Bilag 2

Product Assessment Report

Induline IL-150

Internal registration no:	MST-671-01715
Authorisation/Registration no:	692-6
Granting date/entry into force of authorisation/ registration:	9 December 2011
Expiry date of authorisation/ registration:	31 March 2020
Active ingredient:	Iodopropinyl butylcarbamate (IPBC) and tebuconazole
Product type:	PT8

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

Danish Ministry
of the Environment
Environmental
Protection Agency

Contents

1 General information about the product application

1.1 Applicant

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1.1.1 Person authorised for communication on behalf of the applicant

Name:	Mr. Thomas Fangmeyer
Function:	Regulatory Affairs Manager
Address:	Bernhard-Remmers-Str. 13
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E-mail address:	TFangmeyer@remmers.de

1.2 Current authorisation holder

There is no current authorisation for Induline IL-150 in Denmark.

1.3 Proposed authorisation holder

Company Name:	Remmers Baustofftechnik GmbH
Address:	Bernhard-Remmers-Str. 13
City:	Löningen
Postal Code:	49624
Country:	Germany
Telephone:	Tel.: + 49(0)5432/83-190
Fax:	Fax: + 49(0)5432/83-713
E-mail address:	TFangmeyer@remmers.de
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	-

1.4 Information about the product application

Application received:	25.06.2010
Application reported complete:	March 10, 2011
Type of application:	Product Authorisation

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	Induline IL-150
Manufacturer's development code number(s), if appropriate:	None
Product type:	PT8
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	0.50 % IPBC 0.80 % Tebuconazole
Formulation type:	Solvent 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 No

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	Induline IL-150 is a ready-to-use solvent-based wood preservative for hard- and softwood joinery elements (professional and industrial use).
Target organisms:	Blue stain fungi
Category of users:	Professional and industrial users
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	Brushing, dipping, deluging and spraying (only in closed facilities): 150-165 ml/m^2 (123-135.3 g/m^2) Double vacuum (only in closed facilities): 24.7-27.2 L/m^3 (20-22 kg/m^3)
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/feedingstuff (yes/no)	No
Proposed Label:	Yes

1.5.3 Information on active substance(s)

Active substance chemical name:	IPBC	Tebuconazole
CAS No:	55406-53-6	107534-96-3
EC No:	259-627-5	403-640-2
Purity (minimum, g/kg or g/l):	Min. 980 g/kg	Min. 950 g/kg
Inclusion directive:	2008/79/EF of 28 July 2008	2008/86/EF of 5 September 2008
Date of inclusion:	1 July 2010	1 April 2010
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes	Yes
Manufacturer of active substance(s) used in the biocidal product:		
Company Name:	Troy Vorporatio Inc	LANXESS Deutschland GmbH
Address:	8 Vreeland, Florham Park	
City:	New Jersey	Leverkusen
Postal Code:	NJ, 07105	51369
Country:	USA	Germany
Telephone:	+31 0 10 592-7494	+49 214 30 65109
Fax:		
E-mail address		

1.5.4 Information on the substance(s) of concern

Substance chemical name	Varsol 60
CAS No:	64742-82-1
EC No :	265-185-4
Original ingredient (trade name):	Naphtha (petroleum) hydrodesulfurized heavy

1.6 Documentation

1.6.1 Data submitted in relation to product application

For full specification see reference list in Annex 1.

1.6.2 Access to documentation

A letter of access is available from Troy Corporation Inc. for the product authorisation holder to access the Annex I data for IPBC. The Troy Corporation Inc. is part of the IPBC Task Force and has ownership to all data submitted in the review of IPBC under dir 98/8/EC.

A letter of access is available from LANXESS Deutschland GmbH grants to Remmers Baustofftechnik GmbH the right to refer to the BPD 98/8/EC dossier of Tebuconazole.

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

2 Summary of the product assessment

2.1 Identity related issues

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

Induline IL-150 contains 0.50 % w/w Iodopropynyl butylcarbamate (IPBC) and 0.80 % tebuconazole as active substances.

Further information on the composition of the biocidal product and the identity of its ingredients is confidential and are provided separately in Bilag 3 to the letter of authorisation (Godkendelsesbrev).

One substance of concern is present in the product: Naphtha (petroleum) hydrodesulfurized heavy.

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification and labelling of the biocidal product

According to the criteria of directive 1999/45/EC and to Annex I to Directive 67/548/EEC, the classification and labelling of the product Induline IL-150 should be:

Symbols		
Category of danger	Xn	Harmful
Risk phrases	R65 R38 R66	Harmful: may cause lung damage if swallowed Irritating to skin Repeated exposure may cause skin dryness or cracking
Safety phrases	S2 S13 S28 S37 S62	Keep out of the reach of children. Keep away from food, drink and animal feedingstuffs After contact with skin, wash immediately with plenty of water Wear suitable gloves If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label.
Additional labelling	The following sentence shall be stated on the label: Contains IPBC: May produce an allergic reaction.	

2.2.2 Packaging of the biocidal product

The biocidal product is packed in 20 L tinplate container and 1000 L container made of PE.

2.3 Physico/chemical properties and analytical methods

A letter of access has been submitted for the active substance. An overview of the physico-chemical properties of the active substance can be found in the CAR[1].

2.3.1 Physico-chemical properties

A summary of the physical and chemical properties of Induline IL-150 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).

According to the applicant, the test material VAC PB IT (VP 23333) is identical to the product Induline IL-150 with only one exemption:

VP 23333 contains 0.05% Bifenthrine while Induline IL-150 doesn't. We have concluded that VP 23333 is comparable with Induline IL-150.

[1] Competent Authority Report

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

	Method	Purity/Specification (IPBC and tebuconazole)	Results	Reference
Physical state and nature	Visual inspection	Min. 980 g/kg and min. 950 g/kg according to supplier	Before and after storage at 22 °C for 6 months: Oily clear liquid with volatile parts. (Study was performed with VP 23333.)	Paulus, 2011
Colour	Visual inspection	Min. 980 g/kg and min. 950 g/kg according to supplier	Before storage at 22 °C for 6 months: Very pale yellow. After storage at 22 °C for 6 months: Slightly darker (Study was performed with VP 23333.)	Paulus, 2011
Odour	Olfactory inspection	Min. 980 g/kg and min. 950 g/kg according to supplier	Before and after storage at 22 °C for 6 months: Typical, strong, as solvent. (Study was performed with VP 23333.)	Paulus, 2011
Explosive properties	–	–	The biocidal product does not present explosive properties.	–
Oxidizing properties	–	–	The biocidal product does not present oxidising properties.	–
Flash point	EC method A.9	Min. 980 g/kg and min. 950 g/kg according to supplier	68.8 °C (Study was performed with VAC PB IT (VP 23333).)	Legay, 2010
Autoflammability	EC method A.15	Min. 980 g/kg and min. 950 g/kg according to supplier	Auto ignition temperature: 265 °C (Study was performed with VAC PB IT (VP 23333).)	Paulus, 2010
Acidity / Alkalinity	CIPAC method MT 75	Min. 980 g/kg and min. 950 g/kg according to supplier	Before storage at 22 °C for 6 months: pH = 5.57 After storage at 22 °C for 6 months: pH = 5.69	Paulus, 2011

	Method	Purity/Specification (IPBC and tebuconazole)	Results	Reference
			(Study was performed with VP 23333.) The determination of the acidity or alkalinity, respectively, is not applicable because the pH-value of the formulation is between 4 and 10.	
Relative density / bulk density	EC method A.3	Min. 980 g/kg and min. 950 g/kg according to supplier	Specific gravity: 0.810 g/mL (Study was performed with VAC PB IT (VP 23333).) The determination of the bulk density is not applicable because the biocidal product is liquid. According to the MSDS the density of Induline IL-150 is 0.82 g/cm^3.	Legay, 2010
Storage stability – stability and shelf life				
Accelerated storage stability	CIPAC MT 46.3	Min. 980 g/kg and min. 950 g/kg according to supplier	The study is performed at 40 °C for 8 weeks. No significant changes of physicochemical properties were observed. IPBC content before storage at 40 °C for 8 weeks: 0.46% IPBC content after storage at 40 °C for 8 weeks: 0.41% *Variation of IPBC: 10.9%.* Tebuconazole content before storage 40 °C for 8 weeks: 0.72% Tebuconazole content after storage at	Legay, 2010

	Method	Purity/Specification (IPBC and tebuconazole)	Results	Reference
			40 °C for 8 weeks: 0.67% *Variation of tebuconazole: 6.9%.* (Study was performed with VAC PB IT (VP 23333).)	
Low temperature stability	–	–	Not applicable because the biocidal product should be stored frost-protected.	
Long-term storage stability, shelf life	Storage of the biocidal product for two years at room temperature	Min. 980 g/kg and min. 950 g/kg according to supplier	The study is performed at 22 °C for 6 months (interim result). No significant changes of physicochemical properties occurred during the tests. IPBC content before storage: 0.55% IPBC content after storage: 0.47% *Variation of IPBC: 14.5%.* Tebuconazole content before storage: 0.74% Tebuconazole content after storage: 0.65% *Variation of tebuconazole: 12.1%.* The appearance, pH as well as viscosity were measured before and after storage. Results for these tests were considered acceptable before and after storage. (Study was performed with VP 23333.)	Paulus, 2011
Long-term storage stability, shelf life	Storage of the biocidal product for two	Min. 980 g/kg and min. 950 g/kg according to supplier	Preliminary results after 12 months (not quality	Statement concerning storage stability (Paulus 2011)

	Method	Purity/Specification (IPBC and tebuconazole)	Results	Reference
	years at room temperature		checked) IPBC content before storage: 0.55% IPBC content after storage: 0.48% *Variation of IPBC: 12.7%.* IPBC content after storage (homogenisation): 0.45% *Variation of IPBC: 18.2%.* Tebuconazole content before storage: 0.74% Tebuconazole content after storage: 0.58% *Variation of tebuconazole: 21.6%.* Tebuconazole content after storage (homogenisation): 0.68% *Variation of tebuconazole: 8.1%.*	
Reactivity towards container material	Preliminary Results of accelerated storage and at ambient temperature after 1 year.	Min. 980 g/kg and min. 950 g/kg according to supplier	After storage of the test item at room temperature for 12 months, no optical changes in physical state and no corrosion on the container material have been observed.	Statement concerning storage stability (Paulus 2011)
Technical characteristics in dependence of the formulation type	–	–	The biocidal product has none of the properties mentioned in the TNsG on Data Requirements. Therefore no tests are necessary.	–
Compability with other products	–	–	Not applicable since the biocidal product will not be used with other products including other biocidal products.	–
Surface tension	OECD guideline 115	Min. 980 g/kg and min. 950 g/kg according to supplier	25.70 = mN/m at 20 °C (Study was performed with	Legay, 2010

	Method	Purity/Specification (IPBC and tebuconazole)	Results	Reference
			VAC PB IT (VP 23333).)	
Viscosity	OECD guideline 114	Min. 980 g/kg and min. 950 g/kg according to supplier	22.6 s at 22.9 °C Before storage at 22 °C for 6 months: 2.405 mPa*s After storage at 22 °C for 6 months: 2.237 mPa*s (Study was performed with VAC PB IT (VP 23333).)	Legay, 2010
Particle size distribution	–	–	Not applicable because the biocidal product is liquid.	–

2.3.2 Analytical methods

Analytical methods for the determination of IPBC and tebuconazole residues in relevant environmental media (soil, air and water) as well as in animal and human body fluids and tissues were not submitted for the biocidal product since this point is covered by the data set of the active substances. Please refer to the dossier submitted for the active substances.

