**Bilag 2**

# Product Assessment Report

# Laqvin Ton SX 1420

| | |
|---|---|
| Internal registration/file no: | MST-671-01757 |
| Authorisation/Registration no: | 694-4 |
| Granting date/entry into force of authorisation/ registration: | 9 December 2011 |
| Expiry date of authorisation/ registration: | 31 March 2020 |
| Active ingredient: | IPBC<br>Propiconazole |
| Product type: | PT 8 Wood Preservative |

Biocidal product assessment report related to product authorisation under Directive 98/8/EC

Danish Ministry
of the Environment
Environmental
Protection Agency

# Contents

# 1 General information about the product application

## 1.1 Applicant

| | |
|---|---|
| **Company Name:** | Sherwin-Williams Sweden Coatings KB |
| **Address:** | P.O. Box 2016 |
| **City:** | Märsta |
| **Postal Code:** | SE-19502 |
| **Country:** | Sweden |
| **Telephone:** | +46 38126260 |
| **Fax:** | +46 38126193 |
| **E-mail address:** | peter.weissenborn@sherwin.com |

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

| | |
|---|---|
| **Name:** | Ms. Berit Lindegaard |
| **Function:** | Technician at Danish Technological Institute |
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## 1.2 Current authorisation holder[1]

There is no current authorisation for Laqvin Ton SX 1420 in Denmark.

## 1.3 Proposed authorisation holder

| | |
|---|---|
| **Company Name:** | Sherwin-Williams Sweden Coatings KB |
| **Address:** | P.O. Box 2016 |
| **City:** | Märsta |
| **Postal Code:** | SE-19502 |
| **Country:** | Sweden |
| **Telephone:** | +46 38126260 |
| **Fax:** | +46 38126193 |

[1] Applies only to existing authorisations

| | |
|---|---|
| **E-mail address:** | peter.weissenborn@sherwin.com |

## 1.4 Information about the product application

| | |
|---|---|
| **Application received:** | 29 June 2010 |
| **Application reported complete:** | 21 June 2011 |
| **Type of application:** | Product authorisation |
| **Further information:** | Frame formulation |

## 1.5 Information about the biocidal product

### 1.5.1 General information

| | |
|---|---|
| **Trade name:** | Laqvin Ton |
| **Manufacturer's development code number(s), if appropriate:** | SX 1420 |
| **Product type:** | PT8 |
| **Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):** | IPBC 0.60%<br>Propiconazole 0.40% |
| **Formulation type:** | Liquid water based wood preservative |
| **Ready to use product (yes/no):** | Yes |
| **Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no);<br>If yes: authorisation/registration no. and product name:<br>or<br>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 |

### 1.5.2 Information on the intended use(s)

| | |
|---|---|
| **Overall use pattern (manner and area of use):** | The product is for industrial use, application by dipping (automated), flowcoating or spraying<br>For Use Class 2 and 3 |
| **Target organisms:** | Effective against blue-staining fungi |
| **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:** | The product is applied at a rate of 70-80 g/m$^2$. After application the timber is finally treated with a mould resistant top coat. |
| **Potential for release into the environment (yes/no):** | Yes |
| **Potential for contamination of food/feedingstuff (yes/no)** | No |
| **Proposed Label:** | Yes |

### 1.5.3 Information on active substance(s)

| | | |
|---|---|---|
| **Active substance chemical name:** | IPBC | Propiconazole |
| **CAS No:** | 55406-53-6 | 60207-90-1 |
| **EC No:** | 259-627-5 | 262-104-4 |
| **Purity (minimum, g/kg or g/l):** | Min. 980 g/kg | Min. 930 g/kg |
| **Inclusion directive:** | 2008/79/EF of 28 July 2008 | 2008/78/EF of 25 July 2008 |
| **Date of inclusion:** | 1 July 2010 | 1 April 2010 |
| **Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):** | Yes | Yes |
| **Manufacturer of active substance(s) used in the biocidal product:** | | |
| **Company Name:** | Lanxess Deutschland GmbH | Janssen PMP |
| **Address:** | Chempark | Turnhoutseweg 30 |
| **City:** | Leverkusen | Beerse |
| **Postal Code:** | D-51369 | 2340 |
| **Country:** | Germany | Belgium |
| **Telephone:** | +49 (0) 214 30-57344 | +32(0)14602111 |
| **Fax:** | +49 (0) 214 30-24278 | +32(0)14605951 |
| **E-mail address:** | olga.wittmann@lanxess.com | |

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

Laqvin Ton SX 1420 contains no substances of concern.

## 1.6 Documentation

### 1.6.1 Data submitted in relation to product application

See Annex 1 for complete references.

### 1.6.2 Access to documentation

The applicant has submitted the following letters of access:

Janssen Pharmaceutica grants the right to make reference to the Janssen proprietary data on WOCOSEN™ as used for the annex I inclusion of propiconazole.

Syngenta Crop Protection AG grants the right to make reference to data owned by Syngenta and filed in support of the registration of propiconazole in Denmark.

Lanxess Deutscland GmbH grants the right to refer to the BPD 98/8/EC dossier of IPBC filed by the Task Force.

For further information on specific studies see dossier for application of the product.

# 2 Summary of the product assessment

## 2.1 Identity related issues

The biocidal product contains the active substances IPBC (0.6%) and Propiconazole (0.4%) (Min. purity 980 g/kg and 930 g/kg respectively).

The biocidal product is not identical to the representative product for Annex I inclusion.

The active substances are identical to the active substances listed in Annex I of 98/8/EC.

## 2.2 Classification, labelling and packaging

### 2.2.1 Harmonised classification and labelling of the biocidal product

The current classification and labelling of Laqvin Ton SX 1420 according to Directive 67/548/EEC is shown here:

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

S2: Keep out of the reach of children
S13: Keep away from food, drink and animal foodstuffs

The product shall furthermore be labelled with the following sentence:
Contains IPBC and Propiconazole: May produce an allergic reaction.

### 2.2.2 Packaging of the biocidal product

The biocidal product is packed in 20 L plastic lined metal cans, 120 L, 200 L and 1000 L plastic containers.

## 2.3 Physico/chemical properties and analytical methods

### 2.3.1 Physico-chemical properties

**Physico-chemical properties of the active substance**:

A letter of access has been submitted for the active substances. An overview of the physico-chemical properties of the active substances can be found in the CAR[2].

A summary of the physical and chemical properties of Laqvin Ton SX 1420 is given in Table 2.3-1. The available data is evaluated and determined to be of sufficient quality and reliability for use in risk assessment (evaluation at the Document IIIB level).

[2] Competent Authority Report

**Table 2.3-1: Physico-chemical properties of the biocidal product**:

| | Method | GLP (Y/N) | Results | Reference |
|---|---|---|---|---|
| Physical state and nature | Performed by visual observation at 20ºC. | N | Liquid, dark brown water emulsion. | Lindegaard & Morsing, 2011 |
| Colour | Performed by visual observation at 20ºC. | N | Dark brown due to pigments. | Lindegaard & Morsing, 2011 |
| Odour | Performed by odour observation at 20ºC. | N | No intense odour. As butanol. | Lindegaard & Morsing, 2011 |
| Explosive properties | – | N | The explosive properties are not measured since the product is waterborne.<br><br>None.<br>Contains VOC (Volatile organic compounds) (ISO) 25 g/L. | Becker Acroma |
| Oxidizing properties | – | N | None.<br><br>The product oxidising properties is not measured since the product is waterborne. | Becker Acroma |
| Flash point | ASTM 6450, Closed cup | N | 101°C | Becker Acroma |
| Autoflammability | ASTM 6450 | N | Non-flammable | Becker Acroma |
| Acidity / Alkalinity | pH Meter ID nr. T-1.0021, Denver instrument, Basic. | N | pH of the product undiluted: 6.5 – 8.5.<br><br>The acidity / alkalinity was not determined as the pH-value is between 4 and 10. | Lindegaard & Morsing, 2011 |
| Relative density / bulk density | SS-EN ISO 2811-1:2011 | N | 1.02 g/mL | Becker Acroma<br><br>No official report for the product. The density is measured routinely as part of quality control process. |
| Effects of temperature | CIPAC M46. 35oC for 2 weeks. | N | No changes of biocidal concentration. By visual | Lindegaard & Morsing, 2011 |

| | Method | GLP (Y/N) | Results | Reference |
|---|---|---|---|---|
| | | | observation it was observed that pigments sediments. Easy to stir.<br>By smell observation it was observed that there was no intense odour and the product smelled like butanol.<br><br>Initial analysis:<br>0.59% and 0.57% IPBC.<br>Mean: 0.58<br><br>0.37% and 0.36% propiconazole<br>Mean: 0.365%<br><br>After storage:<br>0.55% and 0.54% IPBC.<br>Mean:0.545%<br><br>0.39% and 0.40% propiconazole.<br>Mean: 0.395%<br><br>Variation:<br>IPBC: 6.0%<br><br>Propiconazole:<br>8.2% | |
| Effects of light | Not applicable | N | Stored in plastic lined metal cans or milky plastic containers. The product is white pigmented and light cannot penetrate the product. | Becker Acroma |
| Reactivity towards container material | CIPAC M46 | N | For 8 weeks at 35°C:<br>There was no reactivity towards container material.<br><br>For 13 months at room temperature<br>There was no reactivity towards container material. | Lindegaard & Morsing, 2011 |
| Technical characteristics in dependence of the formulation type | – | – | The biocidal product has none of the properties | – |

| | Method | GLP (Y/N) | Results | Reference |
|---|---|---|---|---|
| | | | mentioned in the TNsG on Data Requirements. Therefore no tests are necessary. | |
| Compability with other products | – | – | Excellent compatibility with recommended topcoats.<br><br>SX 1420 is used in a coating system and always coated with two layers of high build top coat. | Becker Acroma |
| Surface tension | Calculation | N | Not relevant. Waterborne emulsion with surface tensions between 35-60 mN/m. Contains no aliphatic, aromatic or alicyclic hydrocarbons. | Becker Acroma |
| Viscosity | DIN #4 cup at 23°C | N | 12+2 sec. Kinematic viscosity is approximately 5 Pa s at 20°C. | Becker Acroma<br><br>No official report for the product. The viscosity is measured routinely as part of quality control process. |
| Particle size distribution | – | – | Not applicable because the biocidal product is liquid. | – |

## 2.3.2 Storage stability

The preliminary results from the shelf-life study for the product are listed in Table 2.3-2.
The shelf-life study was conducted at ambient temperature. The active substance content has been analysed by a LC-MS method.
There has been observed no modification of appearance of the biocidal product during the storage period.

**Table 2.3-2: Results from the shelf-life study.**

| Product | Active substance | Variation | |
|---|---|---|---|
| | | Initial | 13 mth |
| Laqvin Ton SX 1420 | IPBC | 0.58 %<br>- | 0.56 %<br>3.4 % |
| | Propiconazole | 0.365 %<br>- | 0.384 %<br>5.5 % |

| | | | |
|---|---|---|---|
| | pH | 8.42 (undiluted) | 8.37 (undiluted) |

References: Lindegaard & Morsing, 2011

### 2.3.3 Analytical methods

Chemical analysis of biocides in product is conducted as follows:
A subsample is weighted and diluted in milli-Q water. 3 mL of the diluted sample was added 2 mL methanol with an internal standard (azaconazole) and thereafter analysed by LC-MS (Liquid Chromatography Mass Spectrometry).
Limit of quantification of propiconazole: 0.002 µg/mL, IPBC: 0.005 µg/mL and PBC: 0.002 µg/mL

#### 2.3.3.1 Formulation analysis

Not available.

## 2.4 Risk assessment for Physico-chemical properties

The submitted physico-chemical data for the product has been evaluated according to 1999/45/EEC and directive 67/548/EEC.

The preliminary results for Laqvin Ton SX 1420 indicate that the formulation is stable with regards to the active substance contents and the visual properties of the product at room temperature.
Furthermore, the other physico-chemical properties are considered acceptable.

Concerning long-term storage stability (shelf life), Denmark has up until now allowed a 15% deviation from the specified content for homogenous products containing less than 2.5% a.i., in line with the FAO recommendations. Due to EU harmonisation, the GIFAP monograph no. 17 may be followed in the future. However, this awaits a final agreement between the Member States. It should be mentioned that an EU harmonisation of long-term stability has been discussed very late in the process without a final decision. Therefore, we accept a 15% deviation in our evaluations of wood preservatives in progress.
It should also be noted that the results from the accelerated studies are overruled by the results from the long-term storage stability studies, if such studies are available.

The results for Laqvin Ton SX 1420 from the accelerated study shows that the degradation of IPBC and propiconazole after 2 weeks at 35ºC is 6.0 % and 8.2 %, respectively, which is above the allowed 5 % (according to OECD 113: Screening test for thermal stability and stability in air).

According to the 13 months results from the shelf-life study, IPBC and propiconazole has degraded by 3.4 % and 5.5 %, respectively.

**Conclusion:**
On the basis of the preliminary results from the long-term stability study, it can be concluded that the product is stable with regards to its contents of IPBC as well as the other physico-chemical properties during the investigated period. A claim for 6 months shelf-life can therefore be accepted on the basis of the available stability data and the level of variation.
The overall conclusion of the risk-assessment for physico-chemical properties is that no unacceptable risk is identified after 13 months.

# 2.5 Effectiveness against target organisms

The efficacy assessment can be found in Bilag 4 to the letter of authorisation (Godkendelsesbrevet).

The recommended minimum and maximum retention is advised to be:
Minimum: 70 g product/$m^2$
Maximum: 80 g product/$m^2$

A mould resistant top coat has to be applied on wood treated with the product.

Can be used for Use Class 2 and 3.

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

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).
Propiconazole belongs to the triazole fungicides. As other triazole fungicides propiconazole inhibits the C14 demethylation step in the ergosterol biosynthesis of fungi.

Due to the unspecific mode of action a development of resistance is neither to be expected nor has been ever observed.

# 2.6 Exposure assessment

## 2.6.1 Description of the intended use(s)

Laqvin Ton SX 1420 contains 0.60% (w/w) IPBC and 0.40% (w/w) propiconazole. It is used as wood preservative (BPD Product Type 8) for Use Class 2 and 3. The modes of application include industrial dipping, flow-coating and automated spraying (usually by robots in closed systems). Manual spray application in spraying cabins can occur.
The product is applied at a rate of 70 – 80 g/$m^2$, which results in a maximum total applied amount of 480 mg IPBC/$m^2$ timber (80 g (Laqvin Prime) x 0.60 %) and 320 mg propiconazole/$m^2$ timber (80 g (Laqvin Prime) x 0.40 %).

