

Bilag 2

Product Assessment Report

Laqvin Prime ED 1401

Internal registration no:	MST-671-01761
Authorisation/Registration no:	694-6
Granting date/entry into force of authorisation/ registration:	9 December 2011
Expiry date of authorisation/ registration:	30 June 2020
Active ingredient:	IPBC
Product type:	PT8 Wood Preservative

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



Danish Ministry
of the Environment
Environmental
Protection Agency

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1 General information about the product application

1.1 Applicant

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City:	Märsta
Postal Code:	SE-19502
Country:	Sweden
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1.1.1 Person authorised for communication on behalf of the applicant

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1.2 Current authorisation holder¹

There is no current authorisation for Laqvin Prime ED 1401 in Denmark.

1.3 Proposed authorisation holder after authorisation

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
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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:	

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	Laqvin Prime
Manufacturer's development code number(s), if appropriate:	ED 1401
Product type:	PT8
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	IPBC 0.50%
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); If yes: authorisation/registration no. and product name: or Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):	No

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 spraying. 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	The product is applied at a rate of 175-200

and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	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

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

1.5.4 Information on the substance(s) of concern

Laqvin Prime ED 1401 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 letter of access:

Lanxess Deutschland GmbH authorizes the right to refer the BPD 98/8/EC dossier of IPBC.

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 substance IPBC (0.5%) (Min. purity 980 g/kg).

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 Prime ED 1401 according to Directive 67/548/EEC is shown here:

S2: Keep out of the reach of children

S13: Keep away from food, drink and animal foodstuffs

Furthermore the product shall be labelled with the following sentence:

Contains IPBC: 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 CAR².

A summary of the physical and chemical properties of Laqvin Prime ED 1401 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).

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

	Method	GLP (Y/N)	Results	Reference
Physical state and nature	Performed by visual	N	Liquid, water dispersion.	Lindegaard & Morsing, 2011

² Competent Authority Report

	Method	GLP (Y/N)	Results	Reference
	observation at 20°C.			
Colour	Performed by visual observation at 20°C.	N	White	Lindegard & Morsing, 2011
Odour	Performed by odour observation at 20°C.	N	No intense odour. As acrylic paint.	Lindegard & Morsing, 2011
Explosive properties	–	N	The explosive properties are not measured since the product is waterborne. Limitations. lower 1.1 % v/v, upper 8.4 % v/v Contains 3 % VOC (Volatile organic compounds).. (36 g/l)	Becker Acroma
Oxidizing properties	–	N	None. 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: 8.0 – 9.0 The acidity / alkalinity was not determined as the pH-value is between 4 and 10.	Lindegard & Morsing, 2011
Relative density / bulk density	SS-EN ISO 2811-1:2011	N	1.33±0.1 g/mL	Becker Acroma No official report for the product. The density is measured routinely as part of quality control process.
Effects of temperature	CIPAC M46. 35°C for 2 weeks.	N	CIPAC M46: No changes of biocidal concentration. By visual observation it was	Lindegard & Morsing, 2011

	Method	GLP (Y/N)	Results	Reference
			<p>observed that there were no sedimentation, colour change or other changes of the product. By smell observation it was observed that there was no intense odour and the product smelled as acrylic paint.</p> <p>Initial analysis: 0.25% and 0.24% IPBC. Mean: 0.245%</p> <p>After storage: 0.26% and 0.25% IPBC. Mean: 0.255%</p> <p>Variation: IPBC: 4.1%</p>	
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	<p>For 2 weeks at 35°C: There was no reactivity towards container material.</p> <p>For 9 months at room temperature There was no reactivity towards container material.</p>	Lindegaard & Morsing, 2011
Technical characteristics in dependence of the formulation type	–	–	The biocidal product has none of the properties mentioned in the TNsG on Data Requirements. Therefore no tests are necessary.	–
Compatibility with other products	–	–	Not applicable since the biocidal product will not be used with other	–

	Method	GLP (Y/N)	Results	Reference
			products including other biocidal products.	
Surface tension	Calculation	N	Between 35-70 mN/m. Waterborne dispersion with surface tensions between 35-70 mN/m. Contains no aliphatic, aromatic or alicyclic hydrocarbons.	Becker Acroma
Viscosity	ASTM D562	N	80-85 KU. 90-100 KU stormer equals to: 1682 mm ² /s	Becker Acroma 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	9 months
Laqvin Prime ED 1401	IPBC	0.49 % -	0.46 % 6.1 %
	pH	8.65 (undiluted)	8.72 (undiluted)

References: Lindegaard & Morsing, 2011

2.3.3 Analytical methods

Chemical analysis of biocides 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 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 Prime ED 1401 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 Prime ED 1401 from the accelerated study shows that the degradation of IPBC after 2 weeks at 35°C is 4.1 %, which is within the limit of 5 % degradation (according to OECD 113: Screening test for thermal stability and stability in air).

According to the 9 months results from the shelf-life study, IPBC has degraded by 6.1 %.

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 9 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: 175 g product/m²

Maximum: 200 g product/m²

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

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)).

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 Prime ED 1401 contains 0.50% (w/w) IPBC. It is used as wood preservative (BPD Product Type 8) for Use Class 2 and 3. The product is intended for industrial use, in wood treatment plants by mechanised industrial techniques by spraying.

The product is applied at a rate of 175 – 200 g/m², which results in a maximum total applied amount of 1000 mg IPBC/m² timber (200 g (Laqvin Prime) x 0.50 %).

