

Bilag 2

Product Assessment Report

Laqvin Clear EM 1401

Internal registration no:	MST-671-01759
Authorisation/Registration no:	694-5
Granting date/entry into force of authorisation/ registration:	9 December 2011
Expiry date of authorisation/ registration:	31 March 2020
Active ingredient:	IPBC Propiconazole
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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Postal Code:	SE-19502
Country:	Sweden
Telephone:	+46 38126260
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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 Clear EM 1401 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
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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

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	Laqvin Clear
Manufacturer's development code number(s), if appropriate:	EM 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 0.4% Propiconazole 0.3%
Formulation type:	Water based liquid
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 stain fungi
Category of users:	For industrial use only
Directions for use including minimum and maximum application rates,	The product is applied twice at a total rate of 260-320 g/m ² .

application rates per time unit (e.g. number of treatments per day), typical size of application area:	
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/feedingstuff (yes/no)	No
Proposed Label:	Yes
Use Restrictions:	

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/EC
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:	Supplier	Supplier
Company Name:	Lanxess Deutschland GmbH	JANSSEN PHARMACEUTICA NV
Address:	Chempark	Turnhoutseweg 30
City:	Leverkusen	Beerse
Postal Code:	D-51369	B-2340
Country:	Germany	Belgium
Telephone:	+49 (0) 214 30-57344	+32 14 6022 22
Fax:	+49 (0) 214 30-24278	n.a.

1.5.4 Information on the substance(s) of concern

Laqvin Clear EM 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 relevant letters of access.

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 pure respectively) and the substance of concern Naphtha (petroleum), hydrotreated heavy.

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 Classification and labelling of the biocidal product

The proposed classification and labelling of Laqvin Clear EM 1401 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 feedingstuffs

The product shall 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 lined metal or lined steel containers of the following capacities: 750 ml, 1 L, 2.5 L, 5 L, 20 L, 120 L, 200 L or 1000 L.

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.

² Competent Authority Report

A summary of the physical and chemical properties of Laqvin Clear EM 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 observation at 20°C.	N	Liquid, water dispersion.	Lindegaard & Morsing, 2011
Colour	Performed by visual observation at 20°C.	N	Milky white with slight yellow tone	Lindegaard & Morsing, 2011
Odour	Performed by odour observation at 20°C.	N	No intense odour. As acrylic paint.	Lindegaard & Morsing, 2011
Explosive properties	–	N	The explosive properties are not measured since the product is waterborne. Limitations. lower 1.1 % v/v, upper 12.7 % v/v Contains VOC (Volatile organic compounds) (ISO) 25 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.	Lindegaard & Morsing, 2011
Relative density / bulk density	SS-EN ISO 2811-1:2011	N	1.03±0.1 g/mL	Becker Acroma No official report for the product. The density is measured routinely as part of

	Method	GLP (Y/N)	Results	Reference
				quality control process.
Effects of temperature	CIPAC M46. 35oC for 8 weeks.	N	<p>CIPAC M46. No changes of biocidal concentration. By visual observation some separation of the product. Easy to stir. By smell observation it was observed that there was no intense odour and the product smelled as acrylic paint.</p> <p>Initial analysis: 0.41% and 0.41% IPBC. Mean: 0.41%</p> <p>0.34% and 0.32% propiconazole Mean: 0.33%</p> <p>After storage: 0.39% and 0.39% IPBC. Mean:0.39%</p> <p>0.32% and 0.31% propiconazole. Mean: 0.315%</p> <p>Variation: IPBC: 4.9%</p> <p>Propiconazole: 4.5%</p>	Lindegaard & Morsing, 2011
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 8 weeks at 35°C: There was no reactivity towards container material.</p> <p>For 11 months at room temperature There was no</p>	Lindegaard & Morsing, 2011

	Method	GLP (Y/N)	Results	Reference
			reactivity towards container material.	
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 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	110±5 KU stormer equals to: 2675 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	11 mth

Laqvin Clear EM 1401	IPBC	0.41 % -	0.375 % 8.5 %
	Propiconazole	0.33 % -	0.305 % 7.6 %
	pH	8.5 (undiluted)	8.4 (undiluted)

References: Lindegaard & Morsing, 2011

B3_1	Berit Lindegaard and Elisabeth Morsing	2011	Test report of storage stability of Laqvin Clear EM 1401 Danish Technological Institute. Wood Technology. 23th June 2011. Order no. 438403-5	Becker Aroma	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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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 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 Clear EM 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 Clear EM 1401 from the accelerated study shows that the degradation of IPBC and propiconazole after 8 weeks at 35°C is 4.9 % and 4.5 %, respectively, which is within the limit of 5 % degradation (according to OECD 113: Screening test for thermal stability and stability in air).

According to the 11 months results from the shelf-life study, IPBC and propiconazole has degraded by 8.5 % and 7.6 %, 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 11 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: 260 g product/m²

Maximum: 320 g product/m²

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 Clear EM 1401 contains 0.4% (w/w) IPBC and 0.3% (w/w) propiconazole. The product is used as a product to protect wooden commodities (E.g. wooden windows and doors) against blue stain fungi. It is used as wood preservative (BPD Product Type 8) for industrial use. The mode of application is automated spraying (usually by robots in closed systems).

Laqvin Clear EM 1401 is delivered as a ready-to-use water based product.

For industrial use (automated spraying) the product is applied at a rate of 260-320 g/m², which results in a maximum total applied amount of 1.04-1.28 g IPBC/m² og 0.78- 0.96 g propiconazol/m² timber.

The intended use is covered by the CAR for IPBC and propiconazole.

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 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 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. However since no dermal absorption values for the water based with an in use concentrations of 0.4% IPBC are available a default value of 100 % has to be set³.