After application of Aqua Primer 2907-02 a top coat must be applied. The environmental assessment covers the use of a topcoat which applies up to 0.59 g IPBC/$m^2$ to the wood.

## 2.6.2 Assessment of exposure to humans and the environment

A semi field leaching study has been submitted. An evaluation of this and flux rates used for the environmental risk assessment is presented in annex 4. A description of the principles of calculation of leaching rates from a leaching experiment is presented in annex 5.

# 2.7 Risk assessment for human health

## 2.7.1 Hazard potential

### 2.7.1.1 Toxicology of the active substances

The toxicology of the active substances was examined extensively according to standard requirements. The results of these toxicological assessments can be found in the corresponding CARs. The threshold limits and labelling regarding human health risks listed in Annex 2 „Toxicology and metabolism" must be taken into consideration.

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

The biocidal product does not contain substances of concern in the definition of Directive 1998/8/EC.

### 2.7.1.3 Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The product was not a dummy product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC.

**Percutaneous absorption**
Dermal absorption studies with the biocidal product have not been conducted.
For IPBC, an *in vitro* study on human skin is available which examines the penetration rates of IPBC for different solvent-based formulations having the following IPBC concentrations: 0.6, 2.3, and 17.1% IPBC (reviewed in the CAR). The resulting dermal penetration rates including skin residues were 30, 10, and 1.6% of the applied radioactivity, respectively. The formulation containing 0.6% IPBC is a representative worst-case for the water-based ready-to-use product Laqvin Ton SX1420 containing 0.6% IPBC. Therefore, the IPBC dermal absorption value of **30%** has been used in the human exposure assessment of Laqvin Ton SX1420.

For propiconazol (reviewed in the CAR and stated in LOEP) dermal absorption values are 1% for a undiluted water based product (10 % a.s., Wocosen 100 SL), and 2% for the dilution (1% a.s.) and the solvent-based product (app. 1.4% a.s., Wocosen 12 OL)[3]. Thus a dermal penetration value of 2% is reasonably assumed for concentrations of water -based products even at lower concentrations of propiconazole than in the representative water-based (1% propiconazol) and solvent-based (approx. 1.4% propiconazol) products submitted for the Annex I inclusion. Therefore, the propiconazol dermal absorption value of **2%** has been used in the human exposure assessment of Laqvin Ton SX1420 containing 0.4% propiconazol.

**Acute toxicity**

No studies have been performed for the end-use product. However, in compliance with the provisions of Council Directive 1999/45/EEC on the classification, packaging and labelling of dangerous preparations, the acute toxicological profile of the end-use product can be deduced from

[3] For Propiconazole, data (reviewed in the CAR) based on tested concentrations of 0.06% and 0.006% (solvent based product) gave dermal penetration values of 2.4% and 1.6%, respectively.

available data of its main ingredients. According to this the product should not be classified for acute toxicity. Even though the data support classification of IPBC for acute toxicity by the inhalation route (T, R23), this water-based product contains less than 3 % w/w IPBC and no other co-formulants are classified for these endpoints. Therefore the product will not attract this classification and this endpoint does not need to be considered further in the risk characterisation.

**Irritation and corrosivity**

No studies have been performed for the end-use product. However, in compliance with the provisions of Council Directive 1999/45/EEC on the classification, packaging and labelling of dangerous preparations, the acute toxicological profile of the end-use product can be deduced from available data of its main ingredients. According to this the product should not be classified for irritation or corrosivity.

**Sensitisation**

No studies have been performed for the end-use product. However, in compliance with the provisions of Council Directive 1999/45/EEC on the classification, packaging and labelling of dangerous preparations, the acute toxicological profile of the end-use product can be deduced from available data of its main ingredients. Propiconazole is classified as a skin sensitizer. IPBC is considered to be a skin sensitizer and proposal for classification has been submitted to ECHA. IPBC is present in the product at the concentration of 0.6% and Propiconazole in the concentration of 0.4%. The product will therefore not be classified as a skin sensitizer. However the following sentence shall be stated on the label: Contains IPBC and propiconazole: May produce an allergic reaction.

## 2.7.2 Exposure

The biocidal product contains the active substances IPBC (0.6%) and propiconazole (0.4%) (Min. purity 980 g/kg and 930 g/kg pure respectively).

### Identification of main paths of human exposure towards active substance from its use in biocidal product

**Table 2.7-1 Main paths of human exposure**

| Exposure path | Industrial use | General public | Secondary exposure |
|---|---|---|---|
| Inhalation | Yes | Yes | Yes |
| Dermal | Yes | Yes | Yes |
| Oral | No | No | Yes |

Laqvin Ton SX1420 is a ready-to-use water-based product and can be applied by industrial users as follow: dipping, flow-coating and automated spraying.

Laqvin Ton SX1420 can also be applied as a ready-to-use product by industrial workers by manual spraying in spraying cabins (this will be dealt with separately in another section).

The exposure to IPBC and Propiconazole in the product Laqvin Ton SX1420 was calculated based on the selected models and default values from the User Guidance, i.e. the TNsG on Human

Exposure 2007 (including the computing database BEAT, the software model ConsExpo and the EXCEL Data Base on Human Exposure). When not available or not relevant in these documents, the information was taken from other sources as the HEEG opinions or the TNsG on Human Exposure 2002.

#### 2.7.2.1 Exposure of industrial users during dipping, flow-coating and automated spraying

**Identification and description of exposure related tasks**

The industrial uses of Laqvin Ton SX1420 are the industrial automated dipping, automated spraying and manual spraying (se specific text below) and flow-coating processes.

The activities are described for each category of user as follows:

- Mixing and loading (transfer of liquids)
- Application
- Post-application: Handling of treated articles
- Maintenance/cleaning of the system and cleaning of the hand-held tools
-

Mixing and loading

Laqvin Ton SX1420 is delivered as ready-to use product for industrial automated processes. Usually Laqvin Ton SX1420 is sold for industrial use in containers ≥ 20 L. It is expected that the mixing/loading process is a fully automated procedure (pumping process) in a closed system. Therefore, it can be considered that this process is not associated with significant exposure.

*For manual spraying*: Laqvin Ton SX1420 is supplied as a ready-to-use formulation. Therefore, there is no mixing and loading process for the spraying application. Regarding the spraying application, the loading phase has been covered by the exposure estimations during the application phase.

Application

During automated process, the operator's exposure is negligible, as it is an automated process and the operator's position is away from the treating area of the wood.

*For manual spraying*: Industrial spraying may lead to exposure via skin and/or via inhalation.
.

Post-application: Handling of treated articles

After the automated process and manual spraying, during the "handling" phase, the operator might be exposed via skin and/or via inhalation by contact with the treated timber, by handling equipment, and/or contaminated clothing.

Maintenance/cleaning of the system

Potential exposure may occur during maintenance, testing/repair of the automated system (hoses, valves, connecting lines, etc.). However, such tasks are expected to be rare and of short duration.

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.

*For manual spraying*: This process is expected to be of short duration and exposure is expected to be mainly dermal. The exposure during cleaning is not covered by any of the proposed TNsG models. For spraying cleaning is considered to be negligible. The use of PPE is recommended during these tasks.

**Industrial exposure – automated dipping / automated spraying / flow-coating**

Automated dipping, automated spraying and flow-coating are industrial and automated processes. It means that during application phase, the operator's exposure is negligible, as it is an automated process and the operator's position is away from the treating area of the wood.

After the automated process, during the "handling" phase, the operator might be exposed via skin and/or via inhalation by contact with the treated timber (water-wet or solvent damp wood), by handling equipment and/or contaminated clothing. Indeed, the "handling" phase entails 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 timber and through contact with ancillary equipment and contaminated process plant. Dermal exposure may also arise from the spread of contamination into areas such as control rooms and from secondary sources such as previously contaminated overalls and gloves.

The duration default value of exposure for automated dipping is stated with 4 cycles of 60 minutes pr. day in the HEEG opinion "Defaults and appropriate models to assess human exposure for dipping processes (PT8)", 2009. This duration has also been considered as a reasonable value for the other industrial processes as the double vacuum, the automated spraying and the flow-coating treatments.

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.

For the dermal absorption 30% and 2% were used for IPBC and propiconazole respectively.

The most suitable model has been chosen from the computing database BEAT (for water-based products):

- BEAT: "timber pre-treatment, water-based products" (defaults taken from BEAT, exposure statistics for measured exposure scenarios); the model describes treatment of timber in sealed vessels; dermal exposure is possible through contact with treated wood when it is removed from the vessel.

See below for other relevant default values.

**Table 2.7-2: Relevant default values**

| Exposure values and exposure durations | Physiological/physical parameters |
|---|---|
| Exposure duration: 60 minutes/cycle, 4 cycles/day (HEEG opinion, Dipping cycles PT8, 2009)<br>Indicative exposure values:<br>Dermal exp. hands (inside gloves): 8.7 mg/min ($75^{th}$ perc.) (50 rec.)<br>Dermal exposure body: 108 mg/min ($75^{th}$ perc.) (45 rec.)<br>Inhaled: 1.8 mg/$m^3$ ($75^{th}$ perc.) (49 rec.)<br>(BEAT)<br><br>Note:<br>BEAT recommends using the $75^{th}$ percentile for the "Timber pre-treatment (water)" scenario | Adult :<br>BW : 60 Kg<br>Inhalation rate : 1.25 $m^3$/h (0.021 $m^3$/ min) (TNsG HE, 2007, pge 61)<br>Coated coveralls: 10% (HEEG, 2010)<br>Gloves are considered in the scenario<br>No RPE |

**Results**

Results are summarised below (for calculations see Annex 3.1 and 3.2)

**Table 2.7-3 Estimated exposures for automated dipping / automated spraying / flow-coating**

| **IPBC** | | | | | |
|---|---|---|---|---|---|
| **Intended use (PT)** | **Exposure scenario** | **PPE** | **Inhalational uptake** | **Dermal uptake** | **Total systemic exposure** |
| | | | Exposure concentration (mg) | Exposure concentration (mg) | mg/kg bw/day |
| PT 8- Wood preservatives | "Timber pre-treatment (Water)" (BEAT) | Coated coveralls<br>Gloves | 0.054 | 8.42 | **0.14** |
| **Propiconazole** | | | | | |
| **Intended use (PT)** | **Exposure scenario** | **PPE** | **Inhalational uptake** | **Dermal uptake** | **Total systemic exposure** |
| | | | Exposure concentration (mg) | Exposure concentration (mg) | mg/kg bw/day |
| PT 8- Wood preservatives | "Timber pre-treatment (water)" (BEAT) | Coated coveralls<br>Gloves | 0.036 | 0.37 | **0.007** |

### 2.7.2.2 Industrial exposure-manual spraying in spray cabins

The b.p. is loaded manually into the spray tank. The application process itself is conducted using a hand-held spray gun. The b.p. is applied at medium pressure (4-7 bar) using an electrical or fuel-driven pump-pressurised sprayer supplied from a reservoir. Loading and application are done as a single scenario.

Exposure calculations are performed according to TNsG 2008 (BEAT). A pre-worked example for timber pre-treatment by medium-pressure spraying with water-based products is available from the BEAT database and is based on published data [Garrod *et al.*, (1998). Occupational exposure through spraying remedial pesticides. *Annals of Occupational Hygiene* **42** 159-165].

Laqvin Ton SX 1240 is rather viscous (5000 mPa s). This property of the b.p. reduces exposure via inhalation and skin contact. Fitted lognormal geometric means were used instead of 75$^{th}$ percentile to reflect the viscosity of the product.
The exposure time proposed by the TNsG Excel database for human exposure gives a default value of 180 min for the daily spray duration.

For the dermal absorption 30% and 2 were used for IPBC and Propiconazole respectively.

**Applied parameters for loading / application:**

| | |
|---|---|
| **Hands** | **8.71 mg/min (actual, geomean, n=67)** |
| **Glove penetration** | **not considered for actual hand exposure values** |
| **Body** | **65 mg/min** (potential, geomean, n=67) |
| **Clothing penetration** | **10%** |
| **Inhalation** | **21.3 mg/m³** (potential, geomean, n=55) |
| **Inhalation rate** | **1.25 m³/h** (default) |
| **Duration** | **180 min** (TNsG, Excel database) |
| **Body weight** | **60 kg** (default) |

**Table 2.7-4: Estimated exposures for manual spraying** (for calculations see Annex 3.3 and 3.4).

| **IPBC** | | | | | |
|---|---|---|---|---|---|
| **Intended use (PT)** | **Exposure scenario** | **PPE** | **Inhalational uptake** | **Dermal uptake** | **Total systemic exposure** |
| | | | Exposure concentration (mg) | Exposure concentration (mg) | mg/kg bw/day |
| PT 8-Wood preservatives | "*Occupational exposure through spraying remedial pesticides* (BEAT) | Dry cotton coveralls<br>Gloves | 0.5 | 4.9 | **0.09** |
| **Propiconazole** | | | | | |
| **Intended use (PT)** | **Exposure scenario** | **PPE** | **Inhalational uptake** | **Dermal uptake** | **Total systemic exposure** |
| | | | Exposure concentration (mg) | Exposure concentration (mg) | mg/kg bw/day |
| PT 8-Wood preservatives | "*Occupational exposure through spraying remedial pesticides* (BEAT) | Dry cotton coveralls<br>Gloves | 0.32 | 0.22 | **0.009** |

***Recommended PPE:***

Suitable protective gloves, footwear and cotton coverall

#### *2.7.2.2.1 Handling of wet treated wood*

Treated wood will typically not be touched until it is dry because otherwise the coating will show fingerprints and other undesired marks. The treated surface is touch-dry after 60 min at 20°C. Thus, only accidental dermal contact with dry wood can make a contribution to human exposure. These incidents are so rare that they will be negligible compared to the dermal exposure experienced during the application phase. No designated exposure assessment of these events is deemed necessary.

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

In the following, relevant secondary exposure scenarios for the application of LAQVIN TON SX1420 within PT8 are described considering worst case assumptions, *i.e.* highest use rates or in-use concentrations. The scenarios were chosen based on the list of likely secondary exposure scenarios as provided in the TNsG, 2002 (part 3), TNsG, 2007, and as described in RIVM report 320005001/2004 (Non-food products: How to assess children's exposure?).

**Acute phase secondary exposure**

**Adult: Inhalation of wood dust during sanding treated wood (acute)**

Exposure of adults towards Laqvin Ton SX1420 dust during sanding of treated wood was estimated using the example calculation provided in the TNsG, 2002, part 3 (worked examples, page 50).