Analytical methods for the determination of active substance residues in/on food or feedstuffs are required if the active substance or the material treated with it is to be used in a manner which may cause contact with food or feedstuffs, or intended to be placed on, in or near soils in agricultural or horticultural use.

The active substances IPBC and tebuconazole are not intended to be used in an above described manner. They are intended to be used as wood preservatives. Their use is only recommended for the treatment of exterior constructions. The treatment of wood which is likely to come into direct contact with food or feedstuffs is excluded.

Since an exposure of IPBC and tebuconazole to food and feedstuffs can be excluded when applied according to the recommended use, it is not necessary to submit an analytical method for the determination of active substance residues in/on food and feedstuffs.

Formulation analysis: A summary of the analytical method for the determination of the active substances IPBC and tebuconazole in the biocidal product, presented under Document IIIB, Section 4.1. is given in Table 2.3-2.

Table 2.3-2: Analytical method for formulation analysis

Sample	Test substance	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of determination	Reference
						Range	Mean	Relative Standard deviation (RSD)		
VP 23333	IPBC Tebuconazole	HPLC-UV	The precision at the "target value" was determined by spiking sample matrix 2 x 6 times with each active substance at following active substance concentrations: IPBC: 100 mg/L Tebuconazole: 160 mg/L The recovery rate was calculated with a comparison between the theoretical "target value" and the mean of 12 spiked matrices.	Five concentrations in the range following range measured. IPBC: 80 to 120 mg/L Tebuconazole: 128 to 192 mg/L Each concentration was measured once. Correlation coefficients: IPBC: 0.9973 Tebuconazole: 0.9992	No interferences observed.	For IPBC the mean recovery rate was 101.9% (range: 98.3-106.3%). For tebuconazole the mean recovery rate was 101.9% (range: 100.5-103.7%). For IPBC the repeatability relative standard deviation was 0.98%. For tebuconazole the repeatability relative standard deviation was 0.31%.			Not determined since the analytical method is only used to check if the active substances contents in the biocidal product comply with the respective specification.	Legay, 2010

The results obtained show that the analytical method is valid for the determination of IPBC and tebuconazole in the biocidal product.

2.4 Risk assessment for Physico-chemical properties

The submitted physico-chemical data for the product has been evaluated and it is concluded that it does not lead to classification of the product according to Directive 67/548/EC and Directive 1999/45/EEC.

Long-term storage stability (shelf life): Up until now, Denmark has allowed 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 for 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 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.

Our final conclusion regarding stability is based on preliminary results of storage stability at ambient temperature after 12 months (repetition after intensive homogenisation):

IPBC

IPBC content before storage: 0.55%

IPBC content after storage: 0.45%

Variation: 18.2%.

Tebuconazole

Tebuconazole content before storage: 0.74%

Tebuconazole content after storage: 0.68%

Variation: 8.1%.

In the storage stability study, the variation of IPBC exceeds the acceptable limit of 15% deviation after 12 months. The variation of IPBC has reached 14.5% after 6 months, so it does not exceed the acceptable limit of deviation.

Conclusion: On the background of the preliminary results from the long-term stability study (after homogenisation), it can be concluded that Induline IL-150 is not stable with regards to its content of IPBC after 12 months. However, the stability of IPBC is acceptable after 6 months. A claim for 6 months shelf-life can 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.

2.5 Effectiveness against target organisms

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

Induline IL-150 is recommended to be approved as a biocide product to protect against wood discolouring fungi and wood destroying basidiomycetes for softwood in use class 2 and 3.

The recommended minimum and maximum retention for superficial treatments is advised to be:
Minimum: 123 g product/m^2 which approximately correspond to 150 ml/m^2
Suggested maximum: 135.3 g product/m^2 which approximately correspond to 165 ml/m^2

The recommended minimum and maximum retention for penetrating treatments is advised to be:
Minimum: 20 kg product/m^3
Suggested maximum: 22 kg product/m^3

A top coat is only required when claimed for wood discolouring fungi.

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).

Tebuconazole belongs to the chemical class of triazole fungicides. Its mode of action has been shown to rely on the inhibition of the demethylation at the C^{14}-position in the fungal sterol biosynthesis.

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)

Induline IL-150 is a ready-to-use solvent-based wood preservative for hard- and softwood joinery elements.

The biocidal product contains 0.80 % w/w tebuconazole and 0.50% w/w IPBC.

The product is used for wood outdoors, which is not covered, not in direct contact with the ground or water (for use up to hazard class 3), and exposed to frequent weathering. The modes of application include brushing by professionals as well as industrial applications by dipping, deluging (flow coating) and spray treatment (only in closed facilities), double-vacuum procedure. The efficacious use rate is 150-165 mL/m^2 for brushing, dipping, deluging (flow coating) and spraying

2.6.2 Assessment of exposure to humans and the environment

Leaching studies have been submitted for the product, an evaluation of these and flux rates used for environmental risk assessment will be presented in Annex 4.

No new studies on human health have been submitted.

2.7 Risk assessment for human health

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The toxicology of the active substances IPBC and tebuconazole was examined extensively according to standard requirements in the review programme under directive 98/8/EC. The results of this toxicological assessment can be found in the CAR.
The threshold limits and labelling used in the evaluation of this product regarding human health risks listed in Annex 2 „Toxicology and metabolism".

2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product Induline IL-150 contains one substance of concern (Naphtha (petroleum) hydrodesulfurized heavy), and due to the high percentage in the product, the classification of this individual co-formulant results in the classification of the product with R65 (Harmful: may cause lung damage if swallowed) and R66 (Repeated exposure may cause skin dryness or cracking).

2.7.1.3 Toxicology of the biocidal product

The toxicology of Induline IL- 150 was examined according to standard requirements. The product is not identical to any representative product in the EU- review program for inclusion of the active substance IPBC and tebuconazole in Annex I of Directive 98/8/EC.
The basis for the health assessment of the biocidal product is laid out in the following.

2.7.1.3.1 Percutaneous absorption

Dermal absorption studies with the b.p. have not been conducted.

For solvent based solutions containing 0.5-0.6% **IPBC**, a dermal absorption value of 30% has been set in the CAR by RMS Denmark. Therefore, a dermal absorption value of 30% will be assumed for the b.p. (0.5% IPBC).

For dilute solvent-based **tebuconazole** solutions (0.63%), a dermal absorption value of 14.4% has been set in the CAR by RMS Denmark. Therefore, a dermal absorption value of 14.4% will be assumed for the b.p. (0.8% tebuconazole).

The default value for **body weight** of an exposed adult is assumed to be **60 kg** (ECETOC, 2001).

2.7.1.3.2 Acute toxicity

The toxicological tests for the product Induline IL-150 has been carried out with the test items VP 23349 and VP 23333. The test items VP 23349 and VP 23333 are identical to the product Induline IL-150 with only one exemption:

- VP 23349 contains 0.03% (m/m) Bifenthrine while Induline IL-150 doesn't
- VP 23333 contains 0.05% (m/m) Bifenthrine while Induline IL-150 doesn't

2.7.1.3.3 Acute oral toxicity:

The acute oral toxicity of the test item was tested according to OECD Guideline 423
Six female Sprague Dawley rats received 2000 mg/kg of the test article via oral gavage.
Under the conditions of the present study, single oral application of the test item to rats at a dose of 2000 mg/kg body weight did not cause mortalities or clinical signs of toxicity. The oral LD_{50} for the test item is > 2000 mg/kg bw.

2.7.1.3.4 Acute dermal toxicity:

The acute dermal toxicity of the test item, was tested in a Limit Test according to OECD Guideline 402.
Male and female Sprague-Dawley rats were exposed to 2000 mg/kg of the test item for 24 h under semi-occlusive conditions.
Treatment with the test item did not cause mortalities or clinical signs of toxicity. No treatment-related gross lesions were observed at necropsy. The dermal LD_{50} for the test item is > 2000 mg/kg bw for both sexes.

2.7.1.3.5 Dermal irritation potential:

The dermal irritation potential of the test item was tested in 3 female Albino New Zealand rabbits.

The methods used in this study were in accordance with OECD-Guideline 404 (2002).
A well defined erythema, associated with a slight to moderate oedema, was noted on the treated area of the three animals 1 hour after the patch removal. The oedematous and erythematous reactions were totally reversible on day 6. On the cutaneous structure, slight dryness was noted from day 3 or day 6 and was totally reversible on day 10 in one animal and not totally reversible in the two others (remaining slight dryness, noted on day 14, last day of the test).
According to the classification system of Directive 67/548/EEC, the product has to be classified as **Xi, R38 – Irritating to skin.**

2.7.1.3.6 Eye irritation potential:

The eye irritation potential of the test item was investigated in three female Albino rabbits.
The study was conducted according to OECD Guideline 405. The test was first conducted in a single animal and then extended to three animals.
The ocular conjunctivae reactions observed during the study have been slight to moderate and totally reversible in the three animals; a moderate redness, noted 1 hour after the test item instillation and totally reversible between day 2 and day 4, associated with a slight to moderate chemosis, noted 1 hour after the test item instillation and totally reversible between day 2 and day 4.

2.7.1.3.7 Skin sensitising potential:

The skin sensitizing potential of Induline IL 150 was investigated in a Maximisation test:
The intradermal induction of the test group animals was performed with 25 % concentrations of the test item in the vehicle (olive oil) and in Freund's Complete Adjuvant (FCA). Control group animals were injected with the vehicle alone and FCA in isotonic sodium chloride alone.
On study day 6 the test areas of the control and test group animals were pre-treated with 10 % sodium-lauryl Sulphate in thick vaseline. Beginning on study day 7, the epidermal induction was conducted for 48 hours with the undiluted test item in the test group animals, whereas the control group animals were treated with 0.5 mL of liquid paraffin.
Two weeks after epidermal induction the control and test animals were challenged by epidermal application of the 25 and 50% diluted test item.
No macroscopic cutaneous reactions was recorded during the examination following the removal of the Occlusive dressing (challenge phase) from the animals of the treated group with the test item at 25 and 50%. No cutaneous intolerance reaction was recorded in animals from the negative control group after the challenge phase, on the treated area with the test item at 25 and 50%.

Table 2.7.1.3.2-1 Classification for acute health effects of Induline IL-150

Endpoint	DPD classification
Acute oral toxicity	None
Acute dermal toxicity	None
Acute inhalation toxicity	Inhalation is not a relevant route of exposure
Skin irritation	**R38. Irritating to skin**
Eye irritation	None
Skin sensitisation	None

IPBC is considered to be a skin sensitizer and proposal for classification has been submitted to ECHA. The product is not classified as a skin sensitiser (Xi, R43) as the b.p. contains less than 1% of the active ingredient IPBC (0.5%). However, the following sentence shall be stated on the label: Contains IPBC: May produce an allergic reaction.