For dilute solutions of propiconazole (0.006% – 1.4%) a dermal absorption values of app. 2% has been set in the CAR. Since Laqvin Clear EM 1401 contains 0.3% propoconazol a dermal absorption value of 2% will be used.

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

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 endpoint. 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 0.4% and Propiconazole in the concentration of 0.3%. The product will therefore not be classified as a skin sensitizer. However the following sentence shall be stated on the label: Contains IPBC, propiconazole (respectively hydroxyphenyl benzotriazol derivate and Bis(1,2,2,6,6-pentamethyl-4-piperidyl)sebacate): May produce an allergic reaction.

2.7.2 Exposure

The biocidal product contains the active substances IPBC (0.4%) and propiconazole (0.3%) (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 Clear EM1401 is a ready-to-use water-based product and can be applied by industrial users as automated spraying.

The exposure to IPBC and Propiconazol in the product Laqvin Clear EM1401 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 uses of Laqvin Clear EM1401 are the industrial automated spraying process.

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 Clear EM1401 is delivered as ready-to use product for industrial automated processes. 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, post-application exposure to the product may occur during manual contact with handling of the treated (wet) wood and by handling equipment, and/or contaminated clothing. Usually, there should be no manual contact with treated wood until the product has completely dried.

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.

The industrial processes are best described by the pre-worked example for timber pre-treatment with water-based products which is available from the BEAT database (TNsG 2007 (BEAT)). This example has been chosen over the Handling model 1 described in the TNsG on human exposure 2002, as it is based on a larger set of data points and newer results.

The BEAT data cover exposures from both handling and incidental exposure; the application phase itself has no significant exposure potential.

As mentioned 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.

For the dermal absorption 100% and 2.0% were used for IPBC and propiconazole respectively.

See below for other relevant default values.

Table 2.7-2: Relevant default values (TNsG 2007 BEAT)

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: Dermal exp. hands (inside gloves): 8.7 mg/min (75th perc.) (50 rec.) Dermal exposure body: 108 mg/min (75th perc.) (45 rec.) 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 3A)

Table 2.7-3 Estimated exposures for automated spraying (Annex 3A)

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	0.036	18.73	0.31
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 Gloves	0.027	0.281	0.0051

Recommended PPE:

Suitable protective gloves, footwear and cotton coverall.

According to the above calculations, which has been based on values from the BEAT database and the HEEG opinion on “Defaults and appropriate models to assess human exposure for dipping processes (PT8)” (2009), the product poses an unacceptable risk due to the exposure to IPBC (156 % of AEL) when applied by automated spraying processes. On the basis of a hearing period during which the Company Sherwin-Williams Sweden Coatings KB have had the opportunity to comment on the risk evaluation, the Danish EPA has accepted to include the exposure calculations of the automated processes according to the TNsG 2002, which has been agreed in EU as an acceptable choice of guideline in the risk evaluation of wood preservatives.

Hence, the exposure calculations are carried out using the following indicative values and duration of exposure according to the TNsG 2002.

The indicative values from the Handling model 1 (TNsG 2002, p. 162) for hand and body exposure have been re-expressed as mg/min instead of mg/cycle using 180 min. as the duration of a cycle for the dipping process (TNsG 2002 database on Human Exposure).

Applied parameters:

Hands	6.0 mg/min (actual, 75 th percentile, n=43)
Glove penetration	not considered for actual hand exposure values
Body	47.6 mg/min (potential, 75 th percentile, n=45)
Clothing penetration	10% (HEEG opinion, 2010)

Inhalation	1.9 mg/m³ (potential, 75 th percentile, n=49)
Inhalation rate	1.25 m³/h (default)
Duration	180 min (TNsG 2002 database on Human Exposure)
Body weight	60 kg (default)

Results are summarised below (for calculations see Annex 3B)

Continued Table 2.7-3 Estimated exposures for automated spraying (Annex 3B)

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	0.029	7.75	0.13
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 Gloves	0.021	0.12	0.0023

2.7.2.2 Exposure of the general public (secondary exposure)

In the following, relevant secondary exposure scenarios for the application of Laqvin Clear EM1401 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 Clear EM1401 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 Clear EM1401 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 and assuming the highest use rate (350 g product/m²) of 1.28 g IPBC/ m² of wood and 0.96 g Propiconazole/ m² of wood, the following result is obtained:

Assumptions:

- IPBC: 1.28 g/ m² of wood
- Propiconazole: 0.96 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 and Propiconazole are concentrated in the outer 1 cm of the wood (volume of outer layer: 3008 cm³)

Results:

- Amount in outer layer:
IPBC: 1.28 g/ m² of wood x 0.4032 m² = 0.51 g IPBC
Propiconazole: 0.96 g/ m² of wood x 0.4032 m² = 0.38 Propiconazole
- Concentration in wood dust:
IPBC: 0.51 g/ 3008 cm³ = 0.17 mg IPBC/cm³
Propiconazole: 0.38 g/ 3008 cm³ = 0.12 mg Propiconazol/cm³
- Amount inhaled:
IPBC: 0.0156 x 0.17 mg IPBC/cm³ = 0.003 mg IPBC
Propiconazole: 0.0156 x 0.12 mg Propiconazol/cm³ = 0.002 mg Propiconazole
- Systemic dose:
IPBC: 0.003 mg IPBC/60 kg bw = **0.000044 mg IPBC/kg bw**
Propiconazole: 0.002 mg Propiconazol/60 kg bw = **0.000033 mg Propiconazole/kg bw**

The exposure of an adult during sanding of wood is estimated to respectively 0.000044 mg IPBC/kg bw and 0.000033 mg Propiconazol/kg bw.