After application of Laqvin Prime ED 1401 a top coat which is mould resistant must be applied. The environmental assessment covers the use of a topcoat containing up to 0.25 % (w/w) IPBC.

The intended use is covered by the CAR for IPBC.

2.6.2 Assessment of exposure to humans and the environment

A leaching study has been submitted, an evaluation of this and flux rates used for the environmental risk assessment will be 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 substance

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR. 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 solvent based formulation containing 0.6% IPBC is considered as a representative worst-case for this water-based ready-to-use product containing 0.5% IPBC. Also taking into consideration that dermal absorption figures are not exact values and undergoes some variation when measured. Therefore, the IPBC dermal absorption value of **30%** has been used in the human exposure assessment of Laqvin Prime ED 1401³

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 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 this 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. 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 0.5%. The product will therefore not be classified as a skin sensitizer. However the following sentence shall be stated on the label: Contains IPBC: May produce an allergic reaction.

³ In the CAR a dermal absorption value of 100% has been used for *in use* concentrations below 0.5%-0.6% IPBC.

2.7.2 Exposure

The biocidal product contains the active substances IPBC (0.5%) with min. purity 980 g/kg.

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 Prime ED 1401 is a ready-to-use water-based product and will be applied by industrial users by automated spraying.

The exposure to IPBC in the product Laqvin Prime ED 1401 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 automated spraying

Identification and description of exposure related tasks

The industrial use of Laqvin Prime ED 1401 is the automated spraying.

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

Mixing and loading

Laqvin Prime ED 1401 is delivered as ready-to use product for industrial automated processes. Usually Laqvin Prime ED 1401 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.

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.

Post-application: Handling of treated articles

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, 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.

Industrial exposure –automated spraying

Automated spraying is an industrial and automated process. 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 automated spraying treatment

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% was used for IPBC.

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
<p>Exposure duration: 60 minutes/cycle, 4 cycles/day (HEEG opinion, Dipping cycles PT8, 2009)</p> <p>Indicative exposure values:</p> <p>Dermal exp. hands (inside gloves): 8.7 mg/min (75th perc.) (50 rec.)</p> <p>Dermal exposure body: 108 mg/min (75th perc.) (45 rec.)</p> <p>Inhaled: 1.8 mg/m³ (75th perc.) (49 rec.) (BEAT)</p> <p><u>Note:</u> BEAT recommends using the 75th percentile for the “Timber pre-treatment (water)” scenario</p>	<p>Adult :</p> <p>BW : 60 Kg</p> <p>Inhalation rate : 1.25 m³/h (0.021 m³/min) (TNsG HE, 2007, pge 61)</p> <p>Coated coveralls: 10% (HEEG, 2010)</p> <p>Gloves are considered in the scenario</p> <p>No RPE</p>

Results

Results are summarised below (for calculations see Annex 3)

Table 2.7-3 Estimated exposures for automated spraying

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 Gloves	0.045	7	0.12

2.7.2.2 Exposure of the general public (secondary exposure)

In the following, relevant secondary exposure scenarios for the application of Laqvin Prime ED 1401 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 Prime ED 1401 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 Prime ED 1401 is assumed to be negligible.

An adult sands industrial treated wood with a sander for one hour. The sander generates 5 mg/m³ wood dust during this one hour work with a density of 0.4 g/cm³ (TM III 2008, MOTA) The resulting wood dust is inhaled with a inhalation rate of 1.25 m³/hour.

The amount of wood dust inhaled is, therefore:

$$5 \text{ mg dust/m}^3 \text{ air} \times 1.25 \text{ m}^3/\text{hour} \times 1 \text{ hour}/0.4 \text{ g/cm}^3 = 0.0156 \text{ cm}^3.$$

When exposure is estimated for a piece of wood treated by spraying, dipping or flow-coating, and assuming the highest use rate (200 g product/m² x 0,5% IPBC) .

Assumptions:

- IPBC: 1 g/ m² 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 m², volume: 0.004 m³)

- IPBC is concentrated in the outer 1 cm of the wood (volume of outer layer: 3008 cm³)

Results:

- Amount in outer layer:
IPBC: 1 g/ m² of wood x 0.4032 m² = 0.4032 g IPBC
- Concentration in wood dust:
IPBC: 0.4032 g/ 3008 cm³ = 0.134 mg IPBC/cm³
- Amount inhaled:
IPBC: 0.0156 x 0.134 mg IPBC/cm³ = 0.002 mg IPBC

- Systemic dose:
IPBC: 0.0012 mg IPBC/60 kg bw = **0.000035 mg IPBC/kg bw**

The exposure of an adult during sanding of wood is estimated to 0.000035 mg IPBC/kg bw.

Infant: Chewing piece of wood

Exposure of infants towards Laqvin Prime ED 1401 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 Prime ED 1401 pre-treated wood. The infant chews on one of the pieces of wood, thereby extracting 10% of the IPBC 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 1 g IPBC/ m² of wood, the following result is obtained:

Assumptions:

- Infant (10kg bw) chewing piece of wood of the following dimensions:
1 cm x 4 cm x 4 cm (area: 4.8x10⁻³ m², volume: 1.6x10⁻⁵ m³)
- IPBC: 1 g/ m² of wood

Results:

- Amount in treated wood:
IPBC: 1 g IPBC/ m² of wood x 4.8x10⁻³ m² = 4.88 mg IPBC
- Amount extracted by chewing:
IPBC: 4.88 mg IPBC x 10% = 0.48 mg IPBC
- Systemic dose:
IPBC: 0.48 mg IPBC/10 kg = **0.048 mg IPBC/kg bw**

The exposure of an infant towards Laqvin Prime ED 1401 after chewing of wood treated at 1 g IPBC/m² is estimated at 0.048 mg IPBC/kg bw.