2.7.2 Exposure

The biocidal product contains the active substance IPBC, 0.50% w/w and tebuconazole, 0.8% w/w as well as Naphtha (petroleum) hydrodesulfurized heavy, which is a substance of concern.

Exposure of professional users to the active substances while handling Induline IL-150 is estimated.

Induline IL-150 is not intended or sold for the treatment of indoor housing areas with the exception of pre-treated window frames to be used indoors. An exposure assessment of residents inhaling volatile residues indoors has been included to estimate potential exposure from this source.

Induline IL-150 contains Naphtha (petroleum) hydrodesulfurized heavy, which is a substance of concern. The substance is classified as R65 (Harmful: may cause lung damage if swallowed) and R66 (Repeated exposure may cause skin dryness or cracking), thus leading to classification of the product as such.
Due to the local effects of the product, the risk is considered to be negligible when appropriate personal protective equipment (PPE) is worn by the professional user.

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

During and after the application of Induline IL-150, operator exposure could theoretically occur by dermal and inhalation routes.

However, the potential of exposure for operators through ingestion of the b.p. during these processes is negligible. The inhalation route is of minimal concern due to the low vapour pressure of the active substances (IPBC: 4.5×10^{-3} Pa at 25°C; tebuconazole: 1.7×10^{-6} Pa at 20°C) and the kind of application (no spray application).

Post-application exposure can occur to professionals handling treated wood and cleaning/maintaining equipment used for timber treatment. Due to the low frequency of the “cleaning out the dipping tank” task and the lack of an appropriate model, no exposure calculation is provided for this activity. It is recommended that appropriate PPE is worn during the task.

Exposure to non-professionals is not considered relevant as the b.p. is not sold to non-professional users.

Some secondary exposure is envisaged if contaminated work clothing is laundered at home.

Infants may be exposed via mouthing of treated wood chips.

Children and infants may be exposed via residues in playground structures.

Secondary exposure can arise if elements consisting of treated woods are sanded; the evolving dust can contain residual wood preservative which is inhaled together with the wood dust. This task can be performed by amateurs (acute scenario) or by professional craftsmen (chronic exposure).

Adults, children and infants may be exposed to volatile residues indoors from e.g. treated window frames.

The main routes of exposure are summarised in Table 2.7.2.1-1.

Table 2.7.2.1-1: Summary of human exposure paths to IPBC / tebuconazole

Exposure path	Industrial use	General public	Via the environment
Inhalation	low	relevant	not relevant
Dermal	relevant	relevant	not relevant
Oral	not relevant	relevant for children	not relevant

In Annex 3 „Human exposure assessment“, the results of the exposure calculations for the active substance for the industrial/ professional user are laid out as well as for the indirect exposure.

2.7.2.2 Summary of primary exposure

The overall summary of primary systemic exposure is given in Table 2.7.2.2-1.

Table 2.7.2.2-1: Summary of primary exposure

Scenario	Systemic dose [mg/kg bw/day]	
	Tebuconazole	**IPBC**
Dipping/double-vacuum, incl. handling	Inhalation: 0.0004 Dermal: 0.0072 **Total: 0.0076**	Inhalation: 0.0002 Dermal: 0.0094 **Total: 0.0096**
Brush application	Inhalation: 0.0005 Dermal: 0.0050 **Total: 0.0055**	Inhalation: 0.0003 Dermal: 0.0066 **Total: 0.0069**
Cleaning the brush after use	**Dermal: 0.0013**	**Dermal: 0.0010**
Total: Brush + cleaning	Inhalation: 0.0005 Dermal: 0.0063 **Total: 0.0068**	Inhalation: 0.0003 Dermal: 0.0076 **Total: 0.0079**

2.7.2.3 Summary of secondary exposure

The overall summary of secondary systemic exposure is given in Table 2.7.2.3-1.

Table 2.7.2.3-1: Summary of secondary exposure

Scenario	Systemic dose [mg/kg bw/day]	
	Tebuconazole	**IPBC**
Acute: sanding of treated wood, amateur *(dipping, deluging)*	Inhalation: 0.00004 Dermal: 0.00087 **Total: 0.00091**	Inhalation: 0.00002 Dermal: 0.00113 **Total: 0.00115**
Acute: sanding of treated wood, amateur *(double vacuum)*	Inhalation: 0.00011 Dermal: 0.00087 **Total: 0.00098**	Inhalation: 0.00007 Dermal: 0.00113 **Total: 0.00120**
Acute: chewing treated wood chip, child *(dipping, deluging)*	**Oral: 0.0173**	**Oral: 0.0108**
Acute: chewing treated wood chip, child *(double vacuum)*	**Oral: 0.0282**	**Oral: 0.0176**
Chronic: sanding of treated wood, professional *(dipping, deluging)*	Inhalation: 0.00023 Dermal: 0.00087 **Total: 0.00110**	Inhalation: 0.00014 Dermal: 0.00113 **Total: 0.00127**
Chronic: sanding of treated wood, professional *(double vacuum)*	Inhalation: 0.00066 Dermal: 0.00087 **Total: 0.00143**	Inhalation: 0.00042 Dermal: 0.00113 **Total: 0.00155**
Chronic: child playing on playground structure outdoors and mouthing	Dermal: 0.0054 Oral: 0.0180 **Total: 0.0234**	Dermal: 0.0041 Oral: 0.0287 **Total: 0.0328**
Chronic, intermittent: adult laundering work clothes at home	**Dermal: 0.00032**	**Dermal: 0.0041**
Chronic: Inhalation of volatile residues, indoors	**Inhalation:** Infant: 0.000009 Child: 0.000009 Adult: 0.000008	**Inhalation:** Infant: 0.0012 Child: 0.0011 Adult: 0.0010

2.7.2.4 Exposure to residues in food

Not relevant, as contact with food is not predicted.

2.7.3 Risk Characterisation

Induline IL-150 has been subjected to acute toxicity testing. The acute oral and dermal LD_{50} values are greater than 2000 mg/kg bw.

Induline IL-150 has been classified for skin irritation but not for eye irritation according to the DPD criteria.

Induline IL-150 does not fulfil the DPD criteria for classification as a skin sensitizer.

2.7.3.1 Industrial and professionals users

According to table 2.7.3.1-1, industrial or professional users involved in wood treatment by brushing, dipping, deluging or double-vacuum impregnation are not exposed to critical doses of either a.s.

The estimated exposures for the intended use are compared to the respective systemic AEL. With the assumption that they use the obligatory PPE, a sufficient margin of exposure is maintained in all reasonable scenarios.

Table 2.7.3.1-1: Risk characterisation for primary exposure

Scenario	AEL [mg/kg bw/day]	Systemic dose [mg/kg bw/day]	% AEL	NOAEL [mg/kg bw/day]	MoE
Tebuconazole					
Dipping/double-vacuum, incl. handling	0.03	0.0076	25%	3	395
Brush application	0.03	0.0055	18%	3	545
Cleaning the brush after use	0.03	0.0013	4.3%	3	2 308
Total brushing + cleaning	0.03	0.0068	23%	3	441
IPBC					
Dipping/double-vacuum, incl. handling	0.2	0.0096	5%	20	2 083
Brush application	0.2	0.0069	3.5%	20	2 899
Cleaning the brush after use	0.2	0.0010	0.5%	20	20 000
Total: Brushing + cleaning	0.2	0.0079	4%	20	2 532

With proper use in accordance with regulations, harmful effects on the health of users are not expected.

2.7.3.2 Non-professional users

The product is not sold to non-professional users.

2.7.3.3 Indirect exposure as a result of use

An acute secondary exposure to a.s. can be anticipated for adult amateurs who work with treated wood (e.g., sanding) and for children who may have oral contact with treated wood (e.g., chewing on a chip of treated wood). Children are not at risk for acute secondary exposure to wood preservatives.

Chronic secondary exposure is relevant for adults (professionals) who cut or sand treated wood as part of their occupation (e.g. carpenters).

Long-term, but intermittent (once per week) exposure can be envisaged for individuals laundering contaminated work clothing at home. Children may have repeated contact to treated wood, e.g., on playgrounds. For children, dermal contact and oral absorption after hand-to-mouth contact are possible routes of exposure.

Inhalation of volatile residues indoors may be relevant for residents.

It can be concluded that the use of wood treated with Induline IL-150 does not pose an acute or chronic health risk for humans.

Table 2.7.3.3-1: Risk characterisation for secondary exposure

Scenario	AEL [mg/kg bw/day]	Systemic dose [mg/kg bw/day]	% AEL	NOAEL [mg/kg bw/day]	MoE
Tebuconazole					
amateur sanding *(dipping, deluging)*	0.03	0.00091	3%	3	3297
amateur sanding *(double vacuum)*	0.03	0.00098	3%	3	3061
child chewing wood *(dipping, deluging)*	0.03	0.0173	58%	3	173
child chewing wood *(double vacuum)*	0.03	0.0282	94%	3	106
professional sanding *(dipping, deluging)*	0.03	0.00110	4%	3	2727
professional sanding *(double vacuum)*	0.03	0.00143	5%	3	2098
child on playground	0.03	0.0329	110%	3	91
laundry	0.03	0.0032	11%	3	938
Inhalation of volatile residues, indoors. Infant	0.03	0.00000924	0.03%	3	324575
Inhalation of volatile residues, indoors. Child	0.03	0.00000899	0.03%	3	333704
Inhalation of volatile residues, indoors. Adult	0.03	0.00000803	0.03%	3	373599
IPBC					
amateur sanding *(dipping, deluging)*	0.35	0.00115	0.3%	35	30435
amateur sanding *(double vacuum)*	0.35	0.00120	0.3%	35	29167
child chewing wood *(dipping, deluging)*	0.35	0.0108	3.1%	35	3241
child chewing wood *(double vacuum)*	0.35	0.0176	5%	35	1989
professional sanding *(dipping, deluging)*	0.2	0.00127	0.6%	20	15748
professional sanding *(double vacuum)*	0.2	0.00155	0.8%	20	12903
child on playground	0.2	0.02334	12%	20	857
laundry	0.2	0.0041	2.1%	20	4878

Inhalation of volatile residues, indoors. Infant	0.2	0.0012	0.51%	20	16949
Inhalation of volatile residues, indoors. Child	0.2	0.0011	0.57%	20	17544
Inhalation of volatile residues, indoors. Adult	0.2	0.0010	0.59%	20	19608

An unacceptable risk is identified for children on playground being exposed to concentrations of tebuconazole, which exceeds AEL by 110 %. However, in the exposure calculations, a worst case of 100 % contamination is assumed, which is not considered realistic.

By assuming a 90 % contamination instead, which is still considered to be an overestimation of the contamination, the risk is no longer unacceptable.

It is therefore concluded that Induline IL-150 does not pose an unacceptable risk to consumers.

2.7.3.4 Combined exposure

Adults are the only subpopulation who may reasonably experience both primary and secondary exposure to the active substances in Induline IL-150. The secondary exposure adds only negligible doses to the primary exposure, and it is furthermore unlikely that a professional would on the same day, cut and sand treated wood after having worked a whole day with application of wood preservatives.

