two years from production date

## Necessary issues accounted for in the product label

In addition to the use conditions and restrictions outlined in section 3.., the product will be labelled:

According to 1999/45/EC:

|  |  |
| --- | --- |
| **Category of danger:** | Irritating  Dangerous for the environment |
| **Danger symbol(s)** | Xi.  N |
| **Risk phrases:** | R43: May cause sensitisation by skin contact.  R51/53 : Harmful to aquatic organisms, may cause long term adverse effects in the aquatic environment |
| **Safety phrases:** | S23: Do not breath mist/spray  S24: Avoid contact with skin.  S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  S36/37/39: Wear suitable protective clothing/gloves/eye protection  S51: Use only in well-ventilated areas  S60: This material and its container must be disposed of as hazardous waste.  S61: Avoid release to the environment. Refer to special instructions/safety data sheets. |

According to Regulation (EC) 1272/2008:

|  |  |
| --- | --- |
| **Pictogram :** | GHS07, GHS09 |
| **Signal word :** | Warning |
| **Indications of danger:** | Skin Sens. cat. 1  Aquatic chronic cat. 2 |
| **Hazard statement** | H317: May cause an allergic skin reaction  H411: Toxic to the aquatic life with long lasting effects |
| **Precautionary statements:** | P280: protective gloves/protective clothing/eye protection/face protection  P261: Avoid breathing mist/spray  P302+P352: ON SKIN: Wash with soap and water  P333+P313: If skin irritation or a rash occurs: Get medical advice/attention  P273: Avoid release to the environment  P391: Collect spillage  P501: Dispose of contents and container in accordance with all local, regional, national and international regulations |

The following information regarding disposal and PPE applies and has to be mentioned of the product label:

Dispose of this material and its container at hazardous or special waste collection points. Appropriate and suitable PPE (gloves, impermeable coverall) has to be used by professionals.

The labels and/or safety data sheets of the product shall also indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

## Requirement for further information

None

**Annexes:**

1. **Summary of Product Characteristics (SPC)**
2. **Confidential Annex to PAR**
3. **List of documents/studies reviewed**
4. **Toxicology and metabolism –active substance**
5. **Toxicology – biocidal product**
6. **Safety for professional operators**

# Annex 1: Summary of Product Characteristics (SPC)

**1. Administrative information**

**1.1. Trade name(s) of the product**

| **Trade name(s)[[7]](#footnote-7)** | Axil 2000 |
| --- | --- |
|  |  |

**1.2. Authorisation holder**

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | BERKEM SAS |
| **Address** | Marais Ouest  Gardonne  F-24680  France |
| **Authorisation number** | BE2015-0017 | |
| *Suffixes to the authorisation number linked to trade names[[8]](#footnote-8)* |  | |
| *R4BP asset reference number* | BE-0008559-0000 | |
| **Date of the authorisation** | 31/07/2015 | |
| **Expiry date of the authorisation** | 31/07/2020 | |

**1.3. Manufacturer(s) of the product**

|  |  |
| --- | --- |
| **Name of manufacturer** | SARPAP & CECIL INDUSTRIES sas - BERKEM Group |
| **Address of manufacturer** | Marais Ouest  F-24680 Gardonne  France |
| **Location of manufacturing sites** | Marais Ouest  F-24680 Gardonne  France |

**1.4. Manufacturer(s) of the active substance(s)**

|  |  |
| --- | --- |
| **Active substance** | Propiconazole |
| **Name of manufacturer** | LANXESS Deutschland GmbH |
| **Address of manufacturer** | Kennedyplatz 1  D-50569 Köln  Germany |
| **Location of manufacturing sites** | Syngenta Crop Protection AG  CH-1870 Monthey  Switzerland |

|  |  |
| --- | --- |
| **Active substance** | Tebuconazole |
| **Name of manufacturer** | LANXESS Deutschland GmbH |
| **Address of manufacturer** | Kennedyplatz 1  D-50569 Köln  Germany |
| **Location of manufacturing sites** | Bayer CropScience Corp.  P.O. Box 4913  Hawthorn Road  MO 64120-001 Kansas City  USA |

|  |  |
| --- | --- |
| **Active substance** | IPBC |
| **Name of manufacturer** | LANXESS Deutschland GmbH |
| **Address of manufacturer** | Kennedyplatz 1  D-50569 Köln  Germany |
| **Location of manufacturing sites** | Shanghai Hui Long Chemicals Co Ltd  201815 Dengta Jiazhu Rd.  District Shanghai  China |

|  |  |
| --- | --- |
| **Active substance** | IPBC |
| **Name of manufacturer** | TROY CORPORATION |
| **Address of manufacturer** | Uiverslaan 12e  3140 AC Maasluis  Nederlands |
| **Location of manufacturing sites** | One Avenue L Newark  07105 New Jersey  USA |