Chronic phase secondary exposure

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

Exposure of adults towards Laqvin Prime ED 1401 (IPBC) 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 Prime ED 1401 is assumed to be negligible.

An adult sands industrial treated wood with a sander for six hours. The sander generates 5 mg/m³ wood dust during one hour work with a density of 0.4 g/cm³. The resulting wood dust (containing IPBC) is inhaled (inhalation rate: 1.25 m³/hour).

The amount of wood dust inhaled is, therefore:

$$5 \text{ mg dust/m}^3 \text{ air} \times 1.25 \text{ m}^3/\text{hour} \times 6 \text{ hours}/0.4 \text{ g/cm}^3 = 0.094 \text{ cm}^3.$$

When exposure is estimated for a piece of wood treated by spraying, dipping or flow-coating, and assuming the highest use rate of 1 g IPBC/m² of wood, the following result is obtained:

Assumptions:

- IPBC: 1 g/m² 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 m², volume: 0.004 m³)
- IPBC is concentrated in the outer 1 cm of the wood (volume of outer layer: 3008 cm³)

Results:

- Amount in outer layer:
IPBC: 1 g/m² of wood x 0.4032 m² = 0.4032 g IPBC
- Concentration in wood dust:
IPBC: 0.4032 g/ 3008 cm³ = 0.13 mg IPBC/cm³
- Amount inhaled:
IPBC: 0.094 cm³ x 0.13 mg IPBC/cm³ = 0.0122 mg IPBC
- Systemic dose:
IPBC: 0.0122 mg IPBC/60 kg bw = **2 x 10⁻⁴ mg IPBC/kg bw/day**

The exposure of an adult during sanding of wood treated at 1 g IPBC/m² is estimated at respectively **2 x 10⁻⁴ mg IPBC/kg bw/day**.

Child and infant: Playing on timber structures (playground)

Assumptions:

- Hand area: 200 cm² (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: 1 g/ m² of wood
- Dermal penetration rate : 30% for IPBC.

Results

- Amount on hands:
IPBC: 1 g IPBC/ m² x 0.02 m² x 20% x 3% = 0.12 mg IPBC
- Systemic dose:
IPBC:
Child: 0.12 mg on hands x 30%/15 kg bw = **0.0024 mg IPBC/kg bw/day**
Infant: 0.12 mg on hands x 30%/10 kg bw = **0.0036 mg IPBC/kg bw/day**

Playing on and touching of timber structures (playground) results in systemic exposure of **0.00024** mg IPBC/ kg bw/day for children and **0.0036** mg IPBC/ kg bw/day for infants.

Adult, child and infant: Inhalation of volatilised 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 has 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 m³ air/h (TNsG on HE, 2007, p 61)
- Child: 15 kg bw, residential time 18 hours, inhaling 0.35 m³ air/h (TGD, page 274)
- Infant: 10 kg bw, residential time 18 hours, inhaling 0.24 m³ air/h (TGD, page 274)
- Vapour pressure IPBC : 2.36x10⁻³ Pa (at 20°C)
- Molecular weight of IPBC : 281 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 : 2.36x10⁻³ Pa x 1%/101324 x 10⁶ = 2.33 x 10⁻⁴ ppm (mL/m³)
- SVC:
IPBC: 2.33 x 10⁻⁴ ppm x 281 g/mol/24.1L = 2.72 x 10⁻³ mg/m³
- Systemic dose:
IPBC
Adult: 2.72 x 10⁻³ mg/m³ x 1.25 m³/h x 18 h/60 kg bw = 1.02 x 10⁻³ mg/kg bw/day

Child: $2.72 \times 10^{-3} \text{ mg/m}^3 \times 0.35 \text{ m}^3/\text{h} \times 18 \text{ h}/15 \text{ kg bw} = 1.14 \times 10^{-3} \text{ mg/kg bw/day}$

Infant: $2.72 \times 10^{-3} \text{ mg/m}^3 \times 0.24 \text{ m}^3/\text{h} \times 18 \text{ h}/10 \text{ kg bw} = 1.18 \times 10^{-3} \text{ mg/kg bw/day}$

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

2.7.2.3 Combined exposure

Not relevant the product is only for industrial use.

2.7.2.4 Exposure to residues in food

Not relevant.

2.7.3 Risk Characterisation

Laqvin Prime ED 1401 is a ready-to-use water-based product containing 0.5% IPBC.

Laqvin Prime ED 1401 can be applied by industrial users as follow: automated spraying.

There are two different population groups that may be exposed to Laqvin Prime ED 1401: 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 spraying treatments.
- General public secondarily exposed to Laqvin Prime ED 1401.

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 Prime ED 1401 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 Prime ED 1401 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 AEL of 0.2 mg/kg bw/day for IPBC, as well as the calculation of MOE is presented below.