Conclusion

The use of Induline IL-150 can be considered safe for industrial and professional users. Furthermore, the use of treated wood does not pose a risk for human health due to secondary exposure.

2.7.3.5 Risk for consumers via residues

Not relevant, as contact with food is not predicted.

2.8 Risk assessment for the environment

2.8.1 Environmental classification

2.8.1.1 Environmental classification of the active substances

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

Substance	Env. classification	EC_{50} value (mg/L)	Concentration of a.s. in the product
IPBC	N; R50	0.053 (algae)	0.5
Tebuconazole	N; R51/53	2.8 (daphnia)	0.8

2.8.1.2 Environmental classification of the substance(s) of concern

No substances of concern have been identified for Induline IL-150.

2.8.1.3 Environmental classification of the biocidal product

N; R50:	0.5/2.5 = 0.2	<1
N; R51/53:	0.8/25 = 0.032	<1
R52/53:	0.8/2.5 = 0.32	<1

The classification for the product: **None**.

2.8.2 Environmental exposure assessment

The environmental exposure assessment is based on the OECD series on emission scenario documents (OECD ESD) "Emission Scenario Document for Wood Preservatives (Part 1 and 2)" (OECD, 2003[2]). 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 in-situ applications and the service life of the treated wood. Uses of Induline IL-150 include in-situ application by professionals (brushing) as well as by industrial processes. The application treatments of dipping, spraying, deluging and double-vacuum impregnation are undertaken in joineries and carpentry shops. Since no special Emission Scenario for the industrial process of deluging is foreseen by the ESD for product type 8, this mode of application is assumed to be covered by the dipping/immersion process. Compared to the dipping scenario the industrial deluging procedure proves to have similar aspects, i.e. description of a surface treatment process, stocking and treatment of the timber above a liquid collecting vat, no drizzle building is expected during application and, most importantly, collection and recycling of the excessive liquid into the process.
In joineries wooden articles like window frames are treated and they will be further processed, i.e., they are basically not stored in an open outdoor area. In general, emissions to sewage water during applications in joineries are not likely to occur, because treatment containers are stand-alone devices without direct connection to the sewage. Residues and waste solutions from application containers will be treated as special waste and will not be discharged into the public sewage system. Nevertheless, the

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

OECD application and storage scenarios for dipping, automated spraying and double vacuum are considered and provided for reasons of completeness.

For the envisaged fields of use for Induline IL-150 four main scenarios with the following subcategories have been addressed (Table 2.8-1). The fence scenario has not been included as the timber cladded house is a worst case scenario for the terrestrial compartment.

Table 2.8-1: Relevant exposure scenarios for use of Induline IL-150

Main exposure scenario	Subcategory
Industrial application	- Dipping wooden articles (including deluging) - Spraying - Double-vacuum impregnation
Industrial storage	- Dipping wooden articles (including deluging) - Spraying - Double-vacuum impregnation
In-situ brush application by professional users	- Bridge over pond - Timber cladded house
In-service leaching from treated wood	- Bridge over pond - Timber cladded house - Noise barrier

Substances of concern have not been identified for Induline IL-150, so such substances will not be included in the environmental risk assessment. In addition, no ecotoxicological tests are performed with the product. Therefore, the environmental risk assessment will only be based on IPBC and tebuconazole.

2.8.2.1 Assessment of service life

During the Arona Leaching Workshop in June 2005 (ECB, 2005)[3], 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 5, 15 and 20 years for the longer time period (TIME 2).

2.8.2.2 Leaching rates used for environmental risk assessment

The leaching of IPBC and tebuconazole from treated timber was investigated in a semi-field study. The application was superficial treatment (brushing). The leaching study is evaluated and leaching rates for the emission calculation have been calculated, see Annex 4. The leaching rates are based on a yearly rain amount of 700 mm.

The test was performed with Imprägniergrund Plus (VP 23349) as test material. It contains 0.03% (w/w) Bifenthrine while Induline IL-150 doesn't. Both products contain 0.50% (w/w) IPBC and 0.80% (w/w) tebuconazole. On the background of additional information about the ingredients of Imprägniergrund Plus, we have concluded that it is comparable with Induline IL-150.

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

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

Table 2.8-2: Leaching rates for superficial treatment of Induline IL-150

Active substance	Leaching rates (mg/m^2/day)			
	Storage	TIME1 (30 days)	TIME2 (5 years)	TIME2 (15 years)
IPBC	2.81	2.81	0.141	0.0467
Tebuconazole	2.85	2.85	0.152	0.0627

The leaching rates are calculated based on the semi-field leaching study and the leaching rates are corrected according to the maximum application rate from the efficacy evaluation (135.3 g/m^2). Finally, the rates are applied with an assessment factor of 10, as a top coat was used in the study, for further explanation see Annex 5.

Double vacuum impregnation is one of the modes of applications for Induline IL-150, so a leaching study for penetration treatment is needed beyond the test for superficial treatment (according to the Arona Leaching Workshop in June 2005). As no study was submitted, 100 % leaching of the active substances in the assessed periods of time (30 days and 20 years) is set as default value for the double vacuum impregnation. The calculations are further described in Annex 4 and the leaching rates can be seen in Table 2.8-3.

Table 2.8-3: Leaching rates for double vacuum impregnation of Induline IL-150

Active substance	Leaching rates (mg/m^2/day)	
	TIME1 (30 days)	TIME2 (20 years)
IPBC	61.1 *	0.251 *
Tebuconazole	97.8 *	0.402 *

* Values are based on 100% leaching

2.8.2.3 PEC calculations

The PECs for IPBC and tebuconazole 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 2.8-4 substance specific input parameters used for the emission calculations are shown.

Table 2.8-4: Input parameters for the active substances

	IPBC	Tebuconazole
Half-life in the aquatic compartment (12°C)	3.1 hour (31.2 days)*	198 days** 43 days
Half-life in the terrestrial compartment (12°C)	4.7 hour (9.5 days)*	77 days
Fraction staying in the water phase in the STP	0.97* IPBC is completely degraded to PBC in the STP	0.891
Koc	113.25 (198.1)*	992

* 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 (STPs) are calculated for the industrial application stage, and for in-service leaching from the surfaces of the noise barrier (constructed from pre-treated timber). Emissions to sewage water during the industrial applications are not likely to occur, because treatment containers are stand-alone devices without direct connection to a STP. Residues will be treated as hazardous waste and are not allowed to enter the STP. However, the application scenarios for dipping, which include losses to STP, are calculated for reasons of 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 tebuconazole, the STP effluent concentrations do represent predicted environmental concentrations for this compartment.

A risk assessment for soils being target for PBC and tebuconazole emissions via sewage sludge is not considered to be necessary as this is covered by the direct soil emission.

PEC for surface water

Following the ESD for Product Type 8 (OECD 2003), $PECs_{surface\ water}$ for IPBC/PBC and tebuconazole are calculated for different scenarios and applications. The potential PEC values for surface water depend on the input variables selected for each of the scenarios, and the different emission pathways to surface waters.

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 PT 8 (OECD, 2003), the emission of IPBC and tebuconazole to surface water due to leaching from on-site stored wood is calculated considering a small adjacent creek (flow 0.3 m³ per second).

During outdoor service life PECs for industrial and in-situ treated wood are calculated. The target compartments are pond water (scenario “bridge over pond”) and surface water via STP (scenario “noise barrier”). Using the OECD model “bridge over pond”, the concentrations in pond water 30 days after application (TIME 1 = 30 days) and during the service life (TIME 2 = 5 years, 15 years and 20

years) are calculated. The OECD model "noise barrier" assumes that 70 % of the emissions from wood will reach the surface water via sewage treatment plants.

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

PEC for sediment

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

For tebuconazole $PEC_{sediment}$ 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

According to the OECD Emission Scenario Document for Wood Preservatives (OECD, 2003) PECs for tebuconazole and IPBC in soil are calculated for different scenarios considering in-situ application by professionals, storage/leaching period and the scenario-dependent soil volumes for emissions.

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. During outdoor in-situ treatment initial PECs are calculated according to the OECD ESD models (OECD, 2003) for brushing of a timber house, assuming 3% (professionals) emission of the applied product to 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 Danish CA report for tebuconazole, 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 calculations were undertaken for tebuconazole release of 1000 mg/m^2 treated wood over a period of 5 years. For wood preservation use the predicted environmental concentration of tebuconazole in groundwater, as represented by the 80^{th} percentile leachate concentration at 1 m soil depth, were lower than the legal Drinking Water Limit of 0.1 µg/l in all FOCUS-PEARL scenarios. For the intended use of Induline IL-150 groundwater concentrations below 0.1 µg/l can also be expected because the estimated maximum total tebuconazole release is less than that inves-

tigated in the CA-reports. This demonstrates that the use of tebuconazole in the wood preservative Induline IL-150 should not lead to unacceptable concentrations in groundwater.

PEC for atmosphere

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

Based on the vapour pressure (1.7 x 10^{-6} Pa×m^3) and the Henry's Law constant (1 x 10^{-5} Pa×m³/mol at 25 °C), volatilisation of tebuconazole can be regarded as negligible. 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.

PEC for biota

According to the TGD (EC, 2003) the calculation of a possible risk to man via the food chain ($PEC_{oral predator}$) should be conducted if the a.s. shows a potential for bioaccumulation, indicated by a log K_{ow} value >3.

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

According to the CA report for tebuconazole the calculation of predicted concentrations in organisms is not necessary (no calculations are reported). Hence, it is decided to abstain from further considerations in this dossier.

Calculated PEC values are summarised in Table 2.8-5 and Table 2.8-6for IPBC and tebuconazole, 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. $PEC_{sediment}$ for tebuconazole is without degradation but calculated from $PEC_{surface\ water}$ where degradation is included.

PEC values including degradation are shown in cases where there is a direct discharge to the compartment; this is shown by a symbol.