Infant: Chewing piece of wood

Exposure of infants towards Laqvin Clear EM1401 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 Clear EM1401 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 1.28 g IPBC/ m² of wood and 0.96 g Propiconazol/ m² 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 m², volume: 1.6x10⁻⁵ m³)
- IPBC: 1.28 g/ m² of wood
- Propiconazole: 0.96 g/ m² of wood

Results:

- Amount in treated wood:
IPBC: 1.28 g IPBC/ m² of wood x 4.8x10⁻³ m² = 6.1 mg IPBC
Propiconazole: 0.96 g Propiconazole/ m² of wood x 4.8x10⁻³ m² = 4.6 mg Propiconazole
- Amount extracted by chewing:
IPBC: 6.1 mg IPBC x 10% = 0.61 mg IPBC
Propiconazole: 4.6 mg Propiconazole x 10% = 0.46 mg Propiconazole
- Systemic dose:
IPBC: 0.61 mg IPBC/10 kg = **0.061 mg IPBC/kg bw**
Propiconazole: 0.46 mg Propiconazol /10 kg = **0.046 mg Propiconazole/kg bw**

The exposure of an infant towards Laqvin Clear EM1401 after chewing of wood treated at 1.28 g IPBC/m² and 0.96 g Propiconazol/ m² is estimated at 0.061 mg IPBC/kg bw and 0.046 mg Propiconazol/kg bw.

Chronic phase secondary exposure**Adult: Inhalation of wood dust during sanding treated wood (chronic)**

Exposure of adults towards Laqvin Clear EM1401 (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 Clear EM1401 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 and Propiconazole) 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 and assuming the highest use rate of 1.28 g IPBC/ m² of wood and 0.96 g Propiconazole/ m² of wood, the following result is obtained:

Assumptions:

- IPBC: 1.28 g/ m² of wood
- Propiconazole: 0.96 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 and Propiconazole are concentrated in the outer 1 cm of the wood (volume of outer layer: 3008 cm³)

Results:

- Amount in outer layer:
IPBC: 1.28 g/ m² of wood x 0.4032 m² = 0.51 g IPBC
Propiconazole: 0.96 g/ m² of wood x 0.4032 m² = 0.38 Propiconazole
- Concentration in wood dust:
IPBC: 0.51 g/ 3008 cm³ = 0.17 mg IPBC/cm³
Propiconazole: 0.38 g/ 3008 cm³ = 0.12 mg Propiconazol/cm³
- Amount inhaled: hertil tirsdag aften
IPBC: 0.094 cm³ x 0.17 mg IPBC/cm³ = 0.016 mg IPBC
Propiconazole: 0.094 cm³ x 0.12 mg Propiconazol/cm³ = 0.011 mg Propiconazole
- Systemic dose:
IPBC: 0.016 mg IPBC/60 kg bw = **2.68x10⁻⁴ mg IPBC/kg bw/day**
Propiconazole: 0.011 mg Propiconazole/60 kg bw = **2.01 x10⁻⁴mg Propiconazole/kg bw/day.**

The exposure of an adult during sanding of wood treated at 1.28 g IPBC/m² and 0.96 g Propiconazole/ m² is estimated at respectively **2.68 x10⁻⁴ mg IPBC/kg bw/day** and **2.01x10⁻⁴mg Propiconazole/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: 1.28 g/ m² of wood
- Propiconazol: 0.96 g/ m² of wood
- Dermal penetration rate : 100% for IPBC and 2% for Propiconazol

Results

- Amount on hands:

IPBC: $1.28 \text{ g IPBC/ m}^2 \times 0.02 \text{ m}^2 \times 20\% \times 3\% = 0.15 \text{ mg IPBC}$

Propiconazole: $0.96 \text{ g Propiconazole/ m}^2 \times 0.02 \text{ m}^2 \times 20\% \times 3\% = 0.11 \text{ mg Propiconazole}$

- Systemic dose:

IPBC:

Child: $0.17 \text{ mg on hands} \times 100\%/15 \text{ kg bw} = \mathbf{0.010 \text{ mg IPBC/kg bw/day}}$

Infant: $0.13 \text{ mg on hands} \times 100\%/10 \text{ kg bw} = \mathbf{0.015 \text{ mg IPBC/kg bw/day}}$

Propiconazol:

Child: $0.048 \text{ mg on hands} \times 2\%/15 \text{ kg bw} = \mathbf{1.5 \times 10^{-4} \text{ mg Propiconazole/kg bw/day}}$

Infant: $0.048 \text{ mg on hands} \times 2\%/10 \text{ kg bw} = \mathbf{2.3 \times 10^{-4} \text{ mg Propiconazole/kg bw/day}}$

Playing on and touching of timber structures (playground) results in systemic exposure of **0.0010 mg IPBC/ kg bw/day** and **1.5×10^{-4} mg Propiconazole/kg bw/day** for children and **0.015 mg IPBC/ kg bw/day** and **2.3×10^{-4} mg Propiconazole/kg bw/day** for infants, respectively.

Adult, child and infant: Inhalation of volatilsed 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 volatilsed residues indoors was calculated.