Table 2.7-4: Summary of % AEL and MOE values calculated for industrial users (automated spraying)

Operation	Total systemic exposure mg/kg bw/day	AEL _{long-term} mg/kg bw/day	MOE	% AEL
IPBC				
Post-application	0.12	0.2	170	59

Under normal use, Laqvin Prime ED 1401 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 Prime ED 1401 via the oral, dermal and inhalation routes.

The relevant secondary exposure scenarios for the application of Laqvin Prime ED 1401 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 2.7.2.2)

Acute secondary exposure:

- Adult : Inhalation of wood dust during sanding treated wood (acute)
- Infant : Chewing piece of wood

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 2.7-5: Summary of % AEL and MOE values calculated for secondary exposure

Operation	Total systemic exposure (acute) mg/kg bw	AEL _{Acute/Short-term} mg/kg bw/day	MOE	% AEL
Acute secondary exposure				
IPBC				
Adult: Inhalation of wood during sanding treated wood	0.000035	0.35	95492	0,01
Infant: Chewing piece of wood	0.048		729	13.7

Table 2.7-5: 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				
IPBC				
Adult: Inhalation of wood during sanding treated wood	0.00029	0.2	96	0.1
Child and infant: Playing on timber structures (playground) <i>Child</i>	0.0024		8333	1.2
Child and infant: Playing on timber structures (playground) <i>Infant</i>	0.0036		5556	1.8
Adult, child and infant: Inhalation of volatised residues, indoors <i>Adult</i>	1.02×10^{-3}		19 608	0.51
Adult, child and infant: Inhalation of volatised residues, indoors <i>Child</i>	1.1×10^{-3}		17 544	0.57
Adult, child and infant: Inhalation of volatised residues, indoors <i>Infant</i>	1.12×10^{-3}		16 949	0.59

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 substance

The environmental classification of the active substance is 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)	0.5

2.8.1.2 Environmental classification of the substance(s) of concern

The biocidal product does not contain any other substances of concern which contributes 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:

$$N; R50: \quad 0.5/2.5 = 0.2 \quad <1$$

The resulting classification for the product is the following: None

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, 2003⁴). 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 200 g/m². Laqvin Prime ED 1401 is applied by 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 spill in the process shall be collected and disposed according to local legislation. Nevertheless, the OECD application and storage scenarios for spraying are considered and provided for reasons of completeness.

For the envisaged fields of use for Laqvin Prime ED 1401 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 clad 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 Prime ED 1401

Main exposure scenario	Subcategory
Industrial application	- Spraying
Industrial storage	- Spraying
In-service leaching from treated wood	- Bridge over pond - Timber cladded house - 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 substance 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 Spraying treatments an assessment of cumulative leaching from treated wood in-service over a 15 year period was 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 laboratory leaching study has been submitted. It has been evaluated and leaching rates for the emission calculation have been calculated, see annex 4. 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 Prime ED 1401

Active substance	Leaching rates (mg/m ² /day)		
	Storage	TIME1 (30 days)	TIME2 (15 years)
IPBC	47.9	47.9	0.263

2.8.2.3 PEC calculations

The PECs for IPBC 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.

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

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

Table 2.8-3: Input parameters for the active substance

	IPBC
Half-life in the aquatic compartment (12°C)	3.1 hour (31.2 days)*
Half-life in the terrestrial compartment (12°C)	4.7 hour (9.5 days)*
Fraction staying in the water phase in the STP	0.97* IPBC is completely degraded to PBC in the STP
Koc	113.25 (198.1)*

* Value for PBC

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). Emission to sewage water during industrial application is not likely to occur, because spill in the process is collected and treated as hazardous waste and is not allowed to enter the STP. However, application and storage scenarios for 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 of 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.

A risk assessment for soils being target for PBC 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. 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 substance 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 ingredient. 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 m³ was used, this is equivalent to 1 days volume of a small creek with a flow rate of 0.3 m³ 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.

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 active ingredients (OECD 2003; page 118, equation 7.7 and 7.8).

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).

PEC for atmosphere

IPBC, has a low vapour pressure of $2.36 - 4.5 \times 10^{-3}$ Pa at 25°C combined with a Henry's Law constant of $3.38 - 6.45 \times 10^{-3}$ 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 (PEC_{oral 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.

Calculated PEC values are summarised in Table 2.8-4.

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)	43.1	2.30 *	-
Spraying (big plant)	431	23.0 *	-
Industrial storage			
Spraying (30 days – small plant)	-	0.122 #	0.0868 #
Spraying (15 years – small plant)	-	0.122 #	0.0876 #
Spraying (30 days – big plant)	-	1.22 #	0.868 #
Spraying (15 years – big plant)	-	1.22 #	0.876 #
In-service			
Noise Barrier (30 days)	50.3	2.68 *	0.0284 #
Noise Barrier (15 years)	0.276	0.0147 *	1.57 x 10 ⁻⁴ #
House (30 days)	-	-	0.0759 #
House (15 years)	-	-	4.20 x 10 ⁻⁴ #
Bridge over pond (30 days)	-	4.44 #	-
Bridge over pond (15 years)	-	3.24 *#	-

* Values for PBC

Values including 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 2.8-5 are used for the risk characterisation

Table 2.8-5: PNEC values used for risk characterisation

	IPBC/PBC
PNEC _{STP} (µg/L)	440/-
PNEC _{surface water} (µg/L)	0.5/41.3
PNEC _{sediment} (mg/kg wwt)	Covered by surface water
PNEC _{soil} (mg/kg wwt)	0.00434/0.149

Calculated PEC/PNEC values are summarised in Table 2.8-6.