Table 2.8-5: 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)	20.3	1.08*	-
Spraying (big plant)	203	10.8*	-
Dipping	40.6	2.17*	-
Double vacuum	24.8	1.32*	-
Industrial storage			
Spraying (30 days – small plant)	-	$7.14 \times 10^{-3\#}$	$5.08 \times 10^{-3\#}$
Spraying (15 years – small plant)	-	$7.14 \times 10^{-3\#}$	$5.13 \times 10^{-3\#}$
Spraying (30 days – big plant)	-	$0.0714^{\#}$	$0.0508^{\#}$
Spraying (15 years – big plant)	-	$0.0714^{\#}$	$0.0513^{\#}$
Dipping (30 days)	-	$0.0633^{\#}$	$5.08 \times 10^{-3\#}$
Dipping (15 years)	-	$0.0633^{\#}$	$5.13 \times 10^{-3\#}$
Double vacuum (30 days)	-	$0.518^{\#}$	$0.111^{\#}$
Double vacuum (20 years)	-	$0.518^{\#}$	$0.112^{\#}$
In-situ treatments (brush by professionals)			
House (30 days)	-	-	$7.10 \times 10^{-3}*^{\#}$
House (5 years)	-	-	$9.38 \times 10^{-60}*^{\#}$
Bridge over pond (30 days)	-	$3.19*^{\#}$	-
Bridge over pond (5 years)	-	$1.53 \times 10^{-17}*^{\#}$	-
In-service			
Noise Barrier (30 days)	2.95	0.157*	$1.66 \times 10^{-3\#}$
Noise Barrier (15 years)	0.0487	2.60×10^{-3}*	$2.80 \times 10^{-5\#}$
Noise Barrier (30 days) double vacuum	64.2	3.42*	$0.0362^{\#}$
Noise Barrier (20 years) double vacuum	0.264	0.0141*	$1.50 \times 10^{-4\#}$
House (30 days)	-	-	$4.44 \times 10^{-3\#}$
House (5 years)	-	-	$2.27 \times 10^{-4\#}$
House (15 years)	-	-	$7.48 \times 10^{-5\#}$
House (30 days) double vacuum	-	-	$0.0967^{\#}$
House (20 years) double vacuum	-	-	$4.01 \times 10^{-4\#}$
Bridge over pond (30 days)	-	$0.260^{\#}$	-
Bridge over pond (5 years)	-	$1.71*^{\#}$	-
Bridge over pond (15 years)	-	$0.575*^{\#}$	-
Bridge over pond (30 days) double vacuum	-	$5.66^{\#}$	-
Bridge over pond (20 years) double vacuum	-	$3.10*^{\#}$	-
In- service after in-situ treatment			
House (30 days)	-	-	$4.44 \times 10^{-3\#}$
House (5 years)	-	-	$2.27 \times 10^{-4\#}$
Bridge over pond (30 days)	-	$0.260^{\#}$	-
Bridge over pond (5 years)	-	$1.71*^{\#}$	-

* Values for PBC
# Values including degradation

Table 2.8-6: Summary of PEC values (with and without degradation) for tebuconazole

Tebuconazole	PEC_{STP} (µg/L)	$PEC_{surface\ water}$ (µg/L)	$PEC_{sediment}$ (mg/kg_{wwt})	PEC_{soil} (mg/kg_{wwt})
Industrial application				
Spraying (small plant)	28.9	2.89	0.0646	-
Spraying (big plant)	289	28.9	0.646	-
Dipping	57.9	5.78	0.129	-
Double vacuum	35.3	3.52	0.0787	-
Industrial storage				
Spraying (30 days – small plant)	-	$0.0238^{\#}$	$5.31 \times 10^{-4\#\#}$	$0.253^{\#}$
Spraying (15 years – small plant)	-	$0.0238^{\#}$	$5.31 \times 10^{-4\#\#}$	$2.01^{\#}$
Spraying (30 days – big plant)	-	$0.238^{\#}$	$5.31 \times 10^{-3\#\#}$	$2.53^{\#}$
Spraying (15 years – big plant)	-	$0.238^{\#}$	$5.31 \times 10^{-3\#\#}$	$20.1^{\#}$
Dipping (30 days)	-	$0.211^{\#}$	$4.71 \times 10^{-3\#\#}$	$0.253^{\#}$
Dipping (15 years)	-	$0.211^{\#}$	$4.71 \times 10^{-3\#\#}$	$2.01^{\#}$
Double vacuum (30 days)	-	$2.71^{\#}$	$0.0607^{\#\#}$	$8.69^{\#}$
Double vacuum (20 years)	-	$2.71^{\#}$	$0.0607^{\#\#}$	$69.2^{\#}$
In-situ treatments (brush by professionals)				
House (30 days)	-	-	-	$0.140^{\#}$
House (5 years)	-	-	-	$1.35 \times 10^{-8\#}$
Bridge over pond (30 days)	-	$10.3^{\#}$	$0.413^{\#\#}$	-
Bridge over pond (5 years)	-	$1.85 \times 10^{-11\#}$	$0.107^{\#\#}$	-
In-service				
Noise Barrier (30 days)	2.17	0.217	4.84×10^{-3}	$0.0829^{\#}$
Noise Barrier (15 years)	0.0478	4.77×10^{-3}	1.07×10^{-4}	$0.0161^{\#}$
Noise Barrier (30 days) double vacuum	74.4	7.43	0.166	$2.84^{\#}$
Noise Barrier (20 years) double vacuum	0.306	0.0305	6.83×10^{-4}	$0.0931^{\#}$
House (30 days)	-	-	-	$0.221^{\#}$
House (5 years)	-	-	-	$0.104^{\#}$
House (15 years)	-	-	-	$0.0431^{\#}$
House (30 days) double vacuum	-	-	-	$7.60^{\#}$
House (20 years) double vacuum	-	-	-	$0.250^{\#}$
Bridge over pond (30 days)	-	$18.5^{\#}$	$0.413^{\#\#}$	-
Bridge over pond (5 years)	-	$4.79^{\#}$	$0.107^{\#\#}$	-
Bridge over pond (15 years)	-	$2.05^{\#}$	$0.0457^{\#\#}$	-
Bridge over pond (30 days) double vacuum	-	$634^{\#}$	$14.2^{\#\#}$	-
Bridge over pond (20 years) double vacuum	-	$13.2^{\#}$	$0.295^{\#\#}$	-
In- service after in-situ treatment				
House (30 days)	-	-	-	$0.362^{\#}$
House (5 years)	-	-	-	$0.103^{\#}$
Bridge over pond (30 days)	-	$28.8^{\#}$	$0.827^{\#\#}$	-
Bridge over pond (5 years)	-	$4.79^{\#}$	$0.214^{\#\#}$	-

$^{\#}$ Values 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 2.8-7 are used for the risk characterisation

Table 2.8-7: PNEC values used for risk characterisation

	IPBC/PBC	Tebuconazole
$PNEC_{STP}$ (µg/L)	440/-	320
$PNEC_{surface\ water}$ (µg/L)	0.5/41.3	1.0
$PNEC_{sediment}$ (mg/kg wwt)	Covered by surface water	0.55
$PNEC_{soil}$ (mg/kg wwt)	0.00434/0.149	0.1

Calculated PEC/PNEC values are summarised in Table 2.8-8 and Table 2.8-9 for IPBC and tebuconazole, respectively.

Table 2.8-8: 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)	0.0461	0.0262*	-
Spraying (big plant)	0.461	0.262*	-
Dipping	0.0923	0.0524*	-
Double vacuum	0.0563	0.0320*	-
Industrial storage			
Spraying (30 days – small plant)	-	0.0143 #	**1.17#**
Spraying (15 years – small plant)	-	0.0143#	**1.18#**
Spraying (30 days – big plant)	-	0.143#	**11.7 #**
Spraying (15 years – big plant)	-	0.143 #	**11.8 #**
Dipping (30 days)	-	0.127#	**1.17 #**
Dipping (15 years)	-	0.127#	**1.18 #**
Double vacuum (30 days)	-	1.04#	**25.5#**
Double vacuum (20 years)	-	1.04#	**25.7#**
In-situ treatments (brush by professionals)			
House (30 days)	-	-	0.0476 *#
House (5 years)	-	-	6.30×10^{-59} *#
Bridge over pond (30 days)	-	0.0773* #	-
Bridge over pond (5 years)	-	3.71×10^{-19}* #	-
In-service			
Noise Barrier (30 days)	**5.89**	3.81×10^{-3}*	0.383#
Noise Barrier (15 years)	0.0974	6.29×10^{-5}*	6.45×10^{-3}#
Noise Barrier (30 days) double vacuum	**128**	0.0829*	**8.35#**
Noise Barrier (20 years) double vacuum	0.527	3.41×10^{-4}*	0.0346 #
House (30 days)	-	-	1.02#
House (5 years)	-	-	0.0522 #
House (15 years)	-	-	0.0172 #
House (30 days) double vacuum	-	-	**22.3#**
House (20 years) double vacuum	-	-	0.0925 #
Bridge over pond (30 days)	-	0.520 #	-
Bridge over pond (5 years)	-	0.0415 *#	-
Bridge over pond (15 years)	-	0.0139*#	-
Bridge over pond (30 days) double vacuum	-	11.3#	-
Bridge over pond (20 years) double vacuum	-	0.0751* #	-
In- service after in-situ treatment			
House (30 days)	-	-	**1.02#**
House (5 years)	-	-	0.0522 #
Bridge over pond (30 days)	-	0.520#	-
Bridge over pond (5 years)	-	0.0415*#	-

* Values for PBC
# Values including degradation

Table 2.8-9: Summary of PEC/PNEC values (with and without degradation) for tebuconazole

Tebuconazole	$PEC/PNEC_{STP}$	$PEC/PNEC_{surface\ water}$	$PEC/PNEC_{sediment}$	$PEC/PNEC_{soil}$
Industrial application				
Spraying (small plant)	0.0904	**2.89**	0.117	-
Spraying (big plant)	0.904	**28.9**	1.17	-
Dipping	0.181	**5.78**	0.235	-
Double vacuum	0.110	**3.52**	0.143	-
Industrial storage				
Spraying (30 days – small plant)	-	$0.0238^{\#}$	$9.66 \times 10^{-4\#\#}$	**2.53**$^{\#}$
Spraying (15 years – small plant)	-	$0.0238^{\#}$	$9.66 \times 10^{-4\#\#}$	**20.1**$^{\#}$
Spraying (30 days – big plant)	-	$0.238^{\#}$	$9.66 \times 10^{-3\#\#}$	**25.3**$^{\#}$
Spraying (15 years – big plant)	-	$0.238^{\#}$	$9.66 \times 10^{-3\#\#}$	**201**$^{\#}$
Dipping (30 days)	-	$0.211^{\#}$	$8.56 \times 10^{-3\#\#}$	**2.53**$^{\#}$
Dipping (15 years)	-	$0.211^{\#}$	$8.56 \times 10^{-3\#\#}$	**20.1**$^{\#}$
Double vacuum (30 days)	-	**2.71**$^{\#}$	$0.110^{\#\#}$	**86.9**$^{\#}$
Double vacuum (20 years)	-	**2.71**$^{\#}$	$0.110^{\#\#}$	**692**$^{\#}$
In-situ treatments (brush by professionals)				
House (30 days)	-	-	-	**1.40**$^{\#}$
House (5 years)	-	-	-	$1.35 \times 10^{-7\#}$
Bridge over pond (30 days)	-	**10.3**$^{\#}$	$0.752^{\#\#}$	-
Bridge over pond (5 years)	-	$1.85 \times 10^{-11\ \#}$	$0.195^{\#\#}$	-
In-service				
Noise Barrier (30 days)	6.78×10^{-3}	0.217	8.80×10^{-3}	$0.829^{\#}$
Noise Barrier (15 years)	1.49×10^{-4}	4.77×10^{-3}	1.94×10^{-4}	$0.161^{\#}$
Noise Barrier (30 days) double vacuum	0.233	**7.43**	0.302	**28.4**$^{\#}$
Noise Barrier (20 years) double vacuum	9.56×10^{-4}	0.0305	1.24×10^{-3}	$0.931^{\#}$
House (30 days)	-	-	-	**2.21**$^{\#}$
House (5 years)	-	-	-	$1.04^{\#}$
House (15 years)	-	-	-	$0.431^{\#}$
House (30 days) double vacuum	-	-	-	**76.0**$^{\#}$
House (20 years) double vacuum	-	-	-	**2.50**$^{\#}$
Bridge over pond (30 days)	-	**18.5**$^{\#}$	$0.751^{\#\#}$	-
Bridge over pond (5 years)	-	**4.79**$^{\#}$	$0.194^{\#\#}$	-
Bridge over pond (15 years)	-	**2.04**$^{\#}$	$0.0831^{\#\#}$	-
Bridge over pond (30 days) double vacuum	-	**634**$^{\#}$	**25.8**$^{\#\#}$	-
Bridge over pond (20 years) double vacuum	-	**13.2**$^{\#}$	$0.537^{\#\#}$	-
In- service after in-situ treatment				
House (30 days)	-	-	-	**3.62**$^{\#}$
House (5 years)	-	-	-	$1.04^{\#}$
Bridge over pond (30 days)	-	**28.8**$^{\#}$	**1.50**$^{\#\#}$	-
Bridge over pond (5 years)	-	**4.79**$^{\#}$	$0.389^{\#\#}$	-

$^{\#}$ Values including degradation
$^{\#\#}$ Based on value that includes degradation

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

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

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

In Table 2.8-10 $(PEC/PNEC)_{product}$ values for each environmental compartment are summarised.