**2. Product composition and formulation**

**2.1. Qualitative and quantitative information on the composition of the product**

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Propiconazole | 1-[[2-(2,4-dichlorophenyl)- 4-propyl-1,3-dioxolan-2- yl]methyl]-1H-1,2,4-triazole | Active substance | 60207-90-1 | 262-104-4 | 0,75 % |
| Tebuconazole | 1-(4-chlorophenyl)-4,4- dimethyl-3-(1,2,4-triazol- 1-ylmethyl)pentan-3-ol | Active substance | 107534-96-3 | 403-640-2 | 0,75 % |
| IPBC | 3-iodo-2-propynyl butylcarbamate | Active substance | 55406-53-6 | 259-627-5 | 0,75 % |
| Confidential |  | Non-active substances[[9]](#footnote-9) |  |  |  |

Full composition is given in the Confidential Annex of the PAR

**2.2. Type of formulation**

|  |
| --- |
| ME microemulsion |

**3. Hazard and precautionary statements[[10]](#footnote-10)**

**Classification according to Directive 1999/45/EC**

| Category of danger | Xi: Irritating  N: Dangerous for the environment |
| --- | --- |
| Risk phrases | R43  R51/R53 |

**Labelling according to Directive 1999/45/EC**

|  |  |
| --- | --- |
| **Category of danger:** | Irritating  Dangerous for the environment |
| **Danger symbol(s)** | Xi.  N |
| **Risk phrases:** | R43: May cause sensitisation by skin contact.  R51/53 : Harmful to aquatic organisms, may cause long term adverse effects in the aquatic environment |
| **Safety phrases:** | S23: Do not breath mist/spray  S24: Avoid contact with skin.  S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  S36/37/39: Wear suitable protective clothing/gloves/eye protection  S51: Use only in well-ventilated areas  S60: This material and its container must be disposed of as hazardous waste.  S61: Avoid release to the environment. Refer to special instructions/safety data sheets. |

**Classification according to Regulation (EC) 1272/2008**

|  |  |  |
| --- | --- | --- |
| **Category of danger:** | Skin Sens. cat. 1  Aquatic chronic cat. 2 | |
| **Signal Word :** | Warning | |
| **H Phrases:** | H317  H411 | May cause an allergic skin reaction  Toxic to the aquatic life with long lasting effects |

**Labelling according to Regulation (EC) 1272/2008**

|  |  |
| --- | --- |
| **Pictogram :** | GHS07, GHS09 |
| **Signal word :** | Warning |
| **Indications of danger:** | Skin Sens. cat. 1  Aquatic chronic cat. 2 |
| **Hazard statement** | H317: May cause an allergic skin reaction  H411: Toxic to the aquatic life with long lasting effects |
| **Precautionary statements:** | P280: protective gloves/protective clothing/eye protection/face protection  P261: Avoid breathing mist/spray  P302+P352: ON SKIN: Wash with soap and water  P333+P313: If skin irritation or a rash occurs: Get medical advice/attention  P273: Avoid release to the environment  P391: Collect spillage.  P501: Dispose of contents and container in accordance with all local, regional, national and international regulations |