As preserved wood is not placed on the market until the product is dry, dermal exposure during handling of wood treated with Laqvin Ton SX1420 is assumed to be negligible.

An adult sands industrial treated wood with a sander for one hour. The sander generates 5 mg/$m^3$ wood dust during this one hour work with a density of 0.4 g/$cm^3$ (TM III 2008, MOTA) The resulting wood dust is inhaled with a inhalation rate of 1.25 $m^3$/hour.
The amount of wood dust inhaled is, therefore:

5 mg dust/$m^3$ air x 1.25 $m^3$/hour x 1 hour/0.4 g/$cm^3$ = 0.0156 $cm^3$.

When exposure is estimated for a piece of wood treated by spraying, dipping or flow-coating, and assuming the highest use rate (80 g product/$m^2$) of 0.6 g IPBC/ $m^2$ of wood and 0.32 g Propiconazole/ $m^2$ of wood, the following result is obtained:

**Assumptions:**

- IPBC: 0.48 g/ $m^2$ of wood
- Propiconazole: 0.32 g/ $m^2$ of wood
- Piece of wood with the following dimensions to be sanded:
  2.5 m x 0.04 m x 0.04 m (area: 0.4032 $m^2$, volume: 0.004 $m^3$)
- IPBC and Propiconazole are concentrated in the outer 1 cm of the wood (volume of outer layer: 3008 $cm^3$)

**Results:**

- Amount in outer layer:
  IPBC: 0.48 g/ $m^2$ of wood x 0.4032 $m^2$ = 0.193 g IPBC
  Propiconazole: 0.32 g/ $m^2$ of wood x 0.4032 $m^2$ = 0.129 Propiconazole
- Concentration in wood dust:
  IPBC: 0.193 g/ 3008 $cm^3$ = 0.064 mg IPBC/$cm^3$
  Propiconazole: 0.129 g/ 3008 $cm^3$ = 0.04 mg Propiconazol/$cm^3$
- Amount inhaled:

IPBC: 0.0156 x 0.064 mg IPBC/$cm^3$ = 0.001 mg IPBC
Propiconazole: 0.0156 x 0.04 mg Propiconazol/$cm^3$ = 0.00067 mg Propiconazole

- Systemic dose:
  IPBC: 0.001 mg IPBC/60 kg bw = **0.0000168 mg IPBC/kg bw**
  Propiconazole: 0.00067 mg Propiconazol/60 kg bw = **0.000012 mg Propiconazole/kg bw**

The exposure of an adult during sanding of wood is estimated to respectively 1.68 $x10^{-5}$ mg IPBC/kg bw and 1.12 $x10^{-5}$ mg Propiconazol/kg bw.

**Infant: Chewing piece of wood**

Exposure of infants towards Laqvin Ton SX1420 resulting from chewing of treated wood was estimated using the example calculation provided in the TNsG, 2002, part 3 (worked examples, page 50).

It is assumed that an infant plays nearby persons who are handling and sawing Laqvin Ton SX1420 pre-treated wood. The infant chews on one of the pieces of wood, thereby extracting 10% of the IPBC and Propiconazol contained in the cut-off.

When exposure is estimated for a piece of wood treated by spraying, dipping or flow-coating, and assuming the highest use rate of 0.48 g IPBC/ $m^2$ of wood and 0.32 g Propiconazol/ $m^2$ of wood, the following result is obtained:

**Assumptions:**

- Infant (10kg bw) chewing piece of wood of the following dimensions:
  1 cm × 4 cm × 4 cm (area: $4.8x10^{-3}$ $m^2$, volume: $1.6×10^{-5}$ $m^3$)
- IPBC: 0.48 g/ $m^2$ of wood
- Propiconazole: 0.32 g/ $m^2$ of wood

**Results:**

- Amount in treated wood:
  IPBC: 0.48 g IPBC/ $m^2$ of wood x $4.8x10^{-3}$ $m^2$ = 2.30 mg IPBC
  Propiconazole: 0.32 g Propiconazole/ $m^2$ of wood x $4.8x10^{-3}$ $m^2$ = 1.53 mg Propiconazole
- Amount extracted by chewing:
  IPBC: 2.30 mg IPBC x 10% = 0.23 mg IPBC
  Propiconazole: 1.53 mg Propiconazole x 10% = 0.153 mg Propiconazole
- Systemic dose:
  IPBC: 0.23 mg IPBC/10 kg = **0.023 mg IPBC/kg bw**
  Propiconazole: 0.153 mg Propiconazol /10 kg = **0.015 mg Propiconazole/kg bw**

The exposure of an infant towards Laqvin Ton SX1420 after chewing of wood treated at 0.48 g IPBC/$m^2$ and 0.32 g Propiconazol/ $m^2$ is estimated at 0.023 mg IPBC/kg bw and 0.015 mg Propiconazol/kg bw.

**Child and infant: Touching freshly treated surface**

It is assumed that children and infants play nearby persons who are treating wood using Laqvin Ton SX1420. Contact with treated surfaces is assumed to be of short duration, as parents will remove the product from hands as soon as the "accident" is observed.

**Assumptions:**

- Hand area: 200 $cm^2$ (20% of hand area contaminated with Laqvin Ton SX1420) (TNsG 2002, part 3, p 50)
- Bodyweight child: 15 kg; infant: 10 kg
- Dislodgeable residue / transfer coefficient: 20% (As Laqvin Ton SX1420 is a product intended to penetrate the wood, it cannot be expected more than 20% of product transferred to the hands, even in the worst case of a freshly painted piece of wood)
- IPBC: 0.48 g/ $m^2$ of wood
- Propiconazole: 0.32 g / $m^2$ of wood
- Dermal penetration rate : 30% for IPBC and 2% for Propiconazole

**Results**

- Amount on hands:
  IPBC: 0.48 g IPBC/ $m^2$ x 0.02 $m^2$ x 20% x 20% = 0.38 mg IPBC
  Propiconazol: 0.32 g Propiconazole/ $m^2$ x 0.02 $m^2$ x 20% x 20% = 0.25 mg Propiconazole
- Systemic dose:
  IPBC:
  Child: 0.38 mg on hands x 30%/15 kg bw = **0.007 mg IPBC/kg bw**
  Infant: 0.38 mg on hands x 30%/10 kg bw = **0.011 mg IPBC/kg bw**
  Propiconazole:
  Child: 0.25 mg on hands x 2%/15 kg bw = 3**.4 x $10^{-4}$ mg Propiconazole/kg bw**
  Infant: 0.25 mg on hands x 2%/10 kg bw = 5**.1 x $10^{-4}$ mg Propiconazole/kg bw**

Touching of freshly treated timber structures results in systemic exposure of **0.007** mg IPBC/ kg bw/day and **3.4 x $10^{-4}$** mg Propiconazole/kg bw/day for children and **0.011** mg IPBC/ kg bw/day and **5.1 x $10^{-4}$** mg Propiconazole/kg bw/day for infants, respectively. It has to be noted that this scenario describes a worst case, as it is not very likely that children and infants are playing nearby Laqvin Ton SX1420 treated materials.

**Chronic phase secondary exposure**

**Adult: Inhalation of wood dust during sanding treated wood (chronic)**

Exposure of adults towards Laqvin Ton SX1420 (IPBC and Propiconazole) dust during sanding of treated wood was estimated using the example calculation provided in the TNsG, 2002, part 3 (worked examples, page 50).

As preserved wood is not placed on the market until the product is dry, dermal exposure during handling of wood treated with Laqvin Ton SX1420 is assumed to be negligible.

An adult sands industrial treated wood with a sander for six hours. The sander generates 5 mg/$m^3$ wood dust during one hour work with a density of 0.32 g /$cm^3$. The resulting wood dust (containing IPBC and Propiconazole) is inhaled (inhalation rate: 1.25 $m^3$/hour).
The amount of wood dust inhaled is, therefore:

5 mg dust/$m^3$ air x 1.25 $m^3$/hour x 6 hours/0.32 g /$cm^3$ = 0.094 $cm^3$.

When exposure is estimated for a piece of wood treated by spraying, dipping or flow-coating, and assuming the highest use rate of 0.48 g IPBC/ $m^2$ of wood and 0.32 g Propiconazole/ $m^2$ of wood, the following result is obtained:

**Assumptions:**

- IPBC: 0.48 g/ $m^2$ of wood
- Propiconazole: 0.32 g / $m^2$ of wood
- Piece of wood with the following dimensions to be sanded:
  2.5 m x 0.04 m x 0.04 m (area: 0.4032 $m^2$, volume: 0.004 $m^3$)
- IPBC and Propiconazole are concentrated in the outer 1 cm of the wood (volume of outer layer: 3008 $cm^3$)

**Results:**

- Amount in outer layer:
  IPBC: 0.48 g/ $m^2$ of wood x 0.4032 $m^2$ = 0.193 g IPBC
  Propiconazole: 0.32 g/ $m^2$ of wood x 0.4032 $m^2$ = 0.129 Propiconazole

- Concentration in wood dust:
  IPBC: 0.193 g/ 3008 $cm^3$ = 0.064 mg IPBC/$cm^3$
  Propiconazole: 0.129 g/ 3008 $cm^3$ = 0.04 mg Propiconazol/$cm^3$

- Amount inhaled:
  IPBC: 0.094 $cm^3$ x 0.064 mg IPBC/$cm^3$ = 0.006 mg IPBC
  Propiconazole: 0.094 $cm^3$ x 0.04 mg Propiconazole/$cm^3$ = 0.004 mg Propiconazole

- Systemic dose:
  IPBC: 0.006 mg IPBC/60 kg bw = **1.01 x$10^{-4}$ mg IPBC/kg bw/day**
  Propiconazole: 0.004 mg Propiconazole/60 kg bw = **6.7 x$10^{-5}$mg Propiconazole/kg bw/day.**

The exposure of an adult during sanding of wood treated at 0.48 g IPBC/$m^2$ and 0.32 g Propiconazole/ $m^2$ is estimated at respectively **1.01 x $10^{-4}$ mg** IPBC/kg bw/day and **6.7 x$10^{-5}$ mg** Propiconazole/kg bw/day.

**Child and infant: Playing on timber structures (playground)**

**Assumptions:**

- Hand area: 200 $cm^2$ (20% of hand area contaminated with IPBC) (TNsG 2002, part 3, p 50)
- Bodyweight child: 15 kg; infant: 10 kg
- Dislodgeable residue / transfer coefficient: 3% (according to TNsG, 2007, page 102, value for dried fluids in/on painted wood)
- IPBC: 0.48 g/ $m^2$ of wood
- Propiconazol: 0.32 g / $m^2$ of wood
- Dermal penetration rate : 30% for IPBC and 2% for Propiconazol

**Results**

- Amount on hands:
  IPBC: 0.48 g IPBC/ $m^2$ x 0.02 $m^2$ x 20% x 3% = 0.057 mg IPBC
  Propiconazole: 0.32 g Propiconazole/ $m^2$ x 0.02 $m^2$ x 20% x 3% = 0.038 mg Propiconazole
- Systemic dose:
  IPBC:
  Child: 0.057 mg on hands x 30%/15 kg bw = **0.00115 mg IPBC/kg bw/day**
  Infant: 0.057 mg on hands x 30%/10 kg bw = **0.00173 mg IPBC/kg bw/day**
  Propiconazol:
  Child: 0.038 mg on hands x 2%/15 kg bw = 5**.0 x $10^{-5}$ mg Propiconazole/kg bw/day**
  Infant: 0.038 mg on hands x 2%/10 kg bw = **8.0 x $^{-5}$ mg Propiconazole/kg bw/day**

Playing on and touching of timber structures (playground) results in systemic exposure of **0.000115** mg IPBC/ kg bw/day and 5 **x $10^{-5}$** mg Propiconazole/kg bw/day for children and **0.00173** mg IPBC/ kg bw/day and **8.0 x $10^{-5}$** mg Propiconazole/kg bw/day for infants, respectively.

**Adult, child and infant: Inhalation of volatised residues, indoors**

Chronic exposure to wood preservatives may arise from indoor remedial treatment. 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. IPBC and Propiconazol further have a lower vapour pressure. Nevertheless, exposure by volatilised residues indoors was calculated.

The exposure of adults, children and infants to volatilised residues indoors was calculated under the provisions of the example calculation in the TNsG on Human exposure, 2002, part 3, (worked examples, page 50).
As a worst case, inhalation exposure was taken as 1% of the saturated vapour pressure/concentration (SVC; TNsG User guidance, 2002, page 52/53).

**Assumptions:**

- Adult: 60 kg bw, residential time 18 hours, inhaling 1.25 $m^3$ air/h (TNsG on HE, 2007, p 61)
- Child: 15 kg bw, residential time 18 hours, inhaling 0.35 $m^3$ air/h (TGD, page 274)
- Infant: 10 kg bw, residential time 18 hours, inhaling 0.24 $m^3$ air/h (TGD, page 274)
- Vapour pressure IPBC : 2.36x$10^{-3}$ Pa (at 20°C)
- Vapour pressure Propiconazole: 5.6 x $10^{-5}$ Pa (at 25°C)
- Molecular weight of IPBC : 281 g/mol
- Molecular weight of Propiconazole : 342.2 g/mol
- 1 atmosphere (or 1 bar) is equivalent to 101325 Pa
- Molar volume of gas at room temperature: 24.1L

**Results:**

- Airborne concentration:
  IPBC : 2.36x$10^{-3}$ Pa x 1%/101324 x $10^6$ = 2.33 x $10^{-4}$ ppm (mL/$m^3$)
  Propiconazole : 5.6 x $10^{-5}$ Pa x 1%/101324 x $10^6$ = 5.53 x $10^{-6}$ ppm (mL/$m^3$)
- SVC:

IPBC: 2.33 x $10^{-4}$ ppm x 281 g/mol/24.1L = 2.72 x $10^{-3}$ mg/$m^3$

Propiconazole: 5.53 x $10^{-6}$ ppm x 342.2 g/mol/24.1L = 7.85 x $10^{-5}$ mg/$m^3$

- Systemic dose:

IPBC

Adult: 2.72 x $10^{-3}$ mg/$m^3$ x 1.25 $m^3$/h x 18 h/60 kg bw = 1.02 x $10^{-3}$ mg/kg bw/day
Child: 2.72 x $10^{-3}$ mg/$m^3$ x 0.35 $m^3$/h x 18 h/15 kg bw = 1.14 x $10^{-3}$ mg/kg bw/day
Infant: 2.72 x $10^{-3}$ mg/$m^3$ x 0.24 $m^3$/h x 18 h/10 kg bw = 1.18 x $10^{-3}$ mg/kg bw/day

Propiconazole

Adult: 7.85 x $10^{-5}$ mg/$m^3$ x 1.25 $m^3$/h x 18 h/60 kg bw = 2.94 x $10^{-5}$ mg/kg bw/day
Child: 7.85 x $10^{-5}$ mg/$m^3$ x 0.35 $m^3$/h x 18 h/15 kg bw = 3.30 x $10^{-5}$ mg/kg bw/day
Infant: 7.85 x $10^{-5}$ mg/$m^3$ x 0.24 $m^3$/h x 18 h/10 kg bw = 3.39 x $10^{-5}$ mg/kg bw/day

The exposure estimation revealed that chronic exposure to IPBC and Propiconazole during residence time is negligible.