Table 2.8-6: Summary of PEC/PNEC values (with and without degradation) for IPBC/PBC

IPBC/PBC	(PEC/PNEC) _{STP}	(PEC/PNEC) _{surface} water	(PEC/PNEC) _{soil}
Industrial application			
Spraying (small plant)	0.0980	0.0523 *	-
Spraying (big plant)	0.980	0.523 *	-
Industrial storage			
Spraying (30 days – small plant)	-	0.244 #	20.0 #
Spraying (15 years – small plant)	-	0.244 #	20.2 #
Spraying (30 days – big plant)	-	2.44 #	200 #
Spraying (15 years – big plant)	-	2.44 #	202 #
In-service			
Noise Barrier (30 days)	0.114	0.0610 *	6.54 #
Noise Barrier (15 years)	6.27 x 10 ⁻⁴	3.34 x 10 ⁻⁴ *	0.0362 #
House (30 days)	-	-	17.5 #
House (15 years)	-	-	0.0967 #
Bridge over pond (30 days)	-	8.87 #	-
Bridge over pond (15 years)	-	0.0783 **	-

* Values for PBC

Values including degradation

For industrial storage environmental risk for the soil compartment is identified for both the initial and the longer assessment period for both small and big plants. 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.

For the noise barrier scenario and the house scenario risk is identified for the soil compartment within the initial time period. This is however acceptable as the risks are reduced below the trigger value of 1 after 15 years. For the bridge over pond scenario a risk is identified for the aquatic compartment within the initial time period. However the risk is reduced below the trigger of 1 after 15 years.

As stated in section 2.8.1.3, the reported PNEC for the sediment is derived using the equilibrium method. So the risk of the sediment compartment is the same as that assessed for surface water.

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).

Conclusion: The overall conclusion of the environmental risk assessment for the product Laqvin Prime ED 1401 is that no unacceptable risk is identified for secondary poisoning, STP, air and groundwater compartments. However a risk is identified for the soil during storage and as a consequence, the **freshly treated wood is to be stored under shelter or on impermeable hard standing to prevent direct losses to soil. Furthermore any losses must be collected for reuse or disposal.**

2.9 Measures to protect man, animals and the environment

In the following measures to be taken to protect man, animals and the environment from the biocidal product Laqvin Prime ED 1401 are described. The measures to be taken to protect from the active substance IPBC were already described in the dossier submitted for the active substance and are not repeated here.

2.9.1 Recommended methods and precautions concerning handling, use, storage, transport or fire

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 exhaust 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: Use 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.

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.

2.9.2 Emergency measures in case of an accident

First aid measures:

General information:

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

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 12 "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: Within the knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 91/689/EEC

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 9 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 Prime ED 1401 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 175 – 200 g/m² corresponding to 132 - 150 ml/m². 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 the automated spraying process is considered to be acceptable as shown by the exposure calculations. Furthermore, the use of Laqvin Prime ED 1401 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 observed, the use of Laqvin Prime ED 1401 does not pose an unacceptable risk to human health

Environmental assessment:

The conclusion of the environmental risk assessment for the product Laqvin Prime ED 1401 is that no unacceptable risk is identified for secondary poisoning, STP, air, surface water and groundwater compartments. However, risk is identified for soil during storage, and as a consequence, the freshly treated wood is to be stored under shelter or on impermeable hard standing to prevent direct losses to soil. Furthermore any losses must be collected for reuse or disposal.

3.2 Decision regarding Authorisation of the biocidal product

The Danish CA proposes the authorisation of the biocidal product Laqvin Prime ED 1401 as a wood preservative (PT 8) for use by industrial mechanised spraying. The use rate is 175-200 g/m² corresponding to 132-150 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 Prime ED 1401 contains 0.50% (w/w) IPBC.

Particular Conditions

Purity of the Active Substance

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

IPBC: 980 g/kg

Product: Laqvin Prime ED 1401

RMS: DK

December 2011

Applicant: Sherwin-Williams Sweden Coatings KB

Product Type

PT8: Wood preservatives

Expiry Date of the Authorisation:

The authorisation of the product Laqvin Seal AA 1939 expires on 30 June 2020, which is the expiry date of Annex I listing of the active substances, i.e. that of IPBC.

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 data⁶ 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
						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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 Prime ED 1401 Danish Technological Institute. Wood Technology. 23th June 2011. Order no. 438403-2	Becker Aroma	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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	
						<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IVB 5	2	Morsing and Lindegaard	2010	Efficacy data: ED 1401 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	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IVB 7	3	Lindegaard and Morsing	2010	Title: 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 are not covered and are not in Contact with Ground: 23-07-2009. The 2 × 1 hour immersion regime. Laboratory name: Danish Technological Institute Laboratory report number: Order no.: 341814-3	Becker Acroma KB	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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 100% default for solutions containing <0.5%-0.6% IPBC (based on <i>in vitro</i> human skin study with solvent based on model product)

Classification

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

Annex 3: Human exposure assessment**Laqvin Prime ED1401 – Industrial user – Post-application phase – IPBC /
Model : Timber pre-treatment (water) (BEAT)**

Product		Units
active substance	0.5%	%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	2088	mg
Mitigation by gloves	Not applicable	
Actual hand deposit	2088	mg [product]
Total dermal exposure		
Total dermal deposit	4680	mg [product]
Active substance	23.4	mg
Dermal absorption	30.00%	%
Systemic exposure via dermal route	7.02	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	0.045	a.s. mg
Systemic exposure		
Total systemic exposure	7.065	a.s. mg
Body weight kg	60	kg
Systemic exposure	0.11775	mg/kg/day

Annex 4: Leaching calculations

A laboratory leaching test (2 x 1 h) for Laqvin Prime ED 1401 was, with some deviations, conducted in accordance with OECD Guidance No. 107 (2009) "Guidance on the estimation of emission from preservative treated wood to the environment: for wood held in storage after treatment and for wooden commodities that are not covered and are not in contact with ground".