**4. Authorised use(s)**

**4.1. Use description**[[11]](#footnote-11)

**Table 1. Use # 1 – Preventive treatment of construction wood (UC3)**

|  |  |
| --- | --- |
| **Product Type** | PT8 – wood preservative |
| **Where relevant, an exact description of the authorised use** | AXIL 2000 is a wood preservative intended for preventive treatment of construction wood (joinery: window frames, sidings,…) (UC3) against brown rotting fungi.  For exterior use, treated wood has to be coated by a top coat. Axil 2000 is compatible with all types of finishes. |
| **Target organism(s) (including development stage)** | Effective against wood rotting basidiomycetes in preventive treatment of wood construction (UC3).  Brown rot fungi. It acts against wood destroying fungi (basidiomycete fungi, e.g. *Coniophora puteana*, *Gloeophyllum trabeum* and *Poria placenta*.)  White rot fungi claim is not part of the application. |
| **Field(s) of use** | Preventive treatment of construction wood (UC3), outdoor, only softwood. |
| **Application method(s)** | The treatment is performed by surface application : automated spraying and flow-coating (deluge). The treatment effect is immediate and optimal at the fixation step. Mix well the product before application. The product is for industrial use only. |
| **Application rate(s) and frequency** | Axil 2000 is used at a 10 % dilution for preventive wood treatment of construction wood. The product is intended to be used by automated spraying, flow coating (deluge) at an application rate of 120 g/m² (15L/m³) RTU product (at 1/10 dilution) |
| **Category(ies) of users** | For industrial use only |
| **Pack sizes and packaging material** | Axil 2000 is packaged in 1000L containers |

**Table 2. Use # 2 – Temporary preventive treatment of freshly cut wood**

|  |  |
| --- | --- |
| **Product Type** | PT8 – wood preservative |
| **Where relevant, an exact description of the authorised use** | AXIL 2000 is intended for temporary preventive treatment of freshly cut wood against blue stain fungi on fresh wood and mould.  For exterior use, treated wood has to be coated by a top coat. Axil 2000 is compatible with all types of finishes.  Under following conditions: biocidal product diluted at 5% w/w, applied by dipping to freshly sawn timber, the product is authorised in treatment of wood which will be used in materials intended to come into indirect contact with food and/or feeding stuff. |
| **Target organism(s) (including development stage)** | Effective against blue stain fungi and mould in temporary preventive treatment of freshly cut wood.  It acts against mould fungi (*Aspergillus versicolor*) and sapstain fungi (*Ceratocystis spp.*) |
| **Field(s) of use** | Preventive treatment of freshly cut wood |
| **Application method(s)** | The treatement by short dipping is a surface treatment where wood to be treated is immersed in a dipping tank containing the ready for use product during a short dipping period (20s). |
| **Application rate(s) and frequency** | Axil 2000 is used at a 5 % dilution (5g/m²). The product is intended to be used by immersion during 20 sec minimum. |
| **Category(ies) of users** | For industrial use only |
| **Pack sizes and packaging material** | Axil 2000 is packaged in 1000L containers |

***4.1.1.* *Use-specific instructions for use*[[12]](#footnote-12)**

|  |
| --- |
| The treatment is performed by surface application (automated spraying, flow-coating and short dipping). The ready-for-use product is prepared with water by mild stirring. Axil 2000 is miscible in any proportions with water and easily homogenisable. The concentration of the ready-for-use preparation can be checked with a refractometer.  Precautions of use:  Frozen wood must not be treated.  A preliminary test has to be done for treatment of exotic or tannin-rich woods.  Further cuts and notches must be treated.  For an exterior use, the use class 3-treated wood has to be coated.  The treated wood cannot be in contact with livestock: the product should not be used to treat wood of stables, cages and fences in contact with livestock  Cleaning:  After use, rinse equipment with water.  Drying time – fixation:  Fixation: 4 h after dripping under cover on waterproof area.  Treated wood has to be drained above a dip tray so that the drip-off liquid can be collected. Treated wood is considered as drained as soon as the wood doesn’t drip anymore.  Drying time: from 24 to 48 h in well ventilated place and normal conditions.  The wood, after treatment, must be systematically stored in an area sheltered from bad weather for 24 hours minimum and should not be exposed to the bad weathering conditions until it find its service moisture. |