#### 2.7.2.4 Combined exposure

It is unlikely that an industrial worker who have spent a working day using Laqvin Ton SX1420 would also be using the same wood preservative product containing the active substances IPBC and Propiconazole at home the same day. Therefore, it is not deemed necessary to consider this type of combined exposure.

#### 2.7.2.5 Exposure to residues in food

Not relevant.

### 2.7.3 Risk Characterisation

Laqvin Ton SX1420 is a ready-to-use water-based product containing 0.6% IPBC and 0.4% Propiconazole.

Laqvin Ton SX1420 can be applied by industrial users as follow: dipping, flow-coating and automated spraying.

Laqvin Ton SX1420 can also be applied as a ready-to-use product by industrial workers by manual spraying in spray cabins.

There are two different population groups that may be exposed to Laqvin Ton SX1420: industrial users and the general public *via* indirect exposure as a result of use. The risk characterisation will therefore focus on these two populations.

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

- Industrials applying by automated processes as dipping, spraying and flow-coating treatments.
- Industrials applying manual spraying in spray cabins
- General public secondarily exposed to Laqvin Ton SX1420.

The critical end-points used in the human health risk assessments are presented in Annex 2.

### 2.7.3.1 Risk for Industrial Users

**Relevant exposure paths**
The relevant exposure routes when using Laqvin Ton SX1420 during industrial processes are the dermal and inhalation routes. The resulting systemic body doses were estimated based on the predicted exposure concentrations and are presented in 2.7.2.1. Exposure has been estimated with the selected models and default values from the User Guidance, i.e. the TNsG on Human Exposure 2007 and using, when necessary, additionally other sources as for instance the HEEG opinions.

**Risk characterisation for product type 8**
Acute risks were not considered for industrial users. The risk assessment was restricted to the more relevant chronic exposure. Industrial users are expected to use Laqvin Ton SX1420 on a daily basis all over the year.

The comparison of the exposure and the resulting potential health risk is represented by the AEL approach as well as by the margin of exposure (MOE) approach.

Industrial workers are expected to be in a risk controlled area and follow a minimum of instructions. It is assumed that industrial users wear coated coveralls and gloves on a daily basis. Therefore, exposure was only estimated with protective coated coveralls for professional use and gloves.

The exposure assessment for industrial users under post-application activities and the comparison of the estimated exposure values to the AELs of 0.2 mg/kg bw/day and 0.08 mg/kg bw/day, respectively for IPBC and Propiconazole, as well as the calculation of MOE is presented below.

**Table 2.7-5: Summary of % AEL and MOE values calculated for industrial users (dipping, spraying and flow-coating)**

| Operation | Total systemic exposure mg/kg bw/day | AEL $_{\text{long-term}}$ mg/kg bw/day | MOE | % AEL |
|---|---|---|---|---|
| **IPBC** | | | | |
| Post-application | 0.14 | 0.2 | 141 | 71 |
| **Propiconazole** | | | | |
| Post-application | 0.006 | 0.08 | 1169 | 8.6 |

In addition the exposure assessment for industrial workers applying the product by manual spraying and the comparison of the estimated exposure values to the AELs of 0.2 mg/kg bw/day and 0.08 mg/kg bw/day, respectively for IPBC and Propiconazole, as well as the calculation of MOE is presented in the table below.

**Table 2.7-6: Summary of % AEL and MOE values calculated for industrial users (manual spraying)**

| Operation | Total systemic exposure mg/kg bw/day | AEL $_{\text{long-term}}$ mg/kg bw/day | MOE | % AEL |
|---|---|---|---|---|
| **IPBC** | | | | |

| | | | | |
|---|---|---|---|---|
| Application | 0.09 | 0.2 | 222 | 45 |
| **Propiconazole** | | | | |
| Application | 0.009 | 0.08 | 891 | 0.11 |

Under normal use, Laqvin Ton SX1420 does not pose an unacceptable health risk for industrial users when using this product for industrial treatments.

#### 2.7.3.2 Risk from indirect exposure of the general public (secondary exposure)

**Relevant exposure paths**

The general public (adult, child and infant) can be secondarily exposed to Laqvin Ton SX1420 via the oral, dermal and inhalation routes.

The relevant secondary exposure scenarios for the application of Laqvin Ton SX1420 within PT8 have been described considering worst case assumptions (i.e. highest use rates or in-use concentrations).
The exposure estimation values have been calculated on the basis of these scenarios (See 2.7.2.3)

Acute secondary exposure:
- Adult : Inhalation of wood dust during sanding treated wood (acute)
- Infant : Chewing piece of wood
- Child and infant: Touching freshly treated surface

Chronic secondary exposure:
- Adult : Inhalation of wood dust during sanding treated wood (chronic)
- Child and infant: Playing on timber structures (playground)
- Adult, child and infant: Inhalation of volatilised residues, indoors

**Risk characterisation for product type 8**

The comparison of the exposure and the resulting potential health risk is represented by the AEL approach as well as by the margin of exposure (MOE) approach.

The results are presented below.

**Table 2.7-7: Summary of % AEL and MOE values calculated for secondary exposure**

| **Operation** | **Total systemic exposure (acute) mg/kg bw** | **AEL** $_{\text{Acute/Short-term}}$ **mg/kg bw/day** | **MOE** | **% AEL** |
|---|---|---|---|---|
| **Acute secondary exposure** | | | | |
| **IPBC** | | | | |
| Adult: Inhalation of wood during sanding treated wood | $1.68 \times 10^{-5}$ | 0.35 | 2.088.889 | 0.005 |
| Infant: Chewing piece of wood | 0.023 | | 1519 | 6.6 |
| Child and infant: Touching freshly treated surface *Child* | 0.007 | | 4557 | 2.2 |
| Child and infant: Touching freshly treated surface *Infant* | 0.011 | | 3038 | 3.3 |

**Table 2.7-8: Summary of % AEL and MOE values calculated for secondary exposure (*continuation*)**

| Operation | Total systemic exposure (acute) mg/kg bw | AEL $_{Acute/Short-term}$ mg/kg bw/day | MOE | % AEL |
|---|---|---|---|---|
| **Acute secondary exposure** | | | | |
| **Propiconazole** | | | | |
| Adult: Inhalation of wood during sanding treated wood | $1.12 \times 10^{-5}$ | 0.3 | 2.685.714 | 0.0037 |
| Infant: Chewing piece of wood | 0.015 | | 1953 | 5.1 |
| Child and infant: Touching freshly treated surface *Child* | $3.4 \times 10^{-4}$ | | 87.891 | 0.1 |
| Child and infant: Touching freshly treated surface *Infant* | $5.1 \times 10^{-4}$ | | 58.594 | 0.2 |

**Table 2.7-9: Summary of % AEL and MOE values calculated for secondary exposure (*continuation*)**

| Operation | Total Systemic exposure (chronic) mg/kg bw/day | AEL $_{\text{Long-term}}$ mg/kg bw/day | MOE | % AEL |
|---|---|---|---|---|
| **Chronic secondary exposure** | | | | |
| **IPBC** | | | | |
| Adult: Inhalation of wood during sanding treated wood | $1.01 \times 10^{-4}$ | 0.2 | 198.942 | 0.05 |
| Child and infant: Playing on timber structures (playground) *Child* | $1.15 \times 10^{-3}$ | | 17.361 | 0.6 |
| Child and infant: Playing on timber structures (playground) *Infant* | $1.73 \times 10^{-3}$ | | 11.574 | 0.9 |
| Adult, child and infant: Inhalation of volatised residues, indoors *Adult* | $1.02 \times 10^{-3}$ | | 19 608 | 0.51 |
| Adult, child and infant: Inhalation of volatised residues, indoors *Child* | $1.14 \times 10^{-3}$ | | 17 544 | 0.57 |
| Adult, child and infant: Inhalation of volatised residues, indoors *Infant* | $1.18 \times 10^{-3}$ | | 16 949 | 0.59 |

**Table 2.7-10: Summary of % AEL and MOE values calculated for secondary exposure (*continuation*)**

| Operation | Total systemic exposure (chronic) mg/kg bw/day | AEL Long-term mg/kg bw/day | MOE | % AEL |
|---|---|---|---|---|
| **Chronic secondary exposure** | | | | |
| **Propiconazole** | | | | |
| Adult: Inhalation of wood during sanding treated wood | $6.7 \times 10^{-5}$ | 0.08 | 119.365 | 0.08 |
| Child and infant: Playing on timber structutres (playground) *Child* | $5.0 \times 10^{-5}$ | | 156.250 | 0.1 |
| Child and infant: Playing on timber structutres (playground) *Infant* | $8.0 \times 10^{-5}$ | | 104.167 | 0.1 |
| Adult, child and infant: Inhalation of volatised residues, indoors *Adult* | $2.9 \times 10^{-5}$ | | 272 109 | 0.04 |
| Adult, child and infant: Inhalation of volatised residues, indoors *Child* | $3.3 \times 10^{-5}$ | | 242 424 | 0.04 |
| Adult, child and infant: Inhalation of volatised residues, indoors *Infant* | $3.4 \times 10^{-5}$ | | 235 988 | 0.04 |

There is no unacceptable health risk from secondary exposure.

#### 2.7.3.3 Risk from combined exposure

Not relevant.

#### 2.7.3.4 Risk for consumers via residue

Not relevant.

# 2.8 Risk assessment for the environment

## 2.8.1 Environmental classification

### 2.8.1.1 Environmental classification of the active substances

The environmental classifications of the active substances are the following (based on Regulation 1272/2008/EC):

| Substance | Env. classification | Effect concentration (mg/L) | Concentration of a.s. in the product (%) |
|---|---|---|---|
| IPBC | N; R50 | 0.053 (algae) | 0.6 |
| Propiconazole | N; R50/53 | 0.88 (algae) | 0.4 |

### 2.8.1.2 Environmental classification of the substance(s) of concern

The biocidal product does not contain any other substances which contribute to the environmental classification.

### 2.8.1.3 Environmental classification of the biocidal product

Calculations regarding the environmental classification have been performed for the product:

| | | |
|---|---|---|
| N; R50/53 | 0.4/25 = 0.016 | <1 |
| N; R50 | 0.6/2.5 + 0.4/25 = 0.26 | <1 |
| N; R51/53 | 0.4/2.5 = 0.16 | <1 |
| R52/53 | 0.4/0.25 = 1.6 | >1 |

The resulting classification for the product is the following: R52/53

## 2.8.2 Environmental exposure assessment

The environmental exposure assessment is based on the OECD series on emission scenario documents (OECD ESD) "Emission Scenario Document for Wood Preservatives (Part 1 and 2)" (OECD, 2003[4]). Where necessary the "Technical Guidance Document (TGD) for Risk Assessment" (European Commission, 2003) is also taken into consideration.

Emissions to the environment can occur during industrial application and subsequent storage as well as during the service life of the treated wood. The maximum application rate of the product is 80 g/m$^2$. Laqvin Ton SX 1420 is applied by dipping (automated), flowcoating and spraying. After application the elements like window frames, doors, etc. are dried and thereafter stored. The treated elements will not be stored outdoors since this would lead to deformation/twisting of the elements. Emissions to sewage water during applications are not likely to occur, because e.g. dipping containers are stand-alone devices without direct connection to the sewage, and because residues and spill in the process shall be collected and disposed according to local legislation. Nevertheless, the OECD application and storage scenarios for dipping and automated spraying are considered and provided for reasons of completeness.
For the envisaged fields of use for Laqvin Ton SX 1420 three main scenarios with the following sub-categories have been addressed (Table 2.8-1). The fence scenario has not been included as the timber cladded house is a worst case scenario for the terrestrial compartment.

[4] OECD (2003): Emission Scenario Document for Wood Preservatives. OECD Series on Emission Scenario Documents No. 2 (Part 1-2). OECD, Environmental Directorate, Paris.

**Table 2.8-1: Relevant exposure scenarios for use of Laqvin Ton SX 1420**

| Main exposure scenario | Subcategory |
|---|---|
| **Industrial application** | - Dipping wooden articles<br>- Automated spraying |
| **Industrial storage** | - Dipping wooden articles<br>- Automated spraying |
| **In-service leaching from treated wood** | - Bridge over pond<br>- Timber cladded house<br>- Noise barrier |

The product contains no substances of concern which will be included in the environmental risk assessment. Also there are no ecotoxicological tests with the product, the environmental risk assessment will therefore be based on the active substances within the product.

#### 2.8.2.1 Assessment of service life

During the Arona Leaching Workshop in June 2005 (ECB, 2005)[5], it was agreed that a long-term assessment of in-service uses of wood should be carried out. For superficial treatment other than brushing (e.g. dipping or spraying) a service life of 15 years is applied. Hence, the assessment times are 30 days (TIME 1) for short term consideration and 15 years for the longer time period (TIME 2).

#### 2.8.2.2 Leaching rates used for environmental risk assessment

A semi field leaching study has been submitted. It has been evaluated and leaching rates for the emission calculation have been calculated, see annex 4. Within the evaluation period only an interim report was received with a maximum precipitation of 517 mm. This evaluation is therefore based on the leaching within this period. A last point measured after precipitaion of 755 mm rain was however submitted seperately, late in the assessment period. This point is not included in the calculations but is included in the assessment to check that the leaching rates are not increasing after the period of the interim report.
A description of the principles of calculation of leaching rates from a leaching experiment is presented in annex 5.

For the risk assessment the leaching rates as shown in Table 2.8-2 are used.