The exposure of adults, children and infants to volatilsed 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 $1.25 \text{ m}^3 \text{ air/h}$ (TNsG on HE, 2007, p 61)
- Child: 15 kg bw, residential time 18 hours, inhaling $0.35 \text{ m}^3 \text{ air/h}$ (TGD, page 274)
- Infant: 10 kg bw, residential time 18 hours, inhaling $0.24 \text{ m}^3 \text{ air/h}$ (TGD, page 274)
- Vapour pressure IPBC : $2.36 \times 10^{-3} \text{ Pa}$ (at 20°C)
- Vapour pressure Propiconazole: $5.6 \times 10^{-5} \text{ Pa}$ (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 : $2.36 \times 10^{-3} \text{ Pa} \times 1\%/101324 \times 10^6 = 2.33 \times 10^{-4} \text{ ppm (mL/m}^3\text{)}$

Propiconazole : $5.6 \times 10^{-5} \text{ Pa} \times 1\%/101324 \times 10^6 = 5.53 \times 10^{-6} \text{ ppm (mL/m}^3\text{)}$

- SVC:

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

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

- Systemic dose:

IPBC

Adult: $2.72 \times 10^{-3} \text{ mg/m}^3 \times 1.25 \text{ m}^3/\text{h} \times 18 \text{ h}/60 \text{ kg bw} = 1.02 \times 10^{-3} \text{ mg/kg bw/day}$

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

Propiconazole

Adult: $7.85 \times 10^{-5} \text{ mg/m}^3 \times 1.25 \text{ m}^3/\text{h} \times 18 \text{ h}/60 \text{ kg bw} = 2.94 \times 10^{-5} \text{ mg/kg bw/day}$

Child: $7.85 \times 10^{-5} \text{ mg/m}^3 \times 0.35 \text{ m}^3/\text{h} \times 18 \text{ h}/15 \text{ kg bw} = 3.30 \times 10^{-5} \text{ mg/kg bw/day}$

Infant: $7.85 \times 10^{-5} \text{ mg/m}^3 \times 0.24 \text{ m}^3/\text{h} \times 18 \text{ h}/10 \text{ kg bw} = 3.39 \times 10^{-5} \text{ mg/kg bw/day}$

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

2.7.2.3 Combined exposure

Not relevant since the product is for industrial use only.

2.7.2.4 Exposure to residues in food

Not relevant.

2.7.3 Risk characterisation

Laqvin Clear EM1401 is a ready-to-use water-based product containing 0.4% IPBC and 0.3% Propiconazole.

Laqvin Clear EM1401 can be applied by industrial users by automated spraying.

There are two different population groups that may be exposed to Laqvin Clear EM1401: 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.
- General public secondarily exposed to Laqvin Clear EM1401.

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 Clear EM1401 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 or 2002 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 Clear EM1401 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 2.7-4: Summary of % AEL and MOE values calculated for industrial users (automated spraying) using default values according to TNsG 2002 (Annex 3B)

Operation	Total systemic exposure mg/kg bw/day	AEL _{long-term} mg/kg bw/day	MOE	% AEL
IPBC				
Post-application	0.13	0.2	154	65
Propiconazole				
Post-application	0.0023	0.08	3492	3

As shown above in table 2.7-4 the exposure figure for IPBC do not exceed the long term AEL of 0.2 mg/kg bw/day and the MOE ratios was greater than 100 under the given conditions. Thus, the risk for the industrial worker during the automated spraying process is considered to be acceptable.

Under normal use, Laqvin Clear EM1401 does not pose an unacceptable health risk for industrial users when using this product for industrial spraying and approval can be granted.

The exposure calculations are based on a default dermal absorption value of 100% when the a.i concentration of IPBC <0.5%. This is in accordance with the conclusion from the CAR. No studies on dermal absorption of this specific formulation or similar formulation with an concentration of 0.5% IPBC has been submitted for this application or the CAR.

However it has to be stressed that at the next re-evaluation of the product the TNsG 2007 and the HEEG's opinion regarding cycles per day (240 min instead of 180 min) will be used. In addition to

this dermal absorption values of IPBC concentration lower than 0.5% should be provided for the evaluation.

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 Clear EM1401 via the oral, dermal and inhalation routes.

The relevant secondary exposure scenarios for the application of Laqvin Clear EM1401 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 2.7.2.4)

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	0.000047	0.35	783.333	0.0128
Infant: Chewing piece of wood	0.061		570	17.6
Propiconazole				
Adult: Inhalation of wood during sanding treated wood	0.0000335	0.3	895.238	0.0112
Infant: Chewing piece of wood	0.046		651	15.4

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	0.000268	0.2	74.603	0.13
Child and infant: Playing on timber structures (playground) <i>Child</i>	0.010		1953	5.1
Child and infant: Playing on timber structures (playground) <i>Infant</i>	0.015		1302	7.7
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>	1.14×10^{-3}		17 544	0.57
Adult, child and infant: Inhalation of volatised residues, indoors <i>Infant</i>	1.18×10^{-3}		16 949	0.59

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				
Propiconazole				
Adult: Inhalation of wood during sanding treated wood	0.00020	0.08	39788	0.25
Child and infant: Playing on timber structures (playground) <i>Child</i>	1.5×10^{-4}		52083	0.2
Child and infant: Playing on timber structures (playground) <i>Infant</i>	2.3×10^{-4}		34722	0.3
Adult, child and infant: Inhalation of volatised residues, indoors <i>Adult</i>	2.9×10^{-5}		272 109	0.04
Adult, child and infant: Inhalation of volatised residues, indoors <i>Child</i>	3.3×10^{-5}		242 424	0.04
Adult, child and infant: Inhalation of volatised residues, indoors <i>Infant</i>	3.4×10^{-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 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)	0.4
Propiconazole	N; R50/53	0.88 (algae)	0.3

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	$0.3/25 = 0.012$	<1
N; R50	$0.4/2.5 + 0.3/25 = 0.17$	<1
N; R51/53	$0.3/2.5 = 0.12$	<1
R52/53	$0.3/0.25 = 1.2$	>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, 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 320 g/m². The application technique for Laqvin Clear EM 1401 is industrial spraying. Application and storage takes place indoor and neither product nor treated wood are in contact with soil. In general, emissions to sewage water during application are not likely to occur, because residues and waste solutions will be recycled or treated as special waste and will not be discharged into the public sewage system. Nevertheless, the OECD application and storage scenarios for automated spraying are considered and provided for reasons of completeness.