***4.1.2 Use-specific risk mitigation measures***

|  |
| --- |
| Read the information avalaible in the Material Safety Data Sheet.  Use biocides safely. Always read the label and product information before use.  See also precautionary statements as part of the classification and labelling of the product.  Handling:  The product must only be used in fully  automated dipping processes where all steps in the treatment and drying process  are mechanised and no manual handling takes place, including when the treated  articles are transported from the dip tank to draining/drying and storage  (if not already surface dry before moving to storage).  Where appropriate, the wooden articles  to be treated must be fully secured (e.g. via tension belts or clamping  devices) prior treatment, and during the dipping process. , The wooden articles  must not be manually handled until the treated articles surfaces are dry.  If handling of treated wood occurs, wear  PPE (gloves and impermeable coverall).  Good standards of hygiene should be maintained at all times.  Avoid contact with skin, eyes and clothes.  Avoid inhalation of fog and vapours.  Do not eat, drink, and smoke while working.  Appropriate and suitable personal protective equipment (PPE) is needed (gloves, impermeable coverall). Further specification of the type of PPE to be used is given later in the section.  It needs to be emphasized that contact with the skin is to be avoided due to the product’s skin sensitising potential.  Personal protection equipment:  Skin and body: Personnel needs to wear impermeable coveralls (protective coverall at least type 6, EN 13034) which provide a high degree of protection against heavy contamination by being relatively resistant to the penetration of the biocide through the material of which the coverall is made, and wear heavy duty shoes or boots. Change working clothes every day.  Hands: For prolonged or repeated handling, use the following type of gloves: Recommended: latex, neoprene, nitrile. Barrier creams may help to protect the exposed areas of the skin but should not be applied once exposure has occurred. The user must check that the final choice of type of glove selected for handling this product is the most appropriate and takes into account the particular conditions of use, as included in the user's risk assessment.  Storage:  Keep the original container tightly closed and in a dry place, away from light and moisture.  Store in standard conditions of temperature (frost-free)  Ensure adequate ventilation of the storage area.  Keep away from food, drink and animal feeding stuffs.  Dietary exposure :  An intermediate protecting paper or cardboard layer (approved for direct alimentary contact) must always be put between the treated wood and the food (packaged or not).  The treated wood cannot be in contact with livestock. So the product should not be used to treat wood of stables, cages and fences in contact with livestock  Environment:  The product residue, washing water, packaging and any other waste related to the treatment should be considered as hazardous waste and disposed according to national or regional regulation.  During the entire period of storage, it is necessary to ensure that no constituents of the product reaches the ground or water.  Do not empty residues into drains and waterways.  No risks associated with industrial application and storage have been considered and it is assumed that RMM such as bunding and recycling / collection of waste will ensure only small losses to the environment.  As a precautionary measure the application processes and storage of freshly treated wood at industrial sites and joineries must be carried out within a contained area:  • Situated on impermeable hard standing,  • With bunding to prevent run-off and  • A recovery system in place  A top coat is required after the treatment with Axil 2000.  The labels and/or safety data sheets of the product shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. |

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

|  |
| --- |
| Specific treatment in case of an accident, first-aid measures  First aid in general:  Move the affected person into fresh air. Keep warm and at rest. In case of suspected poisoning, you must call a physician immediately. Tell the doctor that no specific antidote is known, a symptomatic treatment is necessary. NEVER give anything by mouth to an unconscious person.  General safety and hygiene measures:  Observe the precautions generally taken with chemicals.  In the event of exposure by inhalation:  If inhaled (vapour/mist) during application. Remove person to fresh air, keep warm and at rest. Call a Poison Center or doctor/physician if person feels unwell.  In the event of dust formed by mechanical action (sanding, sawing, etc…), this dust may cause irritation by inhalation and contact with eyes. If a large quantity is inhaled, move the patient into the fresh air and keep him/her warm and still. If breathing is irregular or has stopped, effect mouth-to-mouth resuscitation and call a doctor. Do not give the patient anything orally.  In the event of eye exposure:  Rinse immediately with plenty of water (tepid if possible) for 15 minutes while holding the eyelids apart. Remove any contact lenses if present.  Refer the patient to an ophthalmologist, in particular if there is any redness, pain or visual impairment.  In the event of dermal exposure:  In the event of splashes or contact with skin, remove contaminated clothes and shoes, and rinse or wash with soap and water all affected parts of the body including hair. Destroy or wash entirely all contaminated clothes and shoes before each re-use.  In the event of oral exposure:  If swallowed, rinse the mouth with water and seek medical advice (immediately).  Note to physician:  No specific antidote known. Symptomatic treatment  Emergency measures to protect the environment:  Do not discharge the product into drains or environment. Prevent entry into waters or soil  Contain and control the leaks or spills with non-combustable absorbent materials suchs as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal. Prevent any material from entering drains or waterways. Use drums to dispose of waste recovered in accordance with applicable regulations.  If the product contaminates waterways, rivers of drains, alert the relevant authorities in accordance with statutory procedures. |