In Figure 1 the measured leaching values, fitted with a power function, are shown.

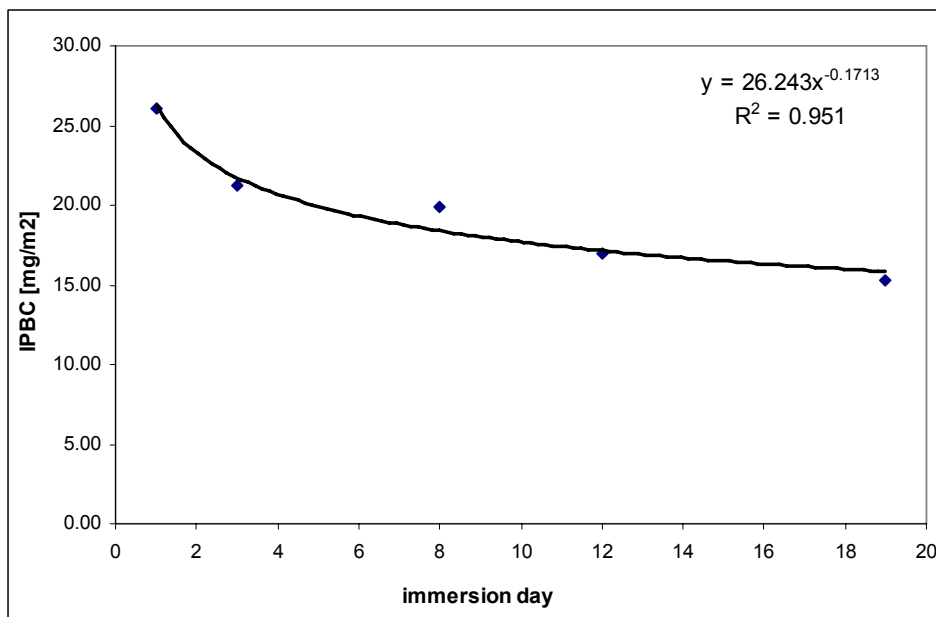


Figure 1 Leaching values of IPBC (mg/m²) measured in the laboratory leaching test, fitted with a power function

In the 2x1 hour immersion regime, described in the OECD guidance document, the wood is immersed in water 2 times, at 9 different days (day 1, 3, 5, 8, 10, 12, 15, 17, 19). According to the OECD guidance document (section 3.6), the water (emissate) should be analyzed on each sampling day. In this study the wood has been immersed in water at 9 days, but as can be seen in Figure 1, only 5 out of 9 water samples has been analyzed.

Based on visual assessment and on the calculated R^2 value of 0.9514, it is clear that the curve shown in Fig 1 fits the data well. The 4 missing data points can therefore be calculated by interpolation. All 9 datapoints (measured and calculated) are shown in Figure 2.

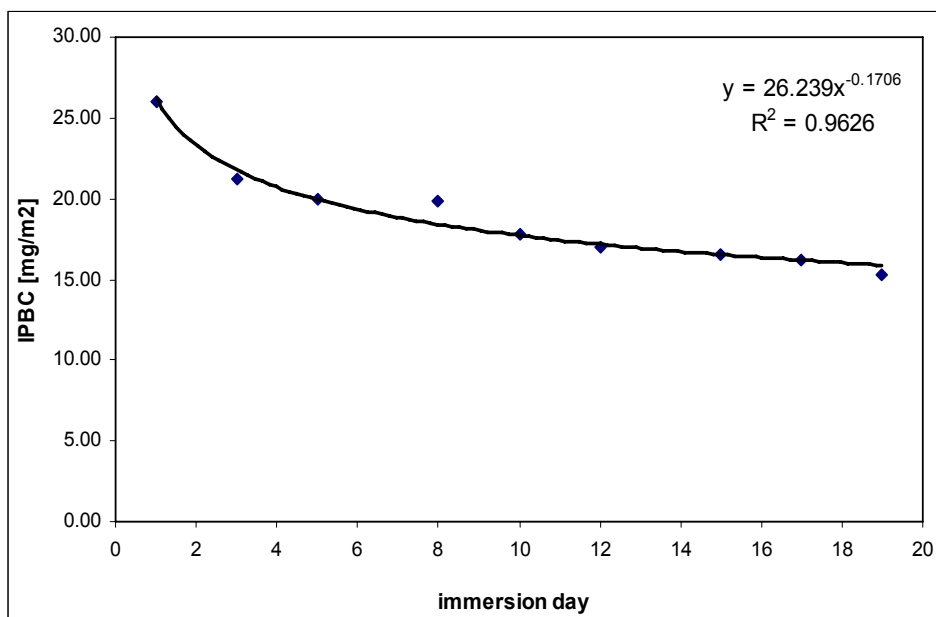


Figure 2 Leaching values of IPBC (mg/m²) both measured and calculated

Calculation of the missing data points is not the optimum procedure, which of course would be to measure all water samples. However subsequent calculations show that in this case it does not influence on the final risk calculations.