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

For the envisaged fields of use for Laqvin Clear EM 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.

Table 2.8-1: Relevant exposure scenarios for use of Laqvin Clear EM 1401

Main exposure scenario	Subcategory
Industrial application	- Automated spraying
Industrial storage	- Automated spraying
In-service leaching from treated wood	- Bridge over pond - Timber clad 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 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 brushing treatments an assessment of cumulative leaching from treated wood in-service over a 5 year period was applied. For other superficially treated wood (e.g., by dipping or automated spraying) a service life of 15 years is applied and for double vacuum a service life of 20 years is applied. Hence, the assessment times are 30 days (TIME 1) for short term consideration and the respective service life 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 549 mm. This evaluation is therefore based on the leaching within this period. A last point measured after precipitation of 782 mm rain was however submitted separately, 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.

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

Table 2.8-2: Leaching rates for Laqvin Clear EM 1401

Active substance	Leaching rates (mg/m ² /day)		
	TIMEstorage	TIME1 (30 days)	TIME2 (15 years)
IPBC	0.177	0.177	0.176
Propiconazole	0.0536	0.0536	0.0786

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** 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* 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 industrial 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, as such application plants are expected to be managed in such a way that emission resulting from the application to an STP is not relevant. Freshly treated wood is to be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to water and any losses must be collected for reuse or disposal. However, application and storage scenarios for dipping, automated enclosed spraying and double vacuum, 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 and in-situ 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 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.

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 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 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 used 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, which was carried out using a worst case scenario of 35 simultaneously treated wooden houses per hectare. The model was based on an application rate of 1 g propiconazole/m² wood. The results showed that the 80th percentile leachate concentration at 1 m soil depth for both propiconazole and the metabolite 1,2 4-triazole was lower than the legal Drinking Water Limit of 0.1 µg/l in all FOCUS-PEARL scenarios. Since the application of propiconazole in Laqvin Clear EM1401 is below 1 g propiconazole/m² wood, groundwater concentrations below 0,1 µg/l can also be expected. This demonstrates that the use of propiconazole in the wood preservative Laqvin Clear EM1401 should not lead to unacceptable concentrations in groundwater.

PEC for atmosphere

Based on the vapour pressure (5.6×10^{-5} Pa×m³ at 25°C) and the Henry's Law constant (9.2×10^{-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 $2.36 - 4.5 \times 10^{-3}$ 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 ($PEC_{\text{Coral}_{\text{predator}}}$) should be conducted if the a.s. shows a potential for bioaccumulation, indicated by a $\log K_{\text{ow}}$ value >3 .

IPBC reveals a $\log K_{\text{ow}}$ of 2.81 and PBC a $\log K_{\text{ow}}$ of 1.64 indicating that no risk for bioaccumulation of the substances to man via the food chain is given.

Although the $\log K_{\text{ow}}$ of propiconazole ($\log K_{\text{ow}} = 3.7$) 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 Table 2.8-5 for IPBC and propiconazole, respectively. For IPBC either IPBC or PBC values are shown for the compartments surface water and soil, dependent on what value result 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)	38.4	2.05 *	-
Spraying (big plant)	384	20.5 *	-
Industrial storage			
Spraying (30 days – small plant)	-	4.49 x 10 ⁻⁴ #	3.20 x 10 ⁻⁴ #
Spraying (15 years – small plant)	-	4.49 x 10 ⁻⁴ #	3.23 x 10 ⁻⁴ #
Spraying (30 days – big plant)	-	0.00449 #	0.00320 #
Spraying (15 years – big plant)	-	0.00449 #	0.00323 #
In-service			
Noise Barrier (30 days)	0.185	0.00989 *	1.05 x 10 ⁻⁴ #
Noise Barrier (15 years)	0.185	0.00989 *	1.06 x 10 ⁻⁴ #
House (30 days)	-	-	2.79 x 10 ⁻⁴ #
House (15 years)	-	-	2.82 x 10 ⁻⁴ #
Bridge over pond (30 days)	-	0.0163 #	-
Bridge over pond (15 years)	-	2.17 *#	-

* Value for PBC

Value 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)	25.8	2.57	0.0548	-
Spraying (big plant)	258	25.7	0.548	-
Industrial storage				
Spraying (30 days – small plant)	-	4.49 x 10 ⁻⁴ #	9.57 x 10 ⁻⁶ ##	0.00493 #
Spraying (15 years – small plant)	-	4.49 x 10 ⁻⁴ #	9.57 x 10 ⁻⁶ ##	0.0624 #
Spraying (30 days – big plant)	-	0.00449 #	9.57 x 10 ⁻⁵ ##	0.0493 #
Spraying (15 years – big plant)	-	0.00449 #	9.57 x 10 ⁻⁵ ##	0.624 #
In-service				
Noise Barrier (30 days)	0.0504	0.00503	1.07 x 10 ⁻⁴	0.00161 #
Noise Barrier (15 years)	0.0739	0.00738	1.57 x 10 ⁻⁴	0.0300 #
House (30 days)	-	-	-	0.00431 #
House (15 years)	-	-	-	0.0801 #
Bridge over pond (30 days)	-	0.174 #	0.00852 ##	-
Bridge over pond (15 years)	-	0.362 #	1.01 ##	-