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

|  |
| --- |
| Empty containers completely. The product residue, washing water, packaging and any other waste related to the treatment should be considered as hazardous waste.  Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company. Do not contaminate the ground or water with waste; do not dispose of waste into the environment.  Dispose of empty containers in an incinerator approved for chemicals by the competent authorities. Damaged containers should be placed in specially marked larger ones. Check possibilities of recycling large empty containers.  Codes of wastes (Decision 2001/573/EC; Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste): 030205 other wood preservatives containing dangerous substances. |

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

|  |
| --- |
| Shelf-life of the product under normal conditions of storage: 2 years  Keep the original container tightly closed and in a dry place, away from light and moisture.  Store in standard conditions of temperature (frost-free)  Ensure adequate ventilation of the storage area.  Keep away from food, drink and animal feeding stuffs. |

**5. General directions for use[[13]](#footnote-13)**

**5.1. Instructions for use6**

|  |
| --- |
| See 4.1.1 |

**5.2. Risk mitigation measures**

|  |
| --- |
| See 4.1.2 |

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

|  |
| --- |
| See 4.1.3 |

**5.4. Instructions for safe disposal of the product and its packaging**

|  |
| --- |
| See 4.1.4 |

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

|  |
| --- |
| See 4.1.5 |

**6. Other information**

|  |
| --- |
| - |

# Annex 2: Confidential Annex to PAR

**See separated document**

# Annex 3: List of documents/studies provided in support of Axil 2000

Please se the confidential version for more details.

# Annex 4: Toxicology and metabolism – active substance(s)

**IPBC**

Threshold Limits and other Values for Human Health Risk Assessment

Date: 31.01.2015

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value | Study | SF |
| AEL long-term | 0.20 mg/kg bw/d | 2-year dog study | 100 |
| AEL medium-term | 0.35 mg/kg bw/d | 90-day rat study | 100 |
| AEL acute | 0.35 mg/kg bw/d | 90-day rat study | 100 |
|  | | | |

|  |  |
| --- | --- |
| Inhalative absorption | **100%** (default) |
| Oral absorption | **100%** (used for risk characterisation)  (>90% based on urinary excretion (~57-71%) and exhaled air (~18-24%) within 72 hours.) |
| Dermal absorption | **75%** for 0.075% in-use solution (default according to EFSA Journal 2012; 10(4):2665)  (1.6, 10, and 30% for solutions containing 17, 2.4 and 0.6% IPBC; 100% default for solutions containing <0.5%-0.6% IPBC  based on *in vitro* human skin study with solvent based model products) |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Dir. 67/548/EEC) | T; R23  Xn; R22  Xi; R37, R41  R43 |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute tox 3 - H331  Acute tox 4 - H302  Eye dam 1 - H318  Skin Sens 1 - H317  STOT RE 1 - H372 (larynx) |

**PROPICONAZOLE**

Threshold Limits and other Values for Human Health Risk Assessment

Date: 31.01.2015

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value | Study | SF |
| AEL long-term | 0.08 mg/kg bw/d | 2-generation study, rat | 100 |
| AEL medium-term | - | - |  |
| AEL acute | 0.30 mg/kg bw/d | Developmental study, rat | 100 |
|  | | | |

|  |  |
| --- | --- |
| Inhalative absorption | **100%** (default) |
| Oral absorption | **100%** (used for risk characterisation)  (86% within 48 h) |
| Dermal absorption | **2 %**  (The estimated dermal absorption in humans is 1% for the Wocosen 100 SL product (10% propiconazole) and 2% for the 1% Wocosen 100 SL dilution and the Wocosen 12 OL product, based on an in vivo study in rat and a comparative in vitro dermal penetration study using rat and human skin. For dilute solutions of propiconazole (0.006-1.4%) a dermal absorption value of appr. 2% has been set in the CAR) |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Dir. 67/548/EEC) | Xn; R22  R43 |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 4 - H302  Skin Sens 1 - H317 |