The combined measured and calculated values were then used for calculation and plotting of the average daily leaching rate for each time interval 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 $FLUX(\Delta t)=f(t)$ curve a polynomial regression of second order was employed:

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

The fitted daily $FLUX(t)$ corresponds to the quantity of the preservative compound leached per m² wood within the one day interval of the specific day t, while the experimental $FLUX(\Delta t)$ represents the average quantities of the active substance leached per m² 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 3.

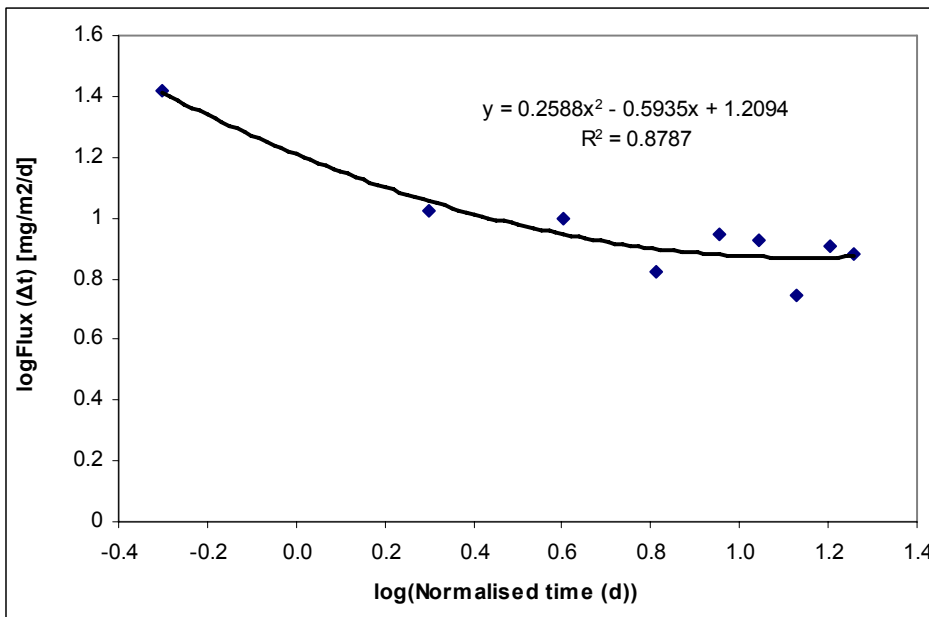


Figure 3 Fitted daily FLUX(Δt) of IPBC versus time

In Figure 4 the curve is extrapolated, and it is seen that the FLUX is increasing over time.

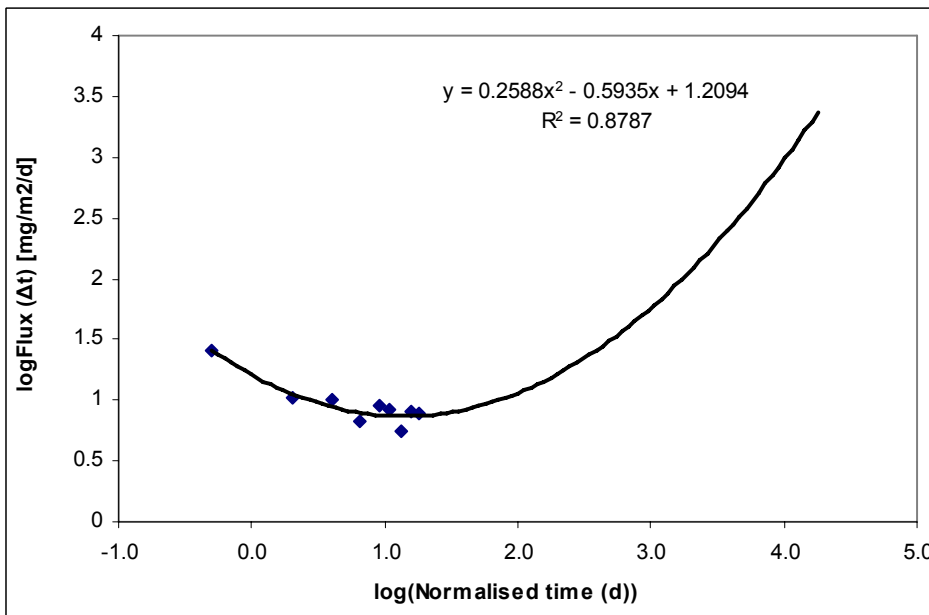


Figure 4 Fitted daily FLUX(Δt) of IPBC versus time, extrapolated to 15 years

This increase in leaching is not realistic, and the curve can not be used for calculation of fluxrates. Instead the FLUX(Δt) values are used:

$$FLUX(\Delta t) = Q_d(\Delta t) / \Delta t$$

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 5. These are only measured values. No calculated values are included here.