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/-	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 Table 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/PNEC) _{STP}	(PEC/PNEC) _{surface water}	(PEC/PNEC) _{soil}
Industrial application			
Spraying (small plant)	0.0873	0.0496 *	-
Spraying (big plant)	0.873	0.496 *	-
Industrial storage			
Spraying (30 days – small plant)	-	8.98 x 10 ⁻⁴ #	0.0737 #
Spraying (15 years – small plant)	-	8.98 x 10 ⁻⁴ #	0.0744 #
Spraying (30 days – big plant)	-	0.00898 #	0.737 #
Spraying (15 years – big plant)	-	0.00898 #	0.744 #
In-service			
Noise Barrier (30 days)	4.21 x 10 ⁻⁴	2.39 x 10 ⁻⁴ *	0.0241 #
Noise Barrier (15 years)	4.21 x 10 ⁻⁴	2.39 x 10 ⁻⁴ *	0.0243 #
House (30 days)	-	-	0.0644 #
House (15 years)	-	-	0.0650 #
Bridge over pond (30 days)	-	0.0327 #	-
Bridge over pond (15 years)	-	0.0526 *#	-

* Value for PBC

Value including degradation

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

Propiconazole	(PEC/PNEC) _{STP}	(PEC/PNEC) _{surface water}	(PEC/PNEC) _{sediment}	(PEC/PNEC) _{soil}
Industrial application				
Spraying (small plant)	0.0258	1.61	1.02	-
Spraying (big plant)	0.258	16.1	10.2	-
Industrial storage				
Spraying (30 days – small plant)	-	2.81 x 10 ⁻⁴ #	1.77 x 10 ⁻⁴ ##	0.0493 #
Spraying (15 years – small plant)	-	2.81 x 10 ⁻⁴ #	1.77 x 10 ⁻⁴ ##	0.624 #
Spraying (30 days – big plant)	-	0.00281 #	0.00177 ##	0.493 #
Spraying (15 years – big plant)	-	0.00281 #	0.00177 ##	6.24 #
In-service				
Noise Barrier (30 days)	5.04 x 10 ⁻⁵	0.00314	0.00198	0.0162 #
Noise Barrier (15 years)	7.39 x 10 ⁻⁵	0.00461	0.00291	0.300 #
House (30 days)	-	-	-	0.0431 #
House (15 years)	-	-	-	0.801 #
Bridge over pond (30 days)	-	0.109 #	0.158 ##	-
Bridge over pond (15 years)	-	0.226 #	18.7 ##	-

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.

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

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 Clear EM 1401	(PEC/PNEC) _{STP}	(PEC/PNEC) _{surface water}	(PEC/PNEC) _{sediment}	(PEC/PNEC) _{soil}
Industrial application				
Spraying (small plant)	0.113	1.66	1.02	-
Spraying (big plant)	1.13	16.6	10.2	-
Industrial storage				
Spraying (30 days – small plant)	-	0.00118	1.77×10^{-4}	0.123
Spraying (15 years – small plant)	-	0.00118	1.77×10^{-4}	0.698
Spraying (30 days – big plant)	-	0.0118	0.00177	1.23
Spraying (15 years – big plant)	-	0.0118	0.00177	6.98
In-service				
Noise Barrier (30 days)	4.72×10^{-4}	0.00338	0.00198	0.0403
Noise Barrier (15 years)	4.95×10^{-4}	0.00485	0.00291	0.324
House (30 days)	-	-	-	0.108
House (15 years)	-	-	-	0.866
Bridge over pond (30 days)	-	0.142	0.158	-
Bridge over pond (15 years)	-	0.279	18.7	-

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 in 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.

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 12.9.

Conclusion: The conclusion of the environmental risk assessment for the product Laqvin Clear EM 1401 is that no unacceptable risk is identified for secondary poisoning, air and groundwater compartments. However, risk is identified for the environment 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.**

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 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):0-5

By use of putty knife, brush, roller etc. for pre- and after treatment in spray booths, where the operator is outside the spray zone and by similar work in new plants of the type combi-cabins, spray cabins and spray booths, where the operator is inside the spray zone. By spraying in new booths and cabins with spray gun without aerosol formation. By operation stops, cleaning and repair of closed plants, spray booth or cabin, if there is a risk of contact with wet paint or organic solvents. By use of putty knife, brush, roller etc. for pre- and after treatment in cabin or booths of the type existing plants, if the operator is inside the spray zone. By use of putty knife, brush, roller etc. for pre and after treatment outside closed plants, spray booths or spray cabins. – Wear protective clothes.

By spraying in existing spray booths if the operator is outside the spray zone.
Wear an air supplied full-face mask and a protective suit.

By spraying without aerosol formation in existing* plants of the type combi-cabins, spray cabins or spray booths, where the operator is inside the spray zone.
Wear a gas filter mask and a protective suit.

By all spraying with aerosol formation in cabins or spray booths, where the operator is inside the spray zone and by spraying outside closed plants, cabins or booths.
Wear an air supplied full-face mask, a protective suit and a hood.

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.

Special personal protection equipment to be worn by fire fighters: Fire fighters should wear appropriate protection equipment and self-sufficient, air supplied breathing equipment (SCBA) and full face mask to be used in positive pressure state.

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 availableFirst 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 environmentMeasures 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 0111 "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 11 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 Clear EM 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 260 – 320 g/m² corresponding to 252 - 311 ml/m².

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 assessment. Furthermore, the use of Laqvin Clear EM 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 Clear EM 1401 does not pose an unacceptable risk to human health.

However it has to be stressed that at the next re-evaluation of the product the TNsG 2007 and the HEEG's opinion regarding cycles per day (240 min instead of 180 min) will be used. In addition to this dermal absorption values of IPBC concentration lower than 0.5% should be provided for the evaluation.

Environmental assessment:

The conclusion of the environmental risk assessment for the product Laqvin Clear EM 1401 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 Clear EM 1401 as a wood preservative (PT 8) for use by industrial automated spraying. The use rate is 260-320 g/m² corresponding to 252-311 ml/m², depending on application and retention capacity of the wood.