Table 2.8-10: Summary of PEC/PNEC values (with and without degradation) for the product

Induline IL-150	$PEC/PNEC_{STP}$	$PEC/PNEC_{surface\ water}$	$PEC_{sediment}$	$PEC/PNEC_{soil}$
Industrial application				
Spraying (small plant)	0.137	**2.92**	0.117	-
Spraying (big plant)	**1.37**	**29.2**	**1.17**	-
Dipping	0.273	**5.83**	0.235	-
Double vacuum	0.167	**3.56**	0.143	-
Industrial storage				
Spraying (30 days – small plant)	-	0.0380	9.66×10^{-4}	**3.70**
Spraying (15 years – small plant)	-	0.0380	9.66×10^{-4}	**21.2**
Spraying (30 days – big plant)	-	0.380	9.66×10^{-3}	**37.0**
Spraying (15 years – big plant)	-	0.380	9.66×10^{-3}	**212**
Dipping (30 days)	-	0.337	8.56×10^{-3}	**3.70**
Dipping (15 years)	-	0.337	8.56×10^{-3}	**21.2**
Double vacuum (30 days)	-	**3.75**	0.110	**112**
Double vacuum (20 years)	-	**3.75**	0.110	**718**
In-situ treatments (brush by professionals)				
House (30 days)	-	-	-	**1.45**
House (5 years)	-	-	-	1.35×10^{-7}
Bridge over pond (30 days)	-	**10.4**	0.752	-
Bridge over pond (5 years)	-	1.85×10^{-11}	0.195	-
In-service				
Noise Barrier (30 days)	**5.90**	0.220	8.80×10^{-3}	**1.21**
Noise Barrier (15 years)	0.0976	4.83×10^{-3}	1.94×10^{-4}	0.168
Noise Barrier (30 days) double vacuum	**129**	**7.52**	0.302	**36.8**
Noise Barrier (20 years) double vacuum	0.528	0.0309	1.24×10^{-3}	0.966
House (30 days)	-	-	-	**3.24**
House (5 years)	-	-	-	1.09
House (15 years)	-	-	-	0.449
House (30 days) double vacuum	-	-	-	**98.3**
House (20 years) double vacuum	-	-	-	**2.59**
Bridge over pond (30 days)	-	**19.0**	0.751	-
Bridge over pond (5 years)	-	**4.83**	0.194	-
Bridge over pond (15 years)	-	**2.06**	0.0831	-
Bridge over pond (30 days) double vacuum	-	**646**	**25.8**	-
Bridge over pond (20 years) double vacuum	-	**13.3**	0.537	-
In- service after in-situ treatment				
House (30 days)	-	-	-	**4.64**
House (5 years)	-	-	-	1.09
Bridge over pond (30 days)	-	**29.3**	**1.50**	-
Bridge over pond (5 years)	-	**4.83**	0.389	-

As stated in section 2.8.3.2, the risk for the sediment compartment of IPBC/PBC is the same as the assessed for surface water. The PEC/PNEC values for IPBC/PBC in sediment are however not added to that of the other active substance in Table 2.8-10. Because tebuconazole are of much greater concern in 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.

A risk is identified for the STP, surface water and sediment during the industrial application. 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 identified for the surface water (double vacuum) and soil compartment. Therefore, freshly treated wood is to be stored after treatment under shelter or on impermeable hard standing to avoid direct losses to water and soil. Any losses must be collected for reuse or disposal.

Risk is identified for the soil and surface water when applied by brushing in-situ by professionals at the initial period.

During the service life risk is identified for the soil at the initial period as well after 5 and 20 years, except for the noise barrier. Even though a risk (PEC/PNEC = 1.09) is identified after 5 years for the house scenario, in this case it is acceptable as it is only a slight exceeding of the limit of 1 and the calculations has been done with an assessment factor of 10.

For the bridge over pond scenario a risk is found for surface water during the entire service life and for the sediment at the initial period for wood treated by double vacuum.

A risk is also identified for the soil and surface water for the combined risk from the in-situ application and service life.

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).

Conclusion: The overall conclusion of the environmental risk assessment for Induline IL-150 is that no unacceptable risk is identified for secondary poisoning, air, and the groundwater compartment. However a risk is identified during industrial 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 avoid direct losses to water and soil. Any losses must be collected for reuse or disposal**. Risk is also identified for the surface water compartment when used in the vicinity of water. As a consequence **the treated wood can not be used close to water**. The application for **double vacuum pressure application can not be authorised** at this point as an unacceptable risk is identified for all the relevant scenarios.

2.9 Measures to protect man, animals and the environment

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

Handling and use:
Information for safe handling: Use only in well ventilated areas. Open and handle container with care. Ensure good interior ventilation, especially at floor level. (Fumes are heavier than air.).
Information about protection against explosions and fires: Keep ignition sources away - Do not smoke. Protect against electrostatic charges. Fumes can combine with air to form an explosive mixture.
Additional information about design of technical systems: Use only in well-ventilated areas.
Components with limit values that require monitoring at the workplace: (2-methoxymethylethoxy)propanol.
Additional information: The lists that were valid during compilation were used as a basis.
Personal protection equipment:
General protective and hygienic measures:

Do not eat, drink or smoke while working. Apply solvent-resistant skin protection preparation before beginning work. Keep away from food, beverages and animal feed. Wash hands before pauses and after work. Do not inhale gases / vapours / aerosols.
Respiratory equipment:
In case of brief exposure or low pollution load, use respiratory protection equipment with filter. In case of intensive or longer exposure, use self-contained respiratory protection equipment. Short term filter device: Filter A (brown).
Protection of hands: Solvent resistant gloves.
Material of gloves: Nitrile rubber, NBR
Penetration time of glove material: Break through time: max. 240 min (DIN EN 374). The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
Eye protection: Safety glasses recommended during refilling.
Body protection: Protective work clothing.

Storage:
Requirements to be met by storerooms and containers: Prevent any penetration into the ground.
Information on storage in a common storage facility: Store away from food.
Further information about storage conditions: Store cool and dry in tightly closed containers. Store container in a well ventilated position. Protect from heat and direct sunlight. Do not smoke in storage areas. Storage temperature: room temperature.

Transport:
Not a hazardous good.

Fire:
Suitable extinguishing agents: Foam, Fire-extinguishing powder, Water spray jet
For safety reasons unsuitable extinguishing agents: Water with a full water jet.
Protective equipment: Wear self-contained breathing apparatus. Wear full protective suit.
Additional information: Cool endangered containers with water spray jet. Collect contaminated fire fighting water separately. It must not enter drains. Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

Emergency measures in case of an accident

Person-related safety precautions:
Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation. Keep away from ignition sources.

First aid measures:
General information: If symptoms occur or in case of doubt, seek medical attention. In case of unconsciousness, do not administer anything orally. Immediately remove any clothing soiled by the product. In case of irregular breathing or respiratory arrest, provide artificial respiration.
After inhalation: Take affected persons into the open air and position comfortably. Seek medical treatment in case of complaints.
After skin contact: Wash immediately with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.
After eye contact: Rinse opened eye for several minutes under running water. Then consult doctor.
After swallowing: Do not induce vomiting; call for medical help immediately. Keep the person affected quiet.
Information for doctor: The following symptoms may occur: In case of prolonged/repeated exposure or in high concentrations: Headache, dizziness and dry skin
Irritating effect on skin and eyes.
Inhalation may have an irritating effect on mucous membranes.
Danger: Swallowing followed by vomiting may lead to aspiration into the lungs which lead to suffocation or toxic pulmonary oedema. Long-term or repeated exposure may cause inflammation of the skin (dermatitis).
Treatment: Symptomatic treatment
To avoid dermatitis (skin inflammation) use skin cream.

Measures for environmental protection:

Do not allow product to reach sewage system or water bodies. Do not allow to enter the ground/soil. Prevent from spreading (e.g. by confining or oil barrier). Inform responsible authorities if the product penetrates into the ground. Inform responsible authorities in case of product reaches bodies of water or sewage system.

Measures for cleaning/collecting:
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Send for recovery or disposal in suitable containers. Ensure adequate ventilation.

Disposal considerations

Product:
Recommendation: Do not dispose of together with household garbage. Do not allow product to reach sewage system. Must be specially treated in compliance with official regulations. Larger amounts must be disposed of as special refuse in compliance with official regulations. The given refuse codes are recommendations based upon the intended use of the product. Because of special use and disposal conditions at the users, other codes may apply under other conditions.
European waste catalogue: 03 02 99 wood preservatives not otherwise specified.

Uncleaned packaging:
Recommendation: Disposal must be made according to official regulations. Only completely empty containers may be recycled.

3 Proposal for decision

3.1 Background to the proposed decision

Physico-chemical properties:
The physico-chemical properties of the active substances and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substances and biocidal product. The authorisation of Induline IL-150 is given on the condition, that the final report on long-term stability is submitted as soon as it is finalised.

Efficacy evaluation:
Induline IL-150 is recommended to be approved as a biocide product to protect against wood discolouring fungi and wood destroying basidiomycetes for softwood in use class 2 and 3 by superficial application at application rate 150-165 ml/m^2 and at 20-22 kg/m^3 for penetrating treatments. When claimed for wood discolouring fungi, a top coat has to be applied.

Human health assessment:
Based on the risk assessment of the active substance, a risk for professional and industrial users resulting from the intended use is unlikely. Regarding occupational safety, there are no objections against the intended use.
The direct exposure, exposure via the environment or to other residues resulting from the intended use is unlikely to cause any unacceptable acute or chronic risk to consumers (non-professionals, bystanders and residents). Regarding consumer health protection, there are no objections against the intended uses.

Environmental assessment:
The overall conclusion of the environmental risk assessment for Induline IL-150 is that no unacceptable risk is identified for secondary poisoning, air, and the groundwater compartment. However a risk is identified during industrial 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 avoid direct losses to water and soil. Any losses must be collected for reuse or disposal. Risk is also identified for the surface water compartment when used in the vicinity of water. As a consequence the treated wood can not be used close to water.