**Table 2.8-2: Leaching rates for Laqvin Ton SX 1420**

| Active substance | Leaching rates (mg/m$^2$/day) | | |
|---|---|---|---|
| | Storage | TIME1 (30 days) | TIME2 (15 years) |
| **IPBC** | 1.69 | 1.69 | 0.256 |
| **Propiconazole** | 0.0724 | 0.0724 | 0.0585 |

The study was conducted with a top coat applied over the product. Because the product is intended to be used with any top coat, all the leaching rates were multiplied with an assessment factor of 10. In the study report, the leaching rates are calculated based on an area of wood including the sides of the test panels. As this is not in accordance with the NT guideline, the rates were recalculated based on an area without the sides.

[5] European Commission (2005): Report of the leaching workshop, 13-14 June 2005, EUR 21878EN, Nov. 2005.

The calculated TIME 2 leaching rates are based on the assumption that 100% of the maximum applied amount (for IPBC this includes the amount of IPBC in the topcoat) will leach out during the service life.

#### 2.8.2.3 PEC calculations

The PECs for IPBC and propiconazole in the environmental compartments derived in the following sections are calculated on the basis of the emission scenarios available for Product Type 8. The PEC values presented are rounded values from EXCEL spread sheets. The calculations for the different PECs within EXCEL are always carried out with unrounded values.

For the general assessment of the environmental fate and behaviour of the active substances refer to the Section on "Fate and Distribution in the Environment" in Doc. II-A of the CAR's.

In Table 2.8-3 substance specific input parameters used for the emission calculations are shown.

**Table 2.8-3: Input parameters for the active substances**

| | IPBC | Propiconazole |
|---|---|---|
| **Half-life in the aquatic compartment (12°C)** | 3.1 hour (31.2 days)* | 1206 days**<br>6.4 days |
| **Half-life in the terrestrial compartment (12°C)** | 4.7 hour (9.5 days)* | 129 days |
| **Fraction staying in the water phase in the STP** | 0.97*<br>IPBC is completely degraded to PBC in the STP | 0.895 |
| **Koc** | 113.25 (198.1)* | 944 |

* Value for PBC
** This value will be used for all calculations of sediment concentration and for emissions to surface water deriving from industial storage

**PEC for sewage treatment plant**

Losses to sewage treatment plants (STP) are calculated for the industrial application stage, and for in-service leaching from the surfaces of noise barriers (constructed from pre-treated timber). Emissions to sewage water during the industrial applications are not likely to occur, because e.g. dipping containers are stand-alone devices without direct connection to a STP. Residues and waste solutions from such dipping containers will be treated as hazardous waste and not allowed to enter the STP. However, application and storage scenarios for dipping and automated enclosed spraying, which include losses to STP are calculated for completeness according to the ESD for Product Type 8 (OECD 2003).

In the Competent Authority Report for IPBC, the influent concentration of IPBC is considered to be relevant in order to assess predicted environmental concentrations in sewage treatment plants. For further modelling surface water concentrations it is assumed, that the whole IPBC in the STP is transformed into PBC. Hence, the STP risk assessment is based on IPBC influent concentration with no removal/degradation or translocation processes.

For propiconazole, the STP effluent concentrations do represent predicted environmental concentrations for this compartment.

A risk assessment for soils being target for PBC or propiconazole emissions via sewage sludge is not considered to be necessary.

**PEC for surface water**

For industrial applications the removal via STP is taken into account. For automated enclosed spraying the calculations are carried out for two plants of different sizes. Refinement of the calculated concentrations due to adsorption of the active substances on suspended matter in the surface water (according to equation 45, p. 76 of the TGD for Risk Assessment) was done.

As indicated above, emissions resulting from IPBC in the product are considered to enter surface water as PBC residues, when the intake proceeds via sewage treatment plants.

Following the Emission Scenario Document for PT8 (OECD 2003), the emission of the active substances to surface water due to leaching from on-site stored wood was calculated considering a small adjacent creek (flow 0.3 m³ per second).

During outdoor service life PECs for industrial pre-treated wood are calculated. The target compartments are pond water (scenario "bridge over pond") and surface water (scenario "noise barrier").

Further refinements of the initial PECs for surface water were done (only for direct emissions to the surface water) taking into account degradation of the active ingredients. According to OECD 2003 (Chapter 7: Removal processes in the receiving compartment, p.119) continuous releases into surface water can be calculated for either static or flowing water bodies. For the flowing water body a water volume of 25920 $m^3$ was used, this is equivalent to 1 days volume of a small creek with a flow rate of 0.3 $m^3$ per second.

**PEC for sediment**

In the Danish CAR (2008) for IPBC the reported PNEC for the sediment was derived using the equilibrium method. So the risk of the sediment compartment is the same as that assessed for surface water. Therefore, the calculation of $PEC_{sediment}$ values is not considered necessary.

For propiconazole $PEC_{sediment}$ values are calculated for relevant application and storage scenarios and for the bridge over pond scenario and the noise barrier scenario. The predicted concentration in sediment is deduced from the $PEC_{sw}$ by a partition of the active substance between suspended matter and the water phase (TGD, equation 50, p.78).

**PEC for soil**

Emissions into soil are assumed to occur during outdoor storage of the treated wood. It is assumed in the OECD models that emissions from the storage place reach the soil directly. For use class 3 outdoor service life the OECD models "timber house" and "noise barrier" are used. The OECD model "noise barrier" assumes that 30 % of the emissions from wood will reach the soil.

A 50 cm distance and soil depth from the treated wood is defined as the receiving soil compartment in the models "timber house" and "noise barrier". For the storage place also a default value of 50 cm for the soil depth was used.

Further refinements of the initial PECs for soil were done taking into account degradation of the

**PEC for groundwater**

The environmental fate and behaviour of IPBC indicate that the substance is not expected to migrate to groundwater during outdoor service life of treated wood since it is rapidly degraded in soil ($DT_{50}$ = 0.196 days (at 12°C)). Thus, the calculation of potential concentrations in groundwater is not considered relevant for the proposed use pattern (*cf.* Danish CAR, p.17).

In the Finnish CA report for propiconazole, a FOCUS-PEARL-3.3.3 groundwater modelling for the compound is described. It was carried out using a worst case scenario of 35 simultaneously treated wooden houses per hectare. The calculations were undertaken for a propiconazole release of 1000 mg/m$^2$ treated wood over a period of 5 years. For wood preservation use the predicted environmental concentration of propiconazole in groundwater, as represented by the 80$^{th}$ percentile leachate concentration at 1 m soil depth, were lower than the legal Drinking Water Limit of 0.1 µg/l in all FOCUS-PEARL scenarios. For the intended use of Laqvin Ton SX 1420 groundwater concentrations below 0.1 µg/l can also be expected because the estimated maximum total propiconazole release is less than that investigated in the CA-report for propiconazole. This demonstrates that the use of propiconazole in the wood preservative Laqvin Ton SX 1420 should not lead to unacceptable concentrations in groundwater.

**PEC for atmosphere**

Based on the vapour pressure (5.6 x $10^{-5}$ Pa×m$^3$ at 25°C) and the Henry`s Law constant (9.2 x $10^{-5}$ Pa×m³/mol), volatilisation of propiconazole can be regarded as negligible. Calculations of the chemical lifetime in the troposphere resulted in a half life between 10.2 and 42 hours (*cf.* Document II-A). According to these results ($DT_{50}$ < 2 days), propiconazole is rapidly degraded by photochemical processes and no accumulation of propiconazole in air is to be expected. Therefore, calculation of PEC values for the atmosphere ($PEC_{air}$) is of no relevance and air is not regarded as a compartment of concern for this Product Type and proposed use patterns.

The second active substance contemplated in this risk assessment, IPBC, will not be a subject of concern likewise. IPBC, has a low vapour pressure of 2.36 – 4.5 x $10^{-3}$ Pa at 25°C combined with a Henry`s Law constant of 3.38 – 6.45 x $10^{-3}$ Pa×m³/mol. This indicates a very low risk of volatilisation. With regard to the fact that IPBC half-life in air is only about 15 hours, the substance is not considered persistent in air (as stated in the Danish CAR). Thus no assessment for a possible risk of the atmosphere ($PEC_{air}$ ) is conducted.

**PEC for biota**

According to the TGD (EC, 2003) the calculation of a possible risk to man via the food chain ($PECoral_{predator}$) should be conducted if the a.s. shows a potential for bioaccumulation, indicated by a log $K_{ow}$ value >3.
IPBC reveals a log $K_{ow}$ of 2.81 and PBC a log $K_{ow}$ of 1.64 indicating that no risk for bioaccumulation of the substances to man via the food chain is given.

Although the log $K_{ow}$ of propiconazole (log $K_{ow}$ = 3.7) reveals a slight potential for bioaccumulation, an assessment of secondary poisoning is not requested in the Finnish CAR (2007, p.18) for the use of propiconazole in wood preservatives.

Calculated PEC values are summarised in Table 2.8-4 and 2.8-5 for IPBC and propiconazole, respectively.

IPBC or PBC values are shown, dependent on what value results in highest PEC/PNEC value. PEC values including degradation are shown in cases where there is a direct discharge to the compartment; this is shown by a symbol.

**Table 2.8-4: Summary of PEC values (with and without degradation) for IPBC/PBC.**

| IPBC/PBC | $PEC_{STP}$ (µg/L) | $PEC_{surface\ water}$ (µg/L) | $PEC_{soil}$ (mg/kg wwt) |
|---|---|---|---|
| **Industrial application** | | | |
| Spraying (small plant) | 42.0 | 2.24 * | - |
| Spraying (big plant) | 420 | 22.4 * | - |
| Dipping | 98.2 | 5.24 * | - |
| **Industrial storage** | | | |
| Spraying (30 days – small plant) | - | 0.00430 # | 0.00306 # |
| Spraying (15 years – small plant) | - | 0.00430 # | 0.00309 # |
| Spraying (30 days – big plant) | - | 0.0430 # | 0.0306 # |
| Spraying (15 years – big plant) | - | 0.0430 # | 0.0309 # |
| Dipping (30 days) | - | 0.0381 # | 0.00306 # |
| Dipping (15 years) | - | 0.0381 # | 0.00309 # |
| **In-service** | | | |
| Noise Barrier (30 days) | 1.77 | 0.0946 * | 0.00100 # |
| Noise Barrier (15 years) | 0.268 | 0.0143 * | $1.53 \times 10^{-4}$ # |
| House (30 days) | - | - | 0.00267 # |
| House (15 years) | - | - | $4.09 \times 10^{-4}$ # |
| Bridge over pond (30 days) | - | 0.156 # | - |
| Bridge over pond (15 years) | - | 3.15 *# | - |

* Values for PBC
# values including degradation

**Table 2.8-5: Summary of PEC values (with and without degradation) for propiconazole.**

| Propiconazole | $PEC_{STP}$ (µg/L) | $PEC_{surface\ water}$ (µg/L) | $PEC_{sediment}$ (mg/kg wwt) | $PEC_{soil}$ (mg/kg wwt) |
|---|---|---|---|---|
| **Industrial application** | | | | |
| Spraying (small plant) | 8.59 | 0.858 | 0.0183 | - |
| Spraying (big plant) | 85.9 | 8.58 | 0.183 | - |
| Dipping | 20.1 | 2.01 | 0.0427 | - |
| **Industrial storage** | | | | |
| Spraying (30 days – small plant) | - | $6.06 \times 10^{-4}$ # | $1.29 \times 10^{-5}$ ## | 0.00666 # |
| Spraying (15 years – small plant) | - | $6.06 \times 10^{-4}$ # | $1.29 \times 10^{-5}$ ## | 0.0842 # |
| Spraying (30 days – big plant) | - | $6.06 \times 10^{-3}$ # | $1.29 \times 10^{-4}$ ## | 0.0666 # |
| Spraying (15 years – big plant) | - | $6.06 \times 10^{-3}$ # | $1.29 \times 10^{-4}$ ## | 0.842 # |
| Dipping (30 days) | - | $5.37 \times 10^{-3}$ # | $1.14 \times 10^{-4}$ ## | 0.00666 # |
| Dipping (15 years) | - | $5.37 \times 10^{-3}$ # | $1.14 \times 10^{-4}$ ## | 0.0842 # |
| **In-service** | | | | |
| Noise Barrier (30 days) | 0.0680 | 0.00679 | $1.45 \times 10^{-4}$ | 0.00218 # |
| Noise Barrier (15 years) | 0.0549 | 0.00548 | $1.17 \times 10^{-4}$ | 0.0223 # |
| House (30 days) | - | - | - | 0.00582 # |
| House (15 years) | - | - | - | 0.0594 # |
| Bridge over pond (30 days) | - | 0.235 # | 0.0115 ## | - |
| Bridge over pond (15 years) | - | 0.269 # | 0.754 ## | - |

# Value including degradation
## Based on value that includes degradation

## 2.8.3 Environmental risk characterisation

The environmental risk characterization for biocidal active substances in the context of Article 5 and Annex VI of Directive 98/8 involves the comparison of PEC and PNEC values for each relevant environmental compartment as well as for non-target organisms. For this purpose Risk Characterisation Ratios (PEC/PNEC) are derived for the use of the wood preservative. The calculated PEC/PNEC ratios are provided for the STP, the aquatic and terrestrial compartment in the following.

If the PEC/PNEC ratio is below 1, this is interpreted as an acceptable risk to the environment.

The PNEC values shown in Table 2.8-6 are used for the risk characterisation

**Table 2.8-6: PNEC values used for risk characterisation**

| | IPBC/PBC | Propiconazole |
|---|---|---|
| **$PNEC_{STP}$ (µg/L)** | 440/440 | 1000 |
| **$PNEC_{surface\ water}$ (µg/L)** | 0.5/41.3 | 1.6 |
| **$PNEC_{sediment}$ (mg/kg wwt)** | Covered by surface water | 0.054 |
| **$PNEC_{soil}$ (mg/kg wwt)** | 0.00434/0.149 | 0.1 |

Calculated PEC/PNEC values are summarised in Table 2.8-7 and 2.8-8 for IPBC and propiconazole, respectively.