Identity of the Biocidal Product

The biocidal product under PT8 Wood preservatives Laqvin Clear EM 1401 contains 0.4% (w/w) IPBC and 0.3% (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 Clear EM 1401 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 data⁶ submitted in support of the evaluation of the active substance*

None

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 Clear EM 1401 Danish Technological Institute. Wood Technology. 23th June 2011. Order no. 438403-5	Becker Acroma KB	<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	2009	Test Report. 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". Laboratory name: Danish Technological Institute Laboratory report number: Order no.: 289802-4	Becker Acroma KB	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IVB 7	3	Klamer and Venås	2011	Test Report. NT BUILD 509 "Leaching of Active Ingredients from Preservative-Treated Timber – Semi field Leaching" Laboratory name: Danish Technological Institute Laboratory report number: Order no.: 352957-4	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). A dermal absorption value of 100% has been used for in use concentrations below 0.5%-0.6% IPBC (CAR for IPBC PT8)

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 2: Toxicology and metabolism –active substance**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	2.0%
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Classification

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

Annex 3A: Human exposure assessment

Laqvin Clear EM 1401– Industrial user – Post-application phase – IPBC /
Model : Timber pre-treatment (water) (TNsG 2007 (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	8.71	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	18.73	mg
Dermal absorption	100.00%	%
Systemic exposure via dermal route	18.73	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	18.76	a.s. mg
Body weight kg	60	kg
Systemic exposure	0.31	mg/kg/day

Annex 3A: Human exposure assessment

Laqvin Clear EM 1401 – Industrial user – Post-application phase – Propiconazol / Model : Timber pre-treatment (water) (TNsG 2007 (BEAT))

Product		Units
active substance	0.3%	%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	2094.4	mg
Mitigation by gloves	Not applicable	
Actual hand deposit	2094.4	mg [product]
Total dermal exposure		
Total dermal deposit	4682.4	mg [product]
Active substance	14.05	mg
Dermal absorption	2%	%
Systemic exposure via dermal route	0.281	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	0.027	a.s. mg
Systemic exposure		
Total systemic exposure	0.03079	a.s. mg
Body weight kg	60	kg
Systemic exposure	0.00513	mg/kg/day

Annex 3B: Human exposure assessment

**Laqvin Clear EM 1401 – Industrial user – Post-application phase – IPBC /
Model : Timber pre-treatment (water) (TNsG 2002 (BEAT))**

Product		Units
active substance	0.4%	%w/w
Potential body exposure		
Indicative value	47.5	mg/min
Duration	180	min
Potential dermal deposit	8568	mg
Clothing type	Coated coveralls	
Clothing penetration	10%	% penetration
Actual dermal deposit	856.6	mg [product]
Hand exposure		
Indicative value	6	mg/min (actual) (inside gloves)
Duration	180	min
Hand deposit	1080	mg
Mitigation by gloves	Not applicable	
Actual hand deposit	1080	mg [product]
Total dermal exposure		
Total dermal deposit	1936.8	mg [product]
Active substance	7.75	mg
Dermal absorption	100.00%	%
Systemic exposure via dermal route	7.7	a.s. mg
Exposure by inhalation		
Indicative value	1.9	mg/m ³
Duration	180	min
Inhalation rate m ³ /h	1.25	m ³ /h
Mitigation by RPE (PF)	1	
Inhaled	7.13	mg [product]
Systemic exposure via inhalation route	0.029	a.s. mg
Systemic exposure		
Total systemic exposure	7.7	a.s. mg
Body weight kg	60	kg
Systemic exposure	0.13	mg/kg/day

Annex 3B: Human exposure assessment

Laqvin Clear EM 1401 – Industrial user – Post-application phase – Propiconazol / Model : Timber pre-treatment (water) (BEAT TNsG 2002)

Product		Units
active substance	0.3%	%w/w
Potential body exposure		
Indicative value	47.5	mg/min
Duration	180	min
Potential dermal deposit	8550	mg
Clothing type	Coated coveralls	
Clothing penetration	10%	% penetration
Actual dermal deposit	855	mg [product]
Hand exposure		
Indicative value	6	mg/min (actual) (inside gloves)
Duration	180	min
Hand deposit	1080	mg
Mitigation by gloves	Not applicable	
Actual hand deposit	1080	mg [product]
Total dermal exposure		
Total dermal deposit	1935	mg [product]
Active substance	5.81	mg
Dermal absorption	2%	%
Systemic exposure via dermal route	0.116	a.s. mg
Exposure by inhalation		
Indicative value	1.9	mg/m ³
Duration	180	min
Inhalation rate m ³ /h	1.25	m ³ /h
Mitigation by RPE (PF)	1	
Inhaled	7.13	mg [product]
Systemic exposure via inhalation route	0.021	a.s. mg
Systemic exposure		
Total systemic exposure	0.13	a.s. mg
Body weight kg	60	kg
Systemic exposure	0.00229	mg/kg/day

Annex 4: Leaching Calculations

A semi-field leaching study for Laqvin Clear EM 1401 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 m² 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:

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

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(Δt) 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 1.