The application for double vacuum pressure application can not be authorised at this point as an unacceptable risk is identified for all the relevant scenarios.

3.2 Proposed Decision regarding Authorisation of the biocidal product

The Danish CA proposes the authorisation of the biocidal product Induline IL-150 as a wood preservative (PT8) fir use by brushing (professionals), dipping, deluging and automated spraying. The use rate is 150-165 ml/m^2, depending on application and retention capacity of the wood.

Identity of the Biocidal Product
The biocidal product, Induline IL-150, contains 0.50% and 0.80% (w/w) IPBC and tebuconazole, respectively.

Particular Conditions
Purity of the Active Substance
The active substance as manufactured shall have the following minimum purities:

IPBC: 980 g/kg
Tebuconazole: 950 g/kg

Product Type
PT8: Wood preservatives

The authorisation of Induline IL-150 is given on the condition, that the final report on physico-chemical properties for Induline IL-150 is submitted as soon as it is finalised.

Expiry Date of the Authorisation

The authorisation of Induline IL-150 expires on 31 March 2020, which is the expiry date of Annex I listing of the active substance, i.e. that of tebuconazole.

Annexes

1. **List of studies reviewed**
2. **Toxicology and metabolism –active substance**
3. **Human exposure assessment**
4. **Leaching calculations**
5. **Additional information about the calculation of leaching rates**

Annex 1: List of studies reviewed

List of new data[4] 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

(Sub)Section / Annex point	Authors (s)	Year	Title	Data Owner	Letter of access (Yes/no)	Data Protection Claimed (Yes/No)
B2.2(01) IIB, II 2.2	Leroy, D.	2011	Confirmation of the purity of the active substance IPBC sold to Remmers Baustofftechnik GmbH. Date: 2011-06-27	Troy		Yes
B3.1(01) IB, III 3.1 *also filed B3.5(01)* *also filed B3.7(02)* *also filed B3.10(02)*	Paulus, J.	2011	Interim report determination of the storage stability of Imprägniergrund Plus/ VP 23333 at room temperature. Date: 2011-01-26	Remmers Baustofftechnik GmbH		Yes
B3.4(01) IIB, III 3.4 *also filed B3.6(01)* *also filed B3.7(01)* *also filed B3.10(01)*	Legay, S.	2010	Physico-chemical tests on a petroleum solvent (ready-to-use) based preservative (VAC PB IT PLUS VP23333). Date: 2010-03-24	Remmers Baustofftechnik GmbH		Yes
B3.4(02) IIB, III 3.4	Paulus, J.	2010	Determination of the auto ignition temperature of Imprägniergrund Plus/ VP23333 according to EU A.15. Date: 2010-06-02	Remmers Baustofftechnik GmbH		Yes
B3.5(01) IIB, III 3.5 *filed B3.1(01)*	Paulus, J.	2011	Interim report determination of the storage stability of Imprägniergrund Plus/ VP 23333 at room temperature. Date: 2011-01-26	Remmers Baustofftechnik GmbH		Yes

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

(Sub)Section / Annex point	Authors (s)	Year	Title	Data Owner	Letter of access (Yes/no)	Data Protection Claimed (Yes/No)
B3.5(02) IIB, III 3.5 *also filed B3.7(03)* *also filed B3.10(03)*	Affolter, O.	2011	Statement concerning Storage Stability.	Remmers Baustofftechnik GmbH		Yes
B3.6(01) IIB, III 3.6 *filed B3.4(01)*	Legay, S.	2010	Physico-chemical tests on a petroleum solvent (ready-to-use) based preservative (VAC PB IT PLUS VP23333). Date: 2010-03-24	Remmers Baustofftechnik GmbH		Yes
B3.7(01) IIB, III 3.7 *filed B3.4(01)*	Legay, S.	2010	Physico-chemical tests on a petroleum solvent (ready-to-use) based preservative (VAC PB IT PLUS VP23333). Date: 2010-03-24	Remmers Baustofftechnik GmbH		Yes
B3.7(02) IIB, III 3.7 *filed B3.1(01)*	Paulus, J.	2011	Interim report determination of the storage stability of Imprägniergrund Plus/ VP 23333 at room temperature. Date: 2011-01-26	Remmers Baustofftechnik GmbH		Yes
B3.7(03) IIB, III 3.7 *filed B3.5(02)*	Affolter, O.	2011	Statement concerning Storage Stability.	Remmers Baustofftechnik GmbH		Yes
B3.10(01) – *filed B3.4(01)*	Legay, S.	2010	Physico-chemical tests on a petroleum solvent (ready-to-use) based preservative (VAC PB IT PLUS VP23333). Date: 2010-03-24	Remmers Baustofftechnik GmbH		Yes
B3.10(02) – *filed B3.1(01)*	Paulus, J.	2011	Interim report determination of the storage stability of Imprägniergrund Plus/ VP 23333 at room temperature. Date: 2011-01-26	Remmers Baustofftechnik GmbH		Yes
B3.10(03) – *filed B3.5(02)*	Affolter, O.	2011	Statement concerning Storage Stability.	Remmers Baustofftechnik GmbH		Yes

(Sub)Section / Annex point	Authors (s)	Year	Title	Data Owner	Letter of access (Yes/no)	Data Protection Claimed (Yes/No)
B5.10(01) IIB, V 5.10	Le Bayon, I., Gabill, M. and Lehn, V.	2009	Determination of the protective efectiveness of VAC PB IT Plus VP 23333 against blue stain in wood in service after an artificial weathering (QUV device). Date: 2009-12-22	Remmers Baustofftechnik GmbH		Yes
B5.10(02) IIB, V 5.10	Le Bayon, I., Gabille, M. and Lehn V.	2010	Determination of the protective effectiveness of VAC PB IT Plus VP 23333 against wood destroying basidiomycetes after leaching procedure according to EN 84: 1997. Date: 2010-02-23	Remmers Baustofftechnik GmbH		Yes
B5.10(03) IIB, V 5.10	Le Bayon, I. and Lehn, V.	2010	Determination of protective effectiveness of VAC PB IT Plus VP 23333 against wood destroying basidiomycetes after evaporative procedure according to EN 73 (1988). Date: 2010-03-10	Remmers Baustofftechnik GmbH		Yes
B5.10(04) IIB, V 5.10	Le Bayon, I. and Lehn, V.	2009	Determination of the protective efectiveness of VP 23349 against blue stain in wood in service after an artficial weathering (QUV device). Date: 2009-12-22	Remmers Baustofftechnik GmbH		Yes
B5.10(05) IIB, V 5.10	Schumacher, P. and Fennert, E-M.	2010	Determination of the depth of efficacy against wood destroying basidiomycetes according to the test – guidelines of DIBt (draft 05/2006) and according to CEN/TS 839 (06/2008) after leaching procedure according to EN 84 (05/97) – planning off test. Date: 2010-03-23	Remmers Baustofftechnik GmbH		Yes

(Sub)Section / Annex point	Authors (s)	Year	Title	Data Owner	Letter of access (Yes/no)	Data Protection Claimed (Yes/No)
B5.10(06) IIB, V 5.10	Morsing, E. and Lindegaard B.	2010a	Determination of the protective efectiveness of VP 23333 with retention of 20 kg/m^3 against blue stain in wood in service after an artificial weathering (QUV device). Date: 2010-07-23	Remmers Baustofftechnik GmbH		Yes
B5.10(07) IIB, V 5.10	Morsing, E. and Lindegaard B.	2010b	Determination of the protective efectiveness of VP 23333 with retention 30 kg/m^3 against blue stain in wood in service after an artificial weathering (QUV device). Date: 2010-07-23	Remmers Baustofftechnik GmbH		Yes
B5.10(08) IIB, V 5.10	Morsing, E. and Lindegaard B.	2010c	Determination of the protective efectiveness of VP 23333, wet film 123 g/m^2 against blue stain in wood in service after an artificial weathering (QUV device). Date: 2010-09-29	Remmers Baustofftechnik GmbH		Yes
B5.10(09) IIB, V 5.10	Morsing, E. and Lindegaard B.	2010d	Determination of the protective efectiveness of VP 23333, wet film 100 g/m^2 against blue stain in wood in service after an artificial weathering (QUV device). Date: 2010-09-29	Remmers Baustofftechnik GmbH		Yes
B5.10(10) IIB, V 5.10	Morsing, E. and Lindegaard B.	2010e	Determination of the protective efectiveness of VP 23349, wet film 150 g/m^2 against blue stain in wood in service after an artificial weathering (QUV device). Date: 2010-07-23	Remmers Baustofftechnik GmbH		Yes
B6.1.1(01) IIB, VI 6.1.1	Colas, S.	2010a	Imprägniergrund Plus/ VP 23333 Evaluation of acute oral toxicity in rats. Date: 2010-04-14	Remmers Baustofftechnik GmbH		Yes

(Sub)Section / Annex point	Authors (s)	Year	Title	Data Owner	Letter of access (Yes/no)	Data Protection Claimed (Yes/No)
B6.1.2(01) IIB, VI 6.1.2	Colas, S.	2010b	VAC PB IT / VP 23333 Evaluation of acute dermal toxicity in rats. Date: 2010-06-03	Remmers Baustofftechnik GmbH		Yes
B6.2.1(01) IIB, VI 6.2	Colas, S.	2010c	VAC PB IT / VP 23333 Assessment of acute dermal irritation. Date: 2010-05-31	Remmers Baustofftechnik GmbH		Yes
B6.2.2(01) IIB, VI 6.2	Colas, S.	2010d	VAC PB IT / VP 23333 Assessment of acute eye irritation. Date: 2010-05-31	Remmers Baustofftechnik GmbH		Yes
B6.3(01) IIB, VI 6.3	Colas, S.	2010e	Imprägniergrund Plus / VP 23333 Assessment of sensitising properties on albino guinea pigs - Maximisation test according to Magnusson and Kligman. Date: 2010-06-10	Remmers Baustofftechnik GmbH		Yes
B7.1(01) IIB, VII 7.1	Wegner, R.	2011	Imprägniergrund Plus - Leaching of active ingredients from preservative-treated timber – Semi-field testing. Date: 2011-03-07	Remmers Baustofftechnik GmbH		Yes
B7.1(02) IIB, VII 7.1	Wegner, R.	2010	Determination of active substances in test product Imprägniergrund Plus (leaching test, reports No. 31/10/1373/01 and 31/09/1325/04). Date: 2010-03-03	Remmers Baustofftechnik GmbH		Yes
B8(01) IIB, VIII 8	Remmers Baustofftechnik GmbH (Ed.)	2010	Safety Data Sheet Induline IL-150. Date: 2010-05-31	Remmers Baustofftechnik GmbH		No

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 *in vitro* human skin study with solvent based on model product)

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

Active substance: tebuconazole

Threshold Limits and other Values for Human Health Risk Assessment

Summary			
	Value	Study	AF
AEL long-term	0.03 mg/kg bw/day	1 year dog	100
AEL medium-term	-	-	-
AEL acute	0.03 mg/kg bw/day	1 year dog	100

Inhalative absorption	Default: 100%
Oral absorption	> 98% (based on urinary (7.4%) and biliary (90.9%) excretion within 48 hours)
Dermal absorption	The ability of tebuconazole to penetrate the skin was examined in-vitro with the solvent-based and water-based guide formulations containing approx. 0.63-0.65% [^{14}C]-tebuconazole. After 24 hours with 8 hours of exposure to the **solvent-based preparation** , the total amount of radioactive material absorbed and residues found in stratum corneum strip 6-20 was 14.4% After 24 hours with 8 hours of exposure to the **water-based preparation**, the absorbed dose and residues found in stratum corneum strip 6-20 was 3.3%.