**Table 2.8-7: Summary of PEC/PNEC values (with and without degradation) for IPBC/PBC.**

| IPBC/PBC | $PEC_{STP}$ (µg/L) | $PEC_{surface\ water}$ (µg/L) | $PEC_{soil}$ (mg/kg wwt) |
|---|---|---|---|
| **Industrial application** | | | |
| Spraying (small plant) | 0.0955 | 0.0543 * | - |
| Spraying (big plant) | 0.955 | 0.543 * | - |
| Dipping | 0.223 | 0.127 * | - |
| **Industrial storage** | | | |
| Spraying (30 days – small plant) | - | 0.00859 # | 0.705 # |
| Spraying (15 years – small plant) | - | 0.00859 # | 0.711 # |
| Spraying (30 days – big plant) | - | 0.0859 # | **7.05** # |
| Spraying (15 years – big plant) | - | 0.0859 # | **7.11** # |
| Dipping (30 days) | - | 0.0762 # | 0.705 # |
| Dipping (15 years) | - | 0.0762 # | 0.711 # |
| **In-service** | | | |
| Noise Barrier (30 days) | 0.00403 | 0.00229 * | 0.231 # |
| Noise Barrier (15 years) | $6.10 \times 10^{-4}$ | $3.47 \times 10^{-4}$ * | 0.0352 # |
| House (30 days) | - | - | 0.616 # |
| House (15 years) | - | - | 0.0941 # |
| Bridge over pond (30 days) | - | 0.313 # | - |
| Bridge over pond (15 years) | - | 0.0763 *# | - |

* Values for PBC
# values including degradation

**Table 2.8-8: Summary of PEC/PNEC values (with and without degradation) for propiconazole.**

| Propiconazole | $PEC_{STP}$ (µg/L) | $PEC_{surface\ water}$ (µg/L) | $PEC_{sediment}$ (mg/kg wwt) | $PEC_{soil}$ (mg/kg wwt) |
|---|---|---|---|---|
| **Industrial application** | | | | |
| Spraying (small plant) | 0.00859 | 0.536 | 0.338 | - |
| Spraying (big plant) | 0.0859 | **5.36** | **3.38** | - |
| Dipping | 0.0201 | **1.25** | 0.792 | - |
| **Industrial storage** | | | | |
| Spraying (30 days – small plant) | - | $3.79 \times 10^{-4}$ # | $2.39 \times 10^{-4}$ ## | 0.0666 # |
| Spraying (15 years – small plant) | - | $3.79 \times 10^{-4}$ # | $2.39 \times 10^{-4}$ ## | 0.842 # |
| Spraying (30 days – big plant) | - | 0.00379 # | 0.00239 ## | 0.666 # |
| Spraying (15 years – big plant) | - | 0.00379 # | 0.00239 ## | **8.42** # |
| Dipping (30 days) | - | 0.00336 # | 0.00212 ## | 0.0666 # |
| Dipping (15 years) | - | 0.00336 # | 0.00212 ## | 0.842 # |
| **In-service** | | | | |
| Noise Barrier (30 days) | $6.80 \times 10^{-5}$ | 0.00424 | 0.00268 | 0.0218 # |
| Noise Barrier (15 years) | $5.49 \times 10^{-5}$ | 0.00343 | 0.00216 | 0.223 # |
| House (30 days) | - | - | - | 0.0582 # |
| House (15 years) | - | - | - | 0.594 # |
| Bridge over pond (30 days) | - | 0.147 # | 0.213 ## | - |
| Bridge over pond (15 years) | - | 0.168 # | **14.0** ## | - |

# Value including degradation
## Based on value that includes degradation

As the biocidal product consists of more than one active substance, the environmental risk should be based on the combined risk. It is found that the model of concentration addition can be recommended as the best reference model when evaluating combined risk of chemical mixtures.

In the first tier a PEC/PNEC summation based on effect data (most sensitive organism) for the individual substances is performed for each environmental compartment of concern.

[ $(PEC/PNEC)_{product} = \sum (PEC/PNEC)_{individual\ substances}$ ] for each environmental compartment

In Table 2.8-9 $(PEC/PNEC)_{product}$ values for each environmental compartment are summarised.

**Table 2.8-9: Summary of PEC/PNEC values (with and without degradation) for the product.**

| Laqvin Ton SX 1420 | $PEC_{STP}$ (µg/L) | $PEC_{surface\ water}$ (µg/L) | $PEC_{sediment}$ (mg/kg wwt) | $PEC_{soil}$ (mg/kg wwt) |
|---|---|---|---|---|
| **Industrial application** | | | | |
| Spraying (small plant) | 0.104 | 0.591 | 0.338 | - |
| Spraying (big plant) | **1.04** | **5.91** | **3.38** | - |
| Dipping | 0.243 | **1.38** | 0.792 | - |
| **Industrial storage** | | | | |
| Spraying (30 days – small plant) | - | 0.00897 | 0.000239 | 0.771 |
| Spraying (15 years – small plant) | - | 0.00897 | 0.000239 | **1.55** |
| Spraying (30 days – big plant) | - | 0.0897 | 0.00239 | **7.71** |
| Spraying (15 years – big plant) | - | 0.0897 | 0.00239 | **15.5** |
| Dipping (30 days) | - | 0.0795 | 0.00212 | 0.771 |
| Dipping (15 years) | - | 0.0795 | 0.00212 | **1.55** |
| **In-service** | | | | |
| Noise Barrier (30 days) | 0.00410 | 0.00654 | 0.00268 | 0.252 |
| Noise Barrier (15 years) | $6.65 \times 10^{-4}$ | 0.00377 | 0.00216 | 0.258 |
| House (30 days) | - | - | - | 0.674 |
| House (15 years) | - | - | - | 0.688 |
| Bridge over pond (30 days) | - | 0.4598 | 0.2129 | - |
| Bridge over pond (15 years) | - | 0.245 | **14.0** | - |

As stated in section 2.8.1.3, groundwater and air are not regarded as compartments of concern for this product with the proposed use patterns; also, there are no concerns of secondary poisoning (section 2.8.1.3).

As stated in 2.8.2.3 the risk for the sediment compartment of IPBC/PBC is the same as that assessed for surface water. The PEC/PNEC values for IPBC/PBC in sediment is however not added to that of the other a.s. in Table 2.8-9. Because propiconazole is of much greater concern for the sediment compared to IPBC/PBC and therefore results in greater PEC/PNEC values, the addition of the PEC/PNEC values for IPBC/PBC is considered to be irrelevant.

In Table 2.8-9 it is seen that for application risk is identified in STP, surface water and sediment. However, emissions to sewage water during the industrial/professional applications are not likely to occur, as such application plants are expected to be managed in such a way that emissions resulting from the application to an STP are not relevant.

During storage a risk is found for the soil. Therefore, freshly treated wood is to be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil. Any losses must be collected for reuse or disposal.

During service life risk is identified for sediment after the longer assessment period of 15 years.
In the study report, the leaching rates are calculated based on an area of wood including the sides of the test panels. As this is not in accordance with the NT guideline, the rates were recalculated based on an area without the sides.

It could however be argued that the treated sides of the panels are actually exposed to weathering to an extent which is comparable to the weathering of the front of the panels, and that the sides therefore should be included in the exposed wood area.
Calculations based on this assumption do however show that the PEC/PNEC values for sediment still exceed the trigger value of 1. After 15 years the PEC/PNEC for sediment is still 14.0 (because the leaching is still 100% of applied amount even when the sides of the panels are included).

**Conclusion:** The conclusion of the environmental risk assessment for the product Laqvin Ton SX 1420 is that no unacceptable risk is identified for secondary poisoning, air and groundwater compartments. However, risk is identified for the soil during storage and as a consequence, the **freshly treated wood is to be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil. Any losses must be collected for reuse or disposal**. During the service life risk is identified for the sediment compartment when used in the vicinity of water. As a consequence **the product can not be used close to water**.

## 2.9 Measures to protect man, animals and the environment

### Methods and precautions concerning handling and use

Keep container tightly closed.

Avoid contact with skin and eyes. Avoid the inhalation of dust, particulates, spray or mist arising from the application of this preparation.

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking.

Never use pressure to empty. Container is not a pressure vessel. Always keep in containers made from the same material as the original one.

Comply with the health and safety at work laws.

Exposure control: Supply sufficient ventilation. Where this is possible, it should be obtained by use of local exhaustion and good sufficient ventilation. If this is insufficient, keep the concentrations of particles and emissions from solvents below the threshold values, breathing masks should be worn according to current legislation.

On basis of the content of organic solvent in the product:
Vapours are heavier than air and can be spread along the floor. Vapours can form explosive mixtures with air. Avoid the formation of combustible or explosive concentrations of vapours in the air and avoid concentrations of vapours that exceed the threshold values set by The Danish Working Environment Service (Arbejdstilsynet). In addition, the product may only be used in areas without open fire or other sources of ignition. Electric installations should be protected according to the "Heavy Current Regulations" (Stærkstrømsreglementet). The packaging should be kept tightly closed. Keep away from heat, sparks and fire. Do not use spark forming tools.

**Personal protection equipment:**
Respiratory system: In case employees get exposed to concentrations that exceed the allowed threshold value, they should wear the appropriate and certified breathing mask. Particle filter, P2-P3.

Skin and body: Personnel should wear antistatic clothing made of natural fibres or of high-temperature-resistant synthetic fibres.

Hands: Wear appropriate safety gloves during work. Recommendation: Silver Shield gloves. The recommendation of type or types of gloves to be worn during handling of the product is based on information from the following source: Composition/information of components. Breakthrough time: Contact the glove supplier for information.

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.

Eyes: Wear safety eyewear designed to protect against splash of liquids.

Protection based on MAL-codes: According to the regulation about work with code numbered products the following regulations apply for use of personal protective equipment:
General: By all work that may imply soiling wear gloves. Wear apron/overalls/protective suit should if soiling takes place to such an extent that usual work clothes does not protect effectively against skin contact to the product. If a full-face mask is not recommended, wear a face screen by splashing work. Recommended eye protection, if any, no longer applies in this case. By all spray work, that involves use of a return spray (backflash), wear a breathing mask and sleeve/apron/overalls/protection suit as recommended or instructed. Mal code (1993):00-1.

**Use:** When spraying in existing spray booths, if the operator is outside the spraying zone.
- Wear sleeve protection. By all spraying with formation of aerosols in cabin or spray booth, if the operator is in the spraying zone or by spraying outside closed facilities, cabin or booth.

- Wear a full-face mask with combined filter, overall and hood.

By all spraying with aerosol formation in cabin or spray booth, where the operator is in the spray zone or spraying outside closed plants, cabin or booth. A full-face mask with combined filter, overalls and hood should always be worn.

Drying: Elements for drying/drying ovens, which are temporarily placed in e.g. a shelf cart, should be equipped with mechanical exhaustion, to prevent vapours from humid specimens to pass the inhalation zone of the workers.

Polishing: By polishing of treated surfaced, wear a dust filter mask. By machine grinding wear safety goggles. Always wear protective gloves

**Methods and precautions concerning storage**

Storage: To be stored according to local regulations. Observe measures stated on the label. Must not be stored below the following temperature: 5°C (41°F). Store at a dry, cool and well ventilated place. To be kept away from heat (max. 35°C) and direct sunlight. Due to the content of organic solvent in the product: Keep away from ignition sources. To be kept away from: oxidation agents, strong bases, strong acids.

No smoking. No admittance. Open containers should be closed carefully and stored in upright position to prevent leakage.

**Methods and precautions concerning transport**

Always transport in closed, upright standing and safe containers. Persons transporting the product should be familiar with measures against spillage and accidents.

**Transport:**

Land - road/railway:
Land - road/railway: 3082
Transport document name : Environmentally hazardous substance nos (propicopazole)
ADR/RID Class: 9
Packing group: III

ADR/RID Label: 

Sea:
UN number : 3082
Proper shipping name: Environmentally hazardous substance nos (propicopazole)
Special provisions: Not available
Marine pollutant Substances: Not available
IMDG Class: 9
Packing group: III
IMDG Label: Not available
Marine pollutant: P
Emergency schedules (EmS): F-A,S-F

Air:
UN number : 3082
Proper shipping name: Environmentally hazardous substance nos (propicopazole)
Special provisions: Not available
ICAO/IATA Classification: 9
Packing group: III
ICAO/IATA label: See MSDS
UN number : 3082
Proper shipping name: Environmentally hazardous substance nos (propicopazole)
ADNR Classification: 9
Packing group: III

ADNR Label: 

**Methods and precautions concerning fire**

Extinguishing agents: Recommended: Alcohol-resistant foam, carbonic acid, powders, water mist

Extinguishing agents NOT to be used: Do not use water jets

Special exposure dangers: Fire will develop a dense, black smoke. Exposure to break down products can constitute a health risk. An appropriate breathing mask can be necessary. Closed containers, which are exposed to fire, should be cooled with water, before drainage from fire to sewers and water pipes.

Identity of relevant combustion products in cases of fire: Carbon monoxide, carbon dioxide, smoke, oxides of nitrogen.

## Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available

First aid measures:

*General:*
In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and seek medical advice.

*Inhalation:*
Remove to fresh air. Keep person warm and at rest. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel.

*Skin contact:*
‘ Remove contaminated clothing and shoes. Wash skin thoroughly with soap and water or use recognised skin cleanser. Do not use solvents or thinners.

*Eye contact:*
Check for and remove any contact lenses. Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open.

*Ingestion:*
If swallowed, seek medical advice immediately and show the container or label. Keep person warm and at rest. Do not induce vomiting.

**Emergency measures to protect the environment**
Measures to be taken in case of leakage by accident
Due to the content of organic compounds in the product: Remove if possible, all sources of ignition and valves in the area. Avoid inhalation of vapours or spray mists. Read protection measures stated in section IIIB 8.1.1, too.
Confine leakages and absorb with non-inflammable material e.g. sand, soil, vermiculite, diatomite and place it in a container and dispose of it according to current regulations, see section IIIB 8.5

Environmental measures: Do not allow to enter sewers/water courses. If the product contaminates lakes, water courses or sewers, contact the responsible authorities according to current regulations

Cleaning methods: Clean preferably with cleaning materials, avoid solvents

**Disposal considerations**
Do not allow to enter drains or watercourses. To be disposed of according to the directions of the local authorities.

European Waste Catalogue (EWC): 08 01 11 “waste paint and varnish other than those mentioned in 08 01 11” 08 01 11 “waste paint and varnish containing organic solvents or other dangerous substances”

Hazardous waste: Yes.

# 3 Proposal for decision

## 3.1 Background for decision

**Physico-chemical properties:**
The overall conclusion of the risk-assessment for physico-chemical properties is that no unacceptable risk is identified after 13 months.
On the basis of the available stability data and the level of variation a claim for 6 months shelf-life can be accepted.

**Efficacy evaluation:**
Laqvin Ton SX 1420 is recommended to be approved as a biocide product to protect against blue stain fungi in use class 2 and 3 by superficial application at application rate 70 – 80 g/m$^2$ corresponding to 69 - 78 ml/m$^2$. A mould resistant top coat is required to be applied after treatment with the product.