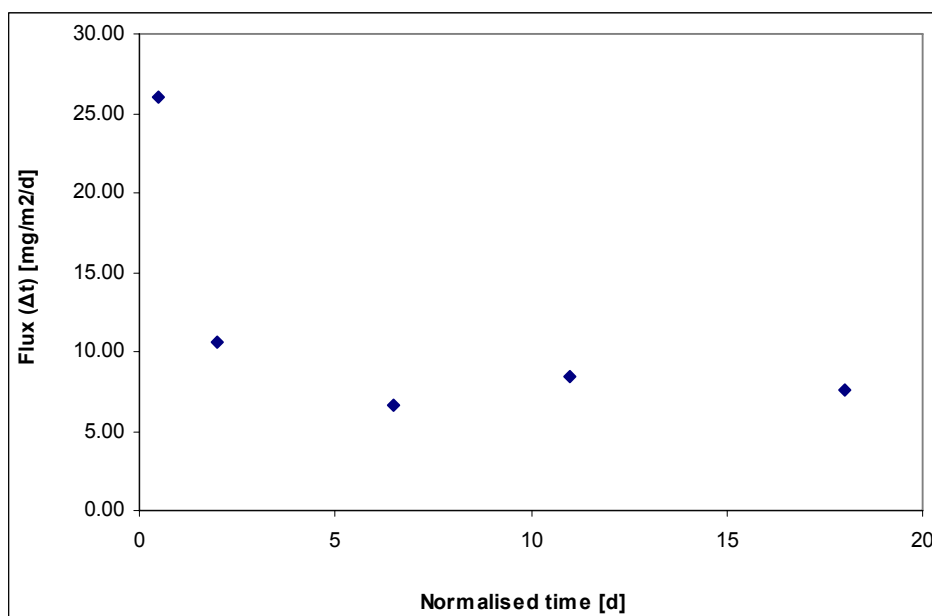


Figure 5 FLUX(Δt) values

The first measured value is used as the short term leaching rate, $Q_{\text{leach, 30 days}}$, while the last measured value is used as the long term leaching rate $Q_{\text{leach, 15 years}}$.

Because the intended application rate is higher than the amounts applied in the laboratory leaching study a correction factor of 1.646 has to be adopted. The maximum intended applied amount of IPBC (including the IPBC from the topcoat (max application) used in the leaching study) is 1.438 g/m², while in the leaching study only 0.873 g/m² was applied. With this approach the following leaching rates can be derived:

TIME 1, 30 days:

$$Q_{\text{leach, 30 days}} = 26.06 \text{ mg/m}^2/\text{d} \times 1.646 = 42.895 \text{ mg/m}^2/\text{d}$$

TIME 2, 15 years:

$$Q_{\text{leach, 15 years}} = 7.64 \text{ mg/m}^2/\text{d} \times 1.646 = 12.567 \text{ mg/m}^2/\text{d}$$

The calculated release for TIME 2 does however exceed the total applied amount. Therefore, according to the suggestions of the Arona Leaching Workshop in June 2005 (ECB, 2005), leaching rates for the long-term assessment are derived by dividing the maximum application rate of the active ingredient by the respective service life time. For the long term risk assessment the following leaching rate is found:

TIME 2, 15 years (100 % leaching):

$$Q_{\text{leach, 15 years}} = 1437.5 \text{ mg/m}^2 / 5475 \text{ d} = 0.2626 \text{ mg/m}^2/\text{d}$$

The leaching study is conducted with a top coat applied over the product. Because the product is intended to be used with any top coat an assessment factor of 10 is used.

The following leaching rates are therefore used as input parameters for the different exposure scenarios:

TIME 1, 30 days: $Q_{\text{leach, 30 days}} = 42.9 \text{ mg/m}^2/\text{d}$

TIME 2, 15 years (100 %): $Q_{\text{leach, 15 years}} = 0.263 \text{ mg/m}^2/\text{d}$

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:

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

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: a) 100% leaching	None
Study with no top coat	No top coat or any top coat	Use: a) calculated leaching rates b) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	None
Study with top coat	No top coat	Use: a) 100% leaching	None
	With top coat which is “stable” according to EN927-2* Amateur use	Use: a) calculated leaching rates x 10 , both for time1 and time2 b) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	a) Treated timber should receive a top coat ... b) Top coat should be maintained
	With top coat which is “stable” according to EN927-2* Industrial/professional use	Use: a) calculated leaching rate for time1. For time2 use calculated leaching rate x 5 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... b) Top coat should be maintained
	With any top coat Amateur, professional or industrial use	Use: a) calculated leaching rates x 10 , both for time1 and time2 b) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	a) Treated timber should receive a top coat ... 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: a) calculated leaching rates (study without top coat) b) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	None
	With top coat which is “stable” according to EN927-2* Amateur use	Use: a) calculated leaching rates x 10 , both for time1 and time2 (study with top coat) b) leaching rates from study without top coat if calculated leaching rates from a) exceed the ones from study without top coat ** c) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	a) Treated timber should receive a top coat ... b) Top coat should be maintained
	With top coat which is “stable” according to EN927-2* Industrial or professional use	Use: a) calculated leaching rate for time1. For time2 use calculated leaching rate x 5 (study with top coat) b) leaching rates from study without top coat if calculated leaching rates from a) exceed the ones from study without top coat** 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... b) Top coat should be maintained
	With any top coat Amateur, professional or industrial use	Use: a) calculated leaching rates x 10 , both for time1 and time2 (study with top coat) b) leaching rates from study without top coat if calculated leaching rates from a) exceed the ones from study without top coat** c) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	a) Treated timber should receive a top coat ... 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