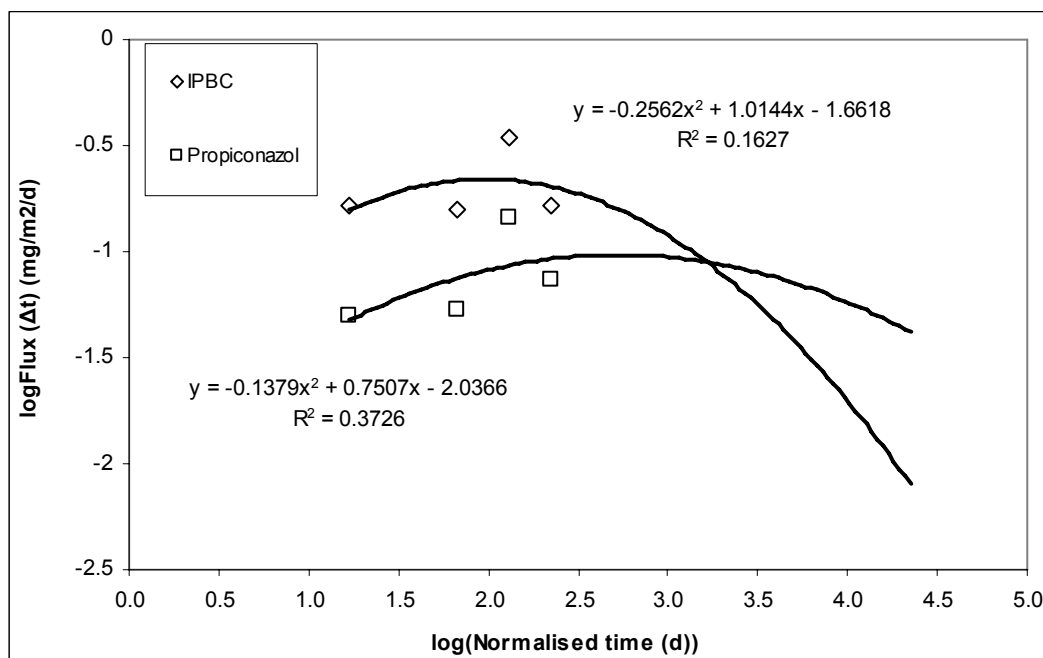


Figure 1 Fitted daily FLUX(Δt) of IPBC and propiconazole versus time

In Figure 2 it is seen that the R^2 values are very low. Therefore these curves can not be used for calculation of fluxrates.

Instead the FLUX(Δt) values are used:

$$\text{FLUX}(\Delta t) = Q_d(\Delta t) / \Delta t$$

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 2.

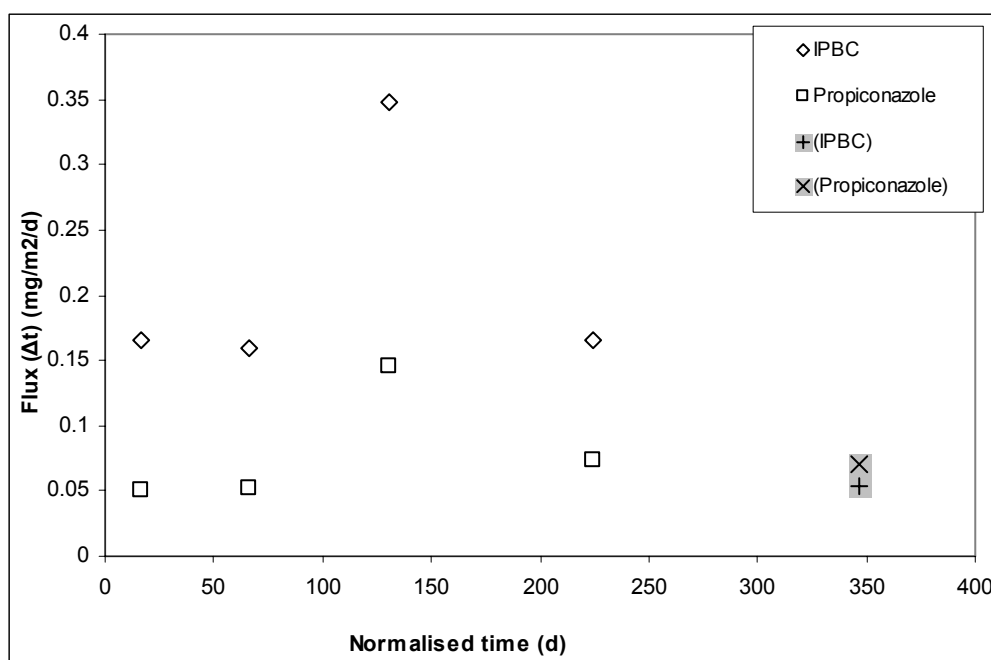


Figure 2 FLUX(Δt) values

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 points of the interim report are scattered, and uncertainty could be raised about whether the use of the last measured point as the long term leaching rate is really worst case. The measured point submitted later does however 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 $Q_{\text{leach}, 15 \text{ years}}$.

For the short term leaching rate, $Q_{\text{leach}, 30 \text{ days}}$ the first value is used.

Because the intended application rate is higher than the amounts applied in the leaching study a correction factor of 1.07 has to be adopted. The maximum intended applied amount is 320 g product/m², while in the leaching study 299 g product/m² was applied.

With this approach the following leaching rates can be derived:

IPBC

TIME 1, 30 days:

$$Q_{\text{leach, 30 days}} = 0.165 \text{ mg/m}^2/\text{d} \times 1.07 = \mathbf{0.177 \text{ mg/m}^2/\text{d}}$$

TIME 2, 15 years:

$$Q_{\text{leach, 15 years}} = 0.165 \text{ mg/m}^2/\text{d} \times 1.07 = \mathbf{0.176 \text{ mg/m}^2/\text{d}}$$

Propiconazole

TIME 1, 30 days:

$$Q_{\text{leach, 30 days}} = 0.0501 \text{ mg/m}^2/\text{d} \times 1.07 = \mathbf{0.0536 \text{ mg/m}^2/\text{d}}$$

TIME 2, 15 years:

$$Q_{\text{leach, 15 years}} = 0.0735 \text{ mg/m}^2/\text{d} \times 1.07 = \mathbf{0.0786 \text{ mg/m}^2/\text{d}}$$

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