**Human health assessment:**
The risk for the industrial workers under normal use of this product during industrial automatic processes (dipping, flow-coating and spraying) and manual processes (spray application in spraying cabins) are considered to be acceptable as shown by the exposure calculations. Furthermore, the use of product treated wood does not pose a risk for human health. Thus the overall outcome of the risk assessment for humans shows that when general and specific risk mitigation measures listed under point 2.9 Measures to protect man and the environment are followed, the use of Laqvin Ton SX1420 does not pose an unacceptable risk to human health.

**Environmental assessment:**
The conclusion of the environmental risk assessment for the product Laqvin Ton SX 1420 is that no unacceptable risk is identified for secondary poisoning, air and groundwater compartments.
However, risk is identified during application and storage, and as a consequence, the freshly treated wood is to be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil. Furthermore any losses must be collected for reuse or disposal. During the service life risk is identified for the sediment compartment when used in the vicinity of water. As a consequence the product can not be used close to water.

## 3.2 Decision regarding Authorisation of the biocidal product

The Danish CA proposes the authorisation of the biocidal product Laqvin Ton SX 1420 as a wood preservative (PT 8) for use by industrial dipping, flow-coating and automated spraying. Manual spray application in spraying cabins can occur. The use rate is 70-80 g/m$^2$ corresponding to 69-78 ml/m², depending on application and retention capacity of the wood. A mould resistant top coat is required to be applied after treatment with the product.

**Identity of the Biocidal Product**

The biocidal product under PT8 Wood preservatives Laqvin Proof ED 1422 contains 0.60% (w/w) IPBC and 0.40% (w/w) propiconazole.

**Particular Conditions**

*Purity of the Active Substance*

The active substance as manufactured shall have the following minimum purities:

IPBC: 980 g/kg

Propiconazole: 930 g/kg

*Product Type*

PT8: Wood preservatives

**Expiry Date of the Authorisation:**

The authorisation of the product Laqvin Ton SX 1420 expires on 31 March 2020, which is the expiry date of Annex I listing of the active substances, i.e. that of propiconazole.

# Annexes

1. **List of studies reviewed**
2. **Toxicology and metabolism –active substance**
3. **Human exposure assessment**
4. **Leaching calculations**
5. **Calculation of leaching rates from a leaching experiment**

## Annex 1: List of studies reviewed

***List of new data[6] submitted in support of the evaluation of the active substance***

| Section No | Reference No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Yes | No | Yes | No |
| | | | | | | ☐ | ☐ | ☐ | ☐ |
| Add rows as necessary | | | | | | | | | |

***List of new data submitted in support of the evaluation of the biocidal product***

| Section No | Reference No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Yes | No | Yes | No |
| B3_1 | 1 | Berit Lindegaard and Elisabeth Morsing | 2011 | Test report of storage stability of Laqvin Ton SX 1420. Danish Technological Institute. Wood Technology. 23th June 2011. Order no. 438403-6 | Becker Aroma | ☐ | ☒ | ☒ | ☐ |

6 Data which have not been already submitted for the purpose of the Annex I inclusion.

| Section No | Reference No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|---|
| IVB 5 | 2 | Morsing and Lindegaard | 2010 | Efficacy data: SX 1420 is tested according to EN 152-1: 1988 “"Wood preservatives - Laboratory method for determining the protective effectiveness of a preservative treatment against blue stain in service. Part 1: Brushing procedure". Modification: Weathering was carried out by QUV according to cycle 1 in the revision of EN 152, CEN TC 38 WG 23 N 107 on 17-03-2005. | Becker Acroma KB | ☐ | ☒ | ☒ | ☐ |
| IVB 7 | 3 | Morsing and Lindegaard | 2010 | Test Report. OECD Guidance on the Estimation of Emissions from Wood Preservative - Treated Wood to the Environment: for Wood held in Storage after Treatment and for Wooden Commodities that were not covered and were not in Contact with Ground: 23-07-2009. The 2 × 1 hour immersion regime. Laboratory name: Danish Technological Institute Laboratory report number: Order no.: 341814-2 | Becker Acroma KB | ☐ | ☒ | ☒ | ☐ |

| Section No | Reference No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|---|
| IVB 7 | 4 | Klamer and Venås | 2011 | Leaching of IPBC and Propiconazole from Painted Wood Surfaces Treated with SX 1420 and Exposed to Outdoor Conditions – Interim Report. 20th June 2011. Laboratory name: Danish Technological Institute Order no.: 352957-2 | Becker Acroma KB | ☐ | ☒ | ☒ | ☐ |

**Annex 2: Toxicology and metabolism –active substance**

## Active Substance: IPBC

Threshold Limits and other Values for Human Health Risk Assessment

| **Summary** | | | |
|---|---|---|---|
| | Value | Study | AF |
| AEL long-term | 0.2 mg/kg bw/day | 2 yr rat | 100 |
| AEL medium-term | 0.35 mg/kg bw/day | 90-day gavage rat | 100 |
| AEL acute | 0.35 mg/kg bw/day | 90-day gavage rat | 100 |

| | |
|---|---|
| Inhalative absorption | Default: 100% |
| Oral absorption | >90% based on urinary excretion (~57-71%) and exhaled air (~18-24%) within 72 hours. |
| Dermal absorption | 1.6, 10, and 30% for solutions containing 17, 2.4 and 0.6% IPBC<br>100% default for solutions containing <0.5%-0.6% IPBC<br>(based on *in vitro* human skin study with solvent based on model product) |

| **Classification** | |
|---|---|
| with regard to toxicological data<br>(according to the criteria in Dir. 67/548/EEC) | T; R23<br>Xn; R22<br>Xi;R37-41<br>R43 |
| with regard to toxicological data<br>(according to the criteria in Reg. 1272/2008) | Acute Tox 3 – H331<br>Acute Tox 4 – H302<br>Eye Dam 1 – H318<br>Skin Sens 1 - H317<br>STOT SE 3 – H335 |

## Active Substance: propiconazole

Threshold Limits and other Values for Human Health Risk Assessment

| **Summary** | | | |
|---|---|---|---|
| | Value | Study | AF |
| AEL long-term | 0.08 mg/kg bw/day | 2-generation rat | 100 |
| AEL medium-term | - | - | - |
| AEL acute | 0.3 mg/kg bw/day | Developmental study in rat | 100 |

| | |
|---|---|
| Inhalative absorption | Default: 100% |
| Oral absorption | 86% within 48 h |
| Dermal absorption | 2% |

| **Classification** | |
|---|---|
| with regard to toxicological data (according to the criteria in Dir. 67/548/EEC) | Xn; R22<br>R43 |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 4 - H302<br>Sens Cat 1 -H317 |

## Annex 3.1: Human exposure assessment

**Laqvin Ton SX1420 – Industrial user – Post-application phase – IPBC / Model : Timber pre-treatment (water) (BEAT)**

| **Product** | | **Units** |
|---|---|---|
| active substance | 0.6% | %w/w |
| **Potential body exposure** | | |
| Indicative value | 108 | mg/min |
| Duration | 240 | min |
| Potential dermal deposit | 25920 | mg |
| Clothing type | Coated coveralls | |
| Clothing penetration | 10% | % penetration |
| Actual dermal deposit | 2592 | mg [product] |
| **Hand exposure** | | |
| Indicative value | 8.71 | mg/min (actual) (inside gloves) |
| Duration | 240 | min |
| Hand deposit | 2090.4 | mg |
| Mitigation by gloves | Not applicable | |
| Actual hand deposit | 2090.4 | mg [product] |
| **Total dermal exposure** | | |
| Total dermal deposit | 4682.4 | mg [product] |
| Active substance | 28.09 | mg |
| Dermal absorption | 30.00% | % |
| Systemic exposure via dermal route | 8.4 | a.s. mg |
| **Exposure by inhalation** | | |
| Indicative value | 1.8 | $mg/m^3$ |
| Duration | 240 | min |
| Inhalation rate $m^3/h$ | 1.25 | $m^3/h$ |
| Mitigation by RPE (PF) | 1 | |
| Inhaled | 9 | mg [product] |
| Systemic exposure via inhalation route | 0.054 | a.s. mg |
| **Systemic exposure** | | |
| Total systemic exposure | 8.4823 | a.s. mg |
| Body weight kg | 60 | kg |
| **Systemic exposure** | **0.14137** | **mg/kg/day** |

**Annex 3.2**

## Laqvin Ton SX1420 – Industrial user – Post-application phase – Propiconazol / Model : Timber pre-treatment (Water) (BEAT)

| Product | | Units |
|---|---|---|
| active substance | 0.4% | %w/w |
| **Potential body exposure** | | |
| Indicative value | 108 | mg/min |
| Duration | 240 | min |
| Potential dermal deposit | 25920 | mg |
| Clothing type | Coated coveralls | |
| Clothing penetration | 10% | % penetration |
| Actual dermal deposit | 2592 | mg [product] |
| **Hand exposure** | | |
| Indicative value | 8.7 | mg/min (actual) (inside gloves) |
| Duration | 240 | min |
| Hand deposit | 2090.4 | mg |
| Mitigation by gloves | Not applicable | |
| Actual hand deposit | 2090.4 | mg [product] |
| **Total dermal exposure** | | |
| Total dermal deposit | 4682.4 | mg [product] |
| Active substance | 18.73 | mg |
| Dermal absorption | 2% | % |
| Systemic exposure via dermal route | 0.375 | a.s. mg |
| **Exposure by inhalation** | | |
| Indicative value | 1.8 | $mg/m^3$ |
| Duration | 240 | min |
| Inhalation rate $m^3/h$ | 1.25 | $m^3/h$ |
| Mitigation by RPE (PF) | 1 | |
| Inhaled | 9 | mg [product] |
| Systemic exposure via inhalation route | 0.036 | a.s. mg |
| **Systemic exposure** | | |
| Total systemic exposure | 0.410 | a.s. mg |
| Body weight kg | 60 | kg |
| **Systemic exposure** | **0.00684** | **mg/kg/day** |

**Annex 3.3**

**Laqvin Ton SX1420- Industrial workers – Manual spraying (loading/application)-IPBC-Model "Occupational exposure through spraying remedial pesticides" (BEAT)**

**Exposure assessment for industrial timber pre-treatment**

| **Spraying - water-based product** | **IPBC** |
|---|---|
| active substance % (w/w) | 0.60% |
| **Potential body exposure** | |
| Indicative value mg/min | 65 |
| Duration min | 180 |
| Potential dermal deposit mg | 11700 |
| Clothing type | Dry cotton coveralls |
| Clothing penetration % | 10% |
| Actual dermal deposit [product] mg | 1170 |
| **Hand exposure** | |
| Indicative value mg/min (actual) | 8.71 |
| Duration min | 180 |
| Hand deposit mg | 1567.8 |
| Mitigation by gloves | Not applicable |
| Actual hand deposit [product] mg | 1567.8 |
| **Total dermal exposure** | |
| Total dermal deposit [product] mg | 2737.859.8 |
| Active substance mg | 16.43 |
| Dermal absorption % | 30% |
| Systemic exposure via dermal route mg | 4.9 |
| **Exposure by inhalation** | |
| Indicative value mg/m³ | 21.3 |
| Duration | 180 |
| Inhalation rate m $^{3}$/h | 1.25 |
| Mitigation by RPE (PF) | 1 |
| Inhaled [product] mg | 79.88 |
| Systemic exposure via inhalation route mg | 0.479 |
| **Systemic exposure** | |
| Total systemic exposure a.s. mg | 5.4 |
| Body weight kg | 60 |
| Systemic exposure mg kg $^{-1}$ day$^{-1}$ | **0.09** |

**Annex 3.4**

**Laqvin Ton SX1420- Industrial workers – Manual spraying (loading/application)-Propiconazol-Model "Occupational exposure through spraying remedial pesticides" (BEAT)**

**Exposure assessment for industrial timber pre-treatment**

| **Spraying - water-based product** | **Propiconazol** |
|---|---|
| active substance % (w/w) | 0.40% |
| **Potential body exposure** | |
| Indicative value mg/min | 65 |
| Duration min | 180 |
| Potential dermal deposit mg | 11700 |
| Clothing type | Dry cotton coveralls |
| Clothing penetration % | 10% |
| Actual dermal deposit [product] mg | 1170 |
| **Hand exposure** | |
| Indicative value mg/min (actual) | 8.71 |
| Duration min | 180 |
| Hand deposit mg | 1567.8 |
| Mitigation by gloves | Not applicable |
| Actual hand deposit [product] mg | 1567.8 |
| **Total dermal exposure** | |
| Total dermal deposit [product] mg | 2737 |
| Active substance mg | 11 |
| Dermal absorption % | 2% |
| Systemic exposure via dermal route mg | 0.219 |
| **Exposure by inhalation** | |
| Indicative value mg/m³ | 21.3 |
| Duration | 180 |
| Inhalation rate m $^{3}$/h | 1.25 |
| Mitigation by RPE (PF) | 1 |
| Inhaled [product] mg | 79.88 |
| Systemic exposure via inhalation route mg | 0.32 |
| **Systemic exposure** | |
| Total systemic exposure a.s. mg | 0.54 |
| Body weight kg | 60 |
| Systemic exposure mg kg $^{-1}$ day$^{-1}$ | **0.009** |

**Annex 4: Leaching Calculations**

A semi-field leaching study for Laqvin Ton SX 1420 was with some deviations conducted in accordance with NT Build 509 (approved 2005-03) "Leaching of active components from preservative treated timber – semi-field testing". Late in the assessment process an extra measurement was submitted.
A laboratory leaching study was also submitted. This was however not used in the assessment, because the semi-field leaching study is higher tier.

The amounts of active ingredients measured in the leachate are given in mg/L. It is then calculated as mg per square meter exposed wood. In the study the sides of the test panels are included in the area. But according to the NT Build 509 guideline the sides should not be included. Before calculation of a FLUX the leaching rates are therefore recalculated as mg per $m^2$ of exposed wood without the sides of the panels. For this purpose a correction factor of (0.798/0.5495) 1.45 is used.

Then the average daily leaching rate for each time interval was plotted versus the mean time of the time interval considered. A detailed description of this procedure can be found in Appendix 1 of the ESD for PT 8 (OECD, 2003).
For fitting the experimental FLUX(Δt)=$f$(t) curve a polynomial regression of second order was employed:

$$\mathbf{\log_{10}FLUX(t) = a + b*\log_{10}(t) + c*\log_{10}(t)^2}$$

The fitted daily FLUX(t) corresponds to the quantity of the preservative compound leached per $m^2$ wood within the one day interval of the specific day t, while the experimental FLUX(Δt) represents the average quantities of the active substance leached per $m^2$ wood per day for a specific time interval Δt, and this time interval is more than one day. The trend lines with the corresponding regression equations and coefficients of variation can be found in Figure 1.