**TEBUCONAZOLE**

Threshold Limits and other Values for Human Health Risk Assessment

Date: 31.01.2015

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value | Study | SF |
| AEL long-term | 0.03 mg/kg bw/d | 1-year dog study | 100 |
| AEL medium-term | 0.03 mg/kg bw/d | 1-year dog study | 100 |
| AEL acute | 0.03 mg/kg bw/d | 1-year dog study | 100 |
|  | | | |

|  |  |
| --- | --- |
| Inhalative absorption | **100%** (default) |
| Oral absorption | **100%** (used for risk characterisation)  (>98%, based on urinary (7.4%) and biliary (90.9%) excretion within 48 hours) |
| Dermal absorption | **75%** for 0.075% in-use solution (default according to EFSA Journal 2012; 10(4):2665)  The active substance: Rapid (peak 0.5-4h) and 50% of the dose within 8 hours in the rat. The vehicle was ethanol  The ability of tebuconazole to penetrate the skin was examined in-vitro with the solvent-based and water-based guide formulations containing approx. 0.63-0.65% [14C]-tebuconazole, . The dermal absorption was studied on dermatomed human skin according to the OECD draft Guideline 428..  After 24 hours with 8 hours of exposure to the **solvent-based preparation** , the total amount of radioactive material absorbed and residues found in stratum corneum strip 6-20 was 14.4%  After 24 hours with 8 hours of exposure to the **water-based preparation**, the absorbed dose and residues found in stratum corneum strip 6-20 was 3.3% |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Dir. 67/548/EEC) | Xn; Repr. Cat 3  R22  R63 |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 4 - H302  Repr 2 - H361 |

# Annex 5: Toxicology – Biocidal Product

Please se the confidential version for more details

# Annex 6 Safety for professional operators

AXIL 2000

Date: 31/01/15

Exposure assessment

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **AXIL 2000** | **INDUSTRIAL USE : automated spraying, flow coating (deluge)** | | | |  |  |  |
|  |  |  |  |  |  |  |  |
| **Model: Handling model 1** | | | | | |  |  |
| **Values valid for WB products, 75th percentiles** |  |  |  |  |  |  |  |
| **PPE: gloves and coated coveralls** |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |

See model below for automated dipping

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **AXIL 2000** | **INDUSTRIAL USE : Automated dipping** | | |  | TIER 1 |  |  |
|  |  |  |  |  |  |  |  |
| **Model: Handling model 1** |  |  |  |  |  |  |  |
| **Values valid for WB products, 75th percentiles** |  |  |  |  |  |  |  |
| **PPE: gloves and coated coveralls** |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  | **Propiconazole** | | **Tebuconazole** | | **IPBC** |  |  |
| **Product** |  |  |  |  |  |  | Unit |
| Active substance in concentrated product | 0,75 |  | 0,75 |  | 0,75 |  | % |
| Dilution | 5 |  | 5 |  | 5 |  | % |
| Active substance in-use concentration | 0,0375 |  | 0,0375 |  | 0,0375 |  | % |
|  |  |  |  |  |  |  |  |
| **Dermal exposure** |  |  |  |  |  |  |  |
| Product on clothing rate | 8570 |  | 8570 |  | 8570 |  | mg / cycle |
| Duration | 1 |  | 1 |  | 1 |  | cycle |
| Relative penetration of clothing | 10 |  | 10 |  | 10 |  | % |
| Deposit of product on skin | 857 |  | 857 |  | 857 |  | mg |
|  |  |  |  |  |  |  |  |
| Product inside gloves rate | 1080 |  | 1080 |  | 1080 |  | mg / cycle |
| Duration | 1 |  | 1 |  | 1 |  | cycle |
| Relative penetration of gloves | 100 |  | 100 |  | 100 |  | % |
| Deposit of product on hands | 1080 |  | 1080 |  | 1080 |  | mg |
|  |  |  |  |  |  |  |  |
| Total deposit of product | 1937 |  | 1937 |  | 1937 |  | mg |
| Total deposit of active substance | 0,726 |  | 0,726 |  | 0,726 |  | mg |
|  |  |  |  |  |  |  |  |
| Exposure to active substance via skin | 0,726 |  | 0,726 |  | 0,726 |  | mg / event |
| Number of events per day | 5 |  | 5 |  | 5 |  | / d |
| Bodyweight | 60 |  | 60 |  | 60 |  | kg |
| Dermal exposure on contact day | **60.5** |  | **60.5** |  | **60.5** |  | **µg / kg bw** |
| Dermal absorption | 2 |  | 75 |  | 75 |  | % |
| Systemic dermal exposure | **1.21** |  | **45.375** |  | **45.375** |  | **µg / kg bw / d** |
|  |  |  |  |  |  |  |  |
| **Systemic exposure** |  |  |  |  |  |  |  |
| Total systemic exposure | 1.21 |  | 45.375 |  | 45.375 |  | **µg /kg bw / d** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **AXIL 2000** | **INDUSTRIAL USE : Dipping tier 2** | | |  |  |  |  |
|  |  |  |  |  |  |  |  |
| **Model: Handling model 1** |  |  |  |  |  |  |  |
| **Values valid for WB products, 75th percentiles** |  |  |  |  |  |  |  |
| **PPE: gloves and impermeable coveralls** |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  | **Propiconazole** | | **Tebuconazole** | | **IPBC** |  |  |
| **Product** |  |  |  |  |  |  | Unit |
| Active substance in concentrated product | 0,75 |  | 0,75 |  | 0,75 |  | % |
| Dilution | 5 |  | 5 |  | 5 |  | % |
| Active substance in-use concentration | 0,0375 |  | 0,0375 |  | 0,0375 |  | g /kg |
|  |  |  |  |  |  |  |  |
| **Dermal exposure** |  |  |  |  |  |  |  |
| Product on clothing rate | 8570 |  | 8570 |  | 8570 |  | mg / cycle |
| Duration | 1 |  | 1 |  | 1 |  | cycle |
| Relative penetration of clothing | 5 |  | 5 |  | 5 |  | % |
| Deposit of product on skin | 429 |  | 429 |  | 429 |  | mg |
|  |  |  |  |  |  |  |  |
| Product inside gloves rate | 1080 |  | 1080 |  | 1080 |  | mg / cycle |
| Duration | 1 |  | 1 |  | 1 |  | cycle |
| Relative penetration of gloves | 100 |  | 100 |  | 100 |  | % |
| Deposit of product on hands | 1080 |  | 1080 |  | 1080 |  | mg |
|  |  |  |  |  |  |  |  |
| Total deposit of product | 1509 |  | 1509 |  | 1509 |  | mg |
| Total deposit of active substance | 0,566 |  | 0,566 |  | 0,566 |  | mg |
|  |  |  |  |  |  |  |  |
| Exposure to active substance via skin | 0,566 |  | 0,566 |  | 0,566 |  | mg / event |
| Number of events per day | 5 |  | 5 |  | 5 |  | / d |
| Bodyweight | 60 |  | 60 |  | 60 |  | kg |
| Dermal exposure on contact day | **47.16** |  | **47.16** |  | **47.16** |  | **µg / kg bw** |
| Dermal absorption | 2 |  | 75 |  | 75 |  | % |
| Systemic dermal exposure | **0,4943** |  | **35.37** |  | **35.37** |  | **µg / kg bw / d** |
|  |  |  |  |  |  |  |  |
| **Systemic exposure** |  |  |  |  |  |  |  |
| Total systemic exposure | 0.943 |  | 35.37 |  | 35.37 |  | **µg /kg bw / d** |
|  |  |  |  |  |  |  |  |

1. Applies only to existing authorisations [↑](#footnote-ref-1)
2. Please insert additional columns as necessary [↑](#footnote-ref-2)
3. Not applicable any more since December 2010. [↑](#footnote-ref-3)
4. Not applicable any more since December 2010. [↑](#footnote-ref-4)
5. Not applicable any more since December 2010. [↑](#footnote-ref-5)
6. Notes for guidance: Comparative assessment of biocidal products – Final version: Ca-March14-Doc.5.4 [↑](#footnote-ref-6)
7. In case the product would have more than one name, all names can be provided in this field. [↑](#footnote-ref-7)
8. Where relevant for the Member State delivering a national authorisation. Insert rows as necessary. [↑](#footnote-ref-8)
9. Non-active substance(s) knowledge of which is essential for proper use of the product. In the draft SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of the non-active substance. [↑](#footnote-ref-9)
10. According to Regulation (EC) 1272/2008, or where relevant, Directive 1999/45/EC. This section shall only include precautionary statements triggered by the CLP legislation. In accordance with paragraph 8 of document CA-May13-Doc.5.4, a precautionary statement that has been proven unnecessary in the risk assessment because of the intended use of the product should be left out of the SPC and of the label. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-10)
11. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a single biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-11)
12. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-12)
13. Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses. [↑](#footnote-ref-13)