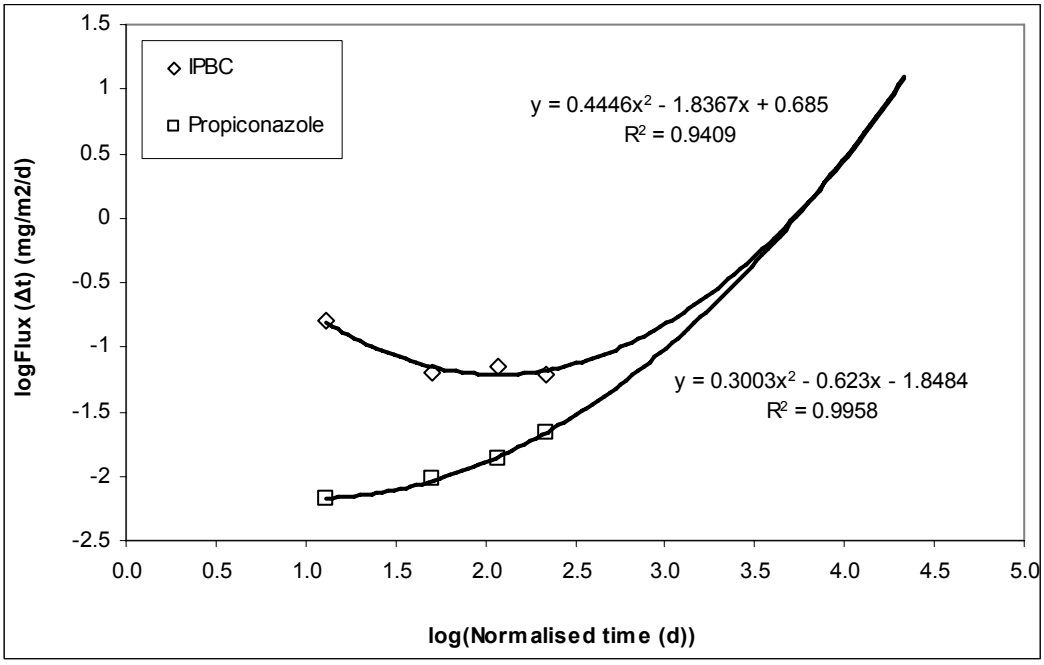


**Figure 1 Fitted daily FLUX(Δt) of IPBC and propiconazole versus time**

In Figure 2 it is seen that the FLUX is increasing over time. This high increase in leaching over time is not realistic, and the curve can not be used for calculation of fluxrates.

There are too few points to calculate fluxrates based on extrapolation of the cumulative leaching.

Instead the FLUX(Δt) values are used:

FLUX (Δt) = $Q_d$ (Δt) / Δt
Where $Q_d$ is the measured leached amount for each time interval

A more detailed description of this procedure can be found in Appendix 1 of the ESD for PT 8 (OECD, 2003).

The FLUX(Δt) values are shown in Figure 2.

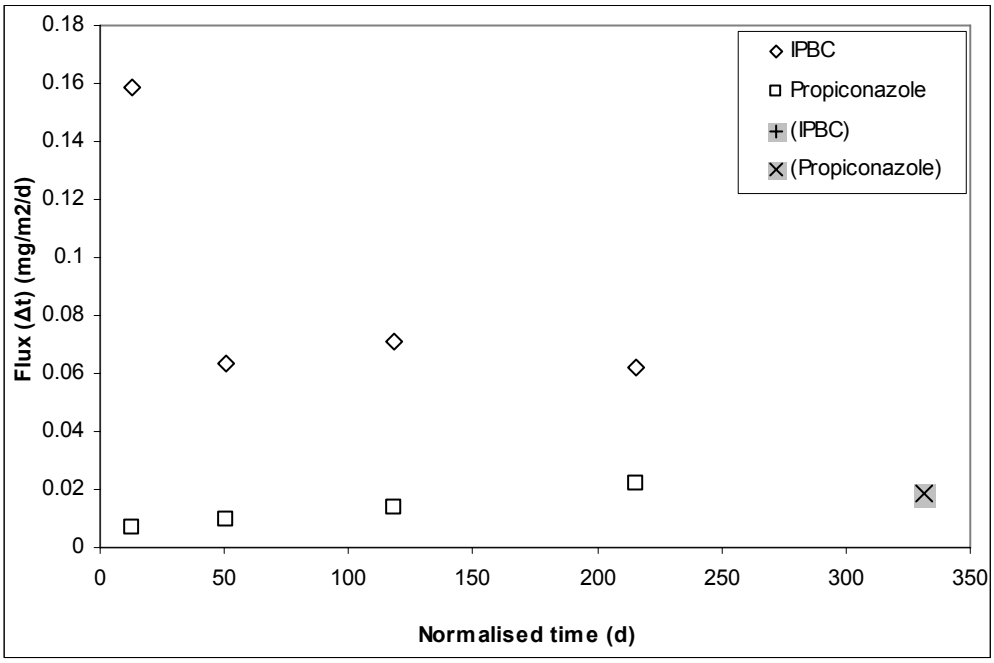


**Figure 2 FLUX(Δt) values**

In figure 2 the FLUX(Δt) values from the interim leaching report are shown. Also the values measured and submitted late in the assessment process are shown as grey marks (the values coincide, therefore only one grey mark is seen in the figure).

The extra measured values show that the leaching rates are decreasing.
It is therefore acceptable to use the last value from the interim report as the long term leaching rate $Q_{leach,\ 15\ years}$.
For the short term leaching rate, $Q_{leach,\ 30\ days}$, the first value is used.

Because the intended application rate is higher than the amounts applied in the leaching study correction factors have to be adopted. The maximum intended applied amount of IPBC (including the IPBC from the

topcoat (max application) used in the leaching study) is 1.40 g/m$^2$, while in the leaching study 1.31 g/m$^2$ was applied, hence an assessment factor of 1.06 has to be applied for IPBC. For propiconazole the maximum intended applied amount is 0.320 g/m$^2$, while in the leaching study 0.297 g/m$^2$ was applied, hence for propiconazole an assessment factor of 1.08 has to be adopted.
With this approach the following leaching rates can be derived:

IPBC

TIME 1, 30 days:
$Q_{leach,\ 30\ days}$ = 0.159 mg/m$^2$/d x 1.06 = 0.169 mg/m$^2$/d

TIME 2, 15 years:
$Q_{leach,\ 15\ years}$ = 0.0618 mg/m$^2$/d x 1.06 = 0.0658 mg/m$^2$/d

Propiconazole

TIME 1, 30 days:
$Q_{leach,\ 30\ days}$ = 0.00672 mg/m$^2$/d x 1.08 = 0.00724 mg/m$^2$/d

TIME 2, 15 years:
$Q_{leach,\ 15\ years}$ = 0.0220 mg/m$^2$/d x 1.08 = 0.0237 mg/m$^2$/d

The leaching study is conducted with a top coat applied over the product and the intention is that Laqvin Ton SX 1420 should be authorized to be used along with any given top coat. This adds an element of uncertainty to the measured values and an assessment factor of 10 has to be used.

This approach does however result in TIME 2 leaching rates exceeding the total applied amount. Therefore, according to the suggestions of the Arona Leaching Workshop in June 2005 (ECB, 2005), leaching rates for these are instead derived by dividing the maximum application rate of the active ingredient by the respective service life time. With these approaches the following leaching rates, which are used as input parameters for the different exposure scenarios, can be derived:

IPBC

TIME 1, 30 days:
$Q_{leach,\ 30\ days}$ = 0.169 mg/m$^2$/d x 10 = **1.69** mg/m$^2$/d

TIME 2, 15 years (100 %):
$Q_{leach,\ 15\ years}$ = 1400 mg/m$^2$ / 5475 d = **0.256** mg/m$^2$/d

Propiconazole

TIME 1, 30 days:
$Q_{leach,\ 30\ days}$ = 0.00724 mg/m$^2$/d x 10 = **0.0724** mg/m$^2$/d

TIME 2, 15 years (100 %):
$Q_{leach,\ 15\ years}$ = 320 mg/m$^2$ / 5475 d = **0.0584** mg/m$^2$/d

## Annex 5: Calculation of leaching rates from a leaching experiment

### Introduction

For the environmental risk assessment of wood preservatives, emission calculations are performed based on leaching rates of the active ingredients and if relevant also for substances of concern.
Leaching rates are calculated according to guidance given in "OECD ESD for wood preservatives" and "Report of the leaching workshop". However, in the "OECD ESD for wood preservatives" several possibilities are stated for how to calculate leaching rates. Moreover, the guidance documents do not cover how to deal with leaching experiments where a top coat is applied.

In this document it is described how DK has approached the calculation of leaching rates also in cases where a top coat has been applied on the surface of the treated wood.

### Calculation of leaching rates

For the calculation of leaching rates it is preferred to use all measurements within the leaching experiment. This has been done by fitting the experimental FLUX($\Delta$t)=*f(t)* curve using a polynomial regression of second order:

$$\mathbf{\log_{10}FLUX(t) = a + b*\log_{10}(t) + c*\log_{10}(t)^2}$$

This curve generally fits measured data well for a number of leaching experiments, and in these cases leaching rates for time1 and time2 is estimated based on the fitted curve. However, in some cases the fitted curve increases after the last measurement, this is not realistic and in these cases the fitted curve will not be used for the calculation of leaching rates. In cases where it is decided that the fitted curve can not be used, calculated FLUX values based on specific measurements will be used for calculation of the leaching rates and extrapolation to time2 is therefore not possible.
In a few cases it has been accepted to calculate the leaching rates from the curve fitting the cumulative quantities leached [$Q_c(t)$], this has only been done in cases where there is good fitting based on several measurements.

For leaching experiments where top coats are applied, measured leaching rates generally vary a lot. In these cases curves generally fits the measured data bad and extrapolation for time2 can not be performed.

### Top coats

For several products, top coats must be applied in order to claim efficacy against blue stain. Moreover, top coats are applied in cases where it is part of a multi component system, e.g. for window and door frames.

In DK we accept the use of top coats applied by industry, professionals and by amateurs. A large number of the leaching experiments that DK has received for the evaluation of the products are performed with the use of a specific top coat.

We have been in contact with the applicants and they have argued that it is not possible to use only one specific top coat. The applicants need that they can use a wide variety of top coats both for industrial, professional and amateur use.

In cases where top coats are used in the leaching experiments additional assessment factors are used in the calculation of leaching rates. In Table 1 it is shown which assessment factors that will be used.

The additional assessment factors are used to cover uncertainties in the estimation of leaching rates, caused by:

- use of other types of top coats (the leaching experiment is normally performed with one specific top coat)
- how well the top coat is applied,
- how long the top coat will be functional and if it is maintained

**Table 1:** Additional assessment factors used for the calculation of leaching rates. Leaching rates are calculated according to guidance given in "OECD ESD for wood preservatives" and "Report of the leaching workshop". Additional guidance and assessment factors are given below:

| Available leaching study | Claim on the biocidal product | How to perform emission calculations? | Requirement regarding top coat |
|---|---|---|---|
| No study | No top coat or any top coat | Use:<br>a) 100% leaching | None |
| Study with no top coat | No top coat or any top coat | Use:<br>a) calculated leaching rates<br>b) 100% leaching if calculated leaching rates from a) exceed 100% leaching** | None |
| Study with top coat | No top coat | Use:<br>a) 100% leaching | None |
| | With top coat which is "stable" according to EN927-2*<br><br>**Amateur use** | Use:<br>a) calculated leaching rates **x 10,** both for time1 and time2<br>b) 100% leaching if calculated leaching rates from a) exceed 100% leaching** | a) Treated timber should receive a top coat …<br>b) Top coat should be maintained |
| | With top coat which is "stable" according to EN927-2*<br>**Industrial/professional use** | Use:<br>a) calculated leaching rate for time1. For time2 use calculated leaching rate **x 5**<br>b) 100% leaching if calculated leaching rates from a) exceed 100% leaching** | a) Treated timber should receive a top coat which is "stable" according to EN927-2…<br>b) Top coat should be maintained |
| | With any top coat<br><br>**Amateur, professional or industrial use** | Use:<br>a) calculated leaching rates **x 10,** both for time1 and time2<br>b) 100% leaching if calculated leaching rates from a) exceed 100% leaching** | a) Treated timber should receive a top coat …<br>b) Top coat should be maintained |

* The top coat used in the leaching study should also be "stable" according to EN927-2

** This can either be for time1, time2 or for both time1 and time2

| Available leaching study | Claim on the biocidal product | How to perform emission calculations? | Requirement regarding top coat |
|---|---|---|---|
| Studies both with and without top coat | No top coat | Use:<br>a) calculated leaching rates (study without top coat)<br>b) 100% leaching if calculated leaching rates from a) exceed 100% leaching** | None |
| | With top coat which is "stable" according to EN927-2*<br><br>**Amateur use** | Use:<br>a) calculated leaching rates **x 10,** both for time1 and time2 (study with top coat)<br>b) leaching rates from study without top coat if calculated leaching rates from a) exceed the ones from study without top coat **<br>c) 100% leaching if calculated leaching rates from a) exceed 100% leaching** | a) Treated timber should receive a top coat …<br>b) Top coat should be maintained |
| | With top coat which is "stable" according to EN927-2*<br><br>**Industrial or professional use** | Use:<br>a) calculated leaching rate for time1. For time2 use calculated leaching rate **x 5** (study with top coat)<br>b) leaching rates from study without top coat if calculated leaching rates from a) exceed the ones from study without top coat**<br>c) 100% leaching if calculated leaching rates from a) exceed 100% leaching** | a) Treated timber should receive a top coat which is "stable" according to EN927-2…<br>b) Top coat should be maintained |
| | With any top coat<br><br>**Amateur, professional or industrial use** | Use:<br>a) calculated leaching rates **x 10,** both for time1 and time2 (study with top coat)<br>b) leaching rates from study without top coat if calculated leaching rates from a) exceed the ones from study without top coat**<br>c) 100% leaching if calculated leaching rates from a) exceed 100% leaching** | a) Treated timber should receive a top coat …<br>b) Top coat should be maintained |

* The top coat used in the leaching study should also be "stable" according to EN927-2
** This can either be for time1 or time2 or for both