Classification	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	Xn; Repr. Cat.3 R63: Possible risk of harm to the unborn child R22: Harmful if swallowed
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Repr. 2 - H361 Acute Tox 4 - H302

Annex 3: Human exposure assessment

Induline IL-150

Human exposure assessment calculations
To estimate dermal exposure, a **clothing penetration** for coated coveralls of **10%** was assumed, as suggested by the HEEG opinion "Default protection factors for protective clothing and gloves" (2010). A clothing penetration for light clothing of **50%** (TNsG 2007 default) was assumed as a worst case for professional users.

For solvent-based solutions containing 0.5-0.6% **IPBC**, a dermal absorption value of 30% has been set in the CAR by RMS Denmark. Therefore, a dermal absorption value of 30% will be assumed for the b.p. (0.5% IPBC).

For dilute solvent-based **tebuconazole** solutions (0.63%), a dermal absorption value of 14.4% has been set in the CAR by RMS Denmark. Therefore, a dermal absorption value of 14.4% will be assumed for the b.p. (0.8% tebuconazole).

The default value for **body weight** of an exposed adult is assumed to be **60 kg** (ECETOC, 2001).

1 Industrial / professional exposure

1.1 Professional brushing - application

Mixing/loading
The b.p. is ready to use. Mixing/loading is therefore no relevant task.

Application

Exposure calculations are given according to TNsG 2007 (BEAT). Data for brush application of solvent-based wood preservatives to garden fences are available from the BEAT database.
In this simulation study volunteers (n=48) applied solvent-based paints containing wood preservatives to wooden fences (Federal Institute for Risk Assessment, Berlin (2005) Human Exposure to Wood Preservatives).
This exposure study does not contain inhalation data. BEAT contains a smaller data set on "garden timber treatment" that also featured solvent-based products (Garrod A.N.I. *et al.* (2000). Potential exposure of amateurs (consumers) through painting wood preservative and antifoulant preparations. *Annals of Occupational Hygiene* **44** 421-426). The 75th percentile inhalation exposure from this data set will be used as surrogate, although inhalation exposure from brushing is going to be very low considering the lack of respirable aerosols and the low vapour pressure of the active substance.
The TNsG Excel database for human exposure gives a default value of 180 min for the duration of brushing of ready-to-use products.
The permeation of active substances through light clothing is 50% in the BEAT database, which is used as a worst case factor for professionals. Protective gloves (PF10) are worn during brushing.

Cleaning
A post-application task which may lead to some degree of exposure is the cleaning of the brush. Cleaning of the equipment (brush) by professionals occurs after the application event and lasts for no more than 15 min. It might result in some exposure to hands. The exposure during cleaning is not cov-

ered by any of the proposed TNsG models; therefore an internal calculation is provided. Exposure during cleaning is calculated in Section 1.2.

Applied parameters for brushing:

Hands	**9.14 mg/min** (potential, 75th percentile, n=48)
Glove penetration	**10%**
Body	**1.12 mg/min** (potential, 75th percentile, n=48)
Clothing penetration	**50%** (light clothing)
Inhalation	**1.04 mg/m³** (potential, 75th percentile, n=15)
Inhalation rate	**1.25 m³/h** (default)
Duration	**180 min** (TNsG, Excel database)
Body weight	**60 kg** (default)

Estimated exposure during brushing is calculated in Table A3-1. **The estimated systemic exposure to tebuconazole and IPBC is 0.0055 and 0.0070 mg/kg bw/day**

Table A3-1: Exposure assessment for professional brush application

Brushing - water-based product		
	IPBC	**Tebuconazole**
active substance % (w/w)	0,50%	0,800%
Potential body exposure		
Indicative value mg/min	1,12	1,12
Duration min	180	180
Potential dermal deposit mg	201,6	201,6
Clothing type	Light clothing	Light clothing
Clothing penetration %	50%	50%
Actual dermal deposit [product] mg	100,8	100,8
Hand exposure		
Indicative value mg/min (potential)	9,14	9,14
Duration min	180	180
Hand deposit mg	1645,2	1645,2
Mitigation by gloves	0,1	0,1
Actual hand deposit [product] mg	164,52	164,52
Total dermal exposure		
Total dermal deposit [product] mg	265,32	265,32
Active substance mg	1,33	2,12
Dermal absorption %	30%	14%
Systemic exposure via dermal route mg	0,3980	0,2972
Exposure by inhalation		
Indicative value mg/m³	1,04	1,04
Duration	180	180
Inhalation rate m^3/h	1,25	1,25
Mitigation by RPE (PF)	1	1
Inhaled [product] mg	3,90	3,90
Systemic exposure via inhalation route mg	0,020	0,031
Systemic exposure		
Total systemic exposure a.s. mg	0,4175	0,3284
Body weight kg	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0,00696**	**0,00547**

1.2 Professional brushing - cleaning the brush

Cleaning a brush used for solvent-based formulations may be done by repeated dipping and swaying it in a vessel containing commercial brush cleaner. A large brush might have a size of 10 x 10 x 2 cm, corresponding to a volume of 200 mL. Cleaning is assumed to be done in three steps, each time using fresh water. The volume at each step should be large enough to allow a sufficient dilution of the residues in the brush. For a brush having a volume of 200 mL, the required water volume would be at least 400 mL per step. Each washing step is assumed to result in an approximately 10-fold dilution of the residues in the brush.
After each step the brush is assumed to be squeezed by the hand to get rid of as much liquid as possible. It is assumed that with this step 50% of the solution in the brush is released and may potentially contaminate the hand. It is further assumed that the squeezing is not done by the bare hand but rather

by wrapping it first with a cleaning rag, which may absorb ca. 90% of the released liquid. Washing and squeezing may be done 3 times each at maximum. It is assumed that gloves (PF10) are worn while cleaning the brush.
The estimated systemic exposure to tebuconazole and IPBC is 0.00102 and 0.00133 mg/kg bw/day, respectively (Table A3-2)**.**

The relevant parameters are summarised as follows:

Brush size : 10 x 10 x 2 cm (large brush, worst case)	200 mL
Volume of residual solution in brush (emptied by brushing)	1/8 of brush volume = 25 mL
Volume of each washing solution	at least 400 mL
Remaining residues in brush after each washing step	10%
Remaining residues in brush after each squeezing	50%
Penetration through cleaning rag during squeezing	50%
Penetration through gloves	10%
Body weight	60 kg
Density of product	0.810 g/ml

Table A3-2: Exposure assessment for professionals cleaning a brush after application

	IPBC	Tebuconazole	Explanation
active substance % (w/w)	0,50%	0,800%	
Amount of a.s. in brush after use (mg)	101,25	162,00	25 mL x %a.s. x density
Residues in brush after 1st washing (mg)	10,13	16,20	10% of initial content
Squeezed out from a brush onto a cloth (mg)	5,06	8,10	50% of residual content
Cloth absorbs 50% of a.s.	2,53	4,05	50% of a.s. squeezed out
Potential dermal exposure 50% (mg)	2,53	4,05	50% of a.s. squeezed out
Amount of a.s. in the brush after 1st wash and squeezing (mg)	5,06	8,10	50% of a.s. remaining after wash
Residues in brush after 2nd washing (mg)	0,506	0,810	10% of a.s. content after 1st cycle
Squeezed out from a brush onto a cloth (mg)	0,253	0,405	50% of residual content
Cloth absorbs 50% of a.s. (mg)	0,127	0,203	50% of a.s. squeezed out
Potential dermal exposure 50% (mg)	0,127	0,203	50% of a.s. squeezed out
Amount of a.s. in the brush after 2nd wash and squeezing	0,253	0,405	50% of a.s. remaining after wash
Residues in brush after 3rd washing (mg)	0,025	0,041	10% of a.s. content after 2nd cycle
Squeezed out from a brush onto a cloth (mg)	0,013	0,020	50% of residual content
Cloth absorbs 50% of a.s. (mg)	0,006	0,010	50% of a.s. squeezed out
Potential dermal exposure 50% (mg)	0,006	0,010	50% of a.s. squeezed out
Total external dermal exposure (mg a.s.)	2,664	4,263	Sum of 3 cycles
Mitigation by gloves	0,1	0,1	
Dermal absorption %	30%	14,4%	
Systemic exposure mg day^{-1}	0,080	0,061	
Body weight kg	60	60	
Systemic dose mg kg^{-1} day^{-1}	**0,00133**	**0,00102**	

1.3 Industrial dipping/ deluging/ double-vacuum impregnation

The activities of the industrial users are:

Mixing/loading:

Mixing/loading is a fully automated process in a closed system. Mixing occurs in large tanks to which the product is automatically supplied in the required quantity via hoses. There is no manual interaction needed. Loading of the dipping tank from the mixing tank also occurs in an automated, closed system, without any need for manual interaction by the operator. The concentration of a.s. may be checked from time to time and adjusted by additional supply of product, all within the same automated, closed system.

The **process of mixing/loading** for dipping of wood in industrial premises is **not associated with significant exposure** of the operator, neither by inhalation nor via dermal contact. No exposure calculation is provided for this activity.

Application:

The application process itself occurs in a large tank, which is opened during loading with wood but closed during treatment. Loading and unloading with wood occurs mechanically by forklift trucks. For the actual treatment process, timber stacks are loaded onto a forklift integrated in the dipping / double-vacuum system. Before removing treated wood from the system, excessive treatment solution is allowed to drain off. Afterwards it is transported mechanically to the storage place. There is no manual interaction needed during the entire process.

The **application process** in industrial premises is **not associated with significant exposure** of the operator, neither by inhalation nor via dermal contact. No separate exposure calculation is provided for this activity. However, the model applied for post-application handling as described below may partly

also cover potential exposure during the treatment process itself. This model may be best described as "intermittent contact with wet objects".

Handling:
Post-application exposure to the product may occur during manual contact during handling of treated (wet) wood. Timber to be treated is generally stacked to large batches which are transported mechanically by forklift trucks. After treatment, they remain on the fork lift above the tank for a certain while (initial drying), before they are transferred to a storage place by a fork lift truck for final drying and fixation of the impregnation. Usually, there should be no manual contact with treated wood until the product has completely dried.

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

Exposure Assessment
Exposure calculations are given according to TNsG 2007 (BEAT). The BEAT database contains measured data for timber pre-treatment with solvent-based products [Garrod *et al.* (1999) Exposure to preservatives used in the industrial pre-treatment of timber. *Annals of Occupational Hygiene* **43**(8) 543-555].
The HEEG opinion from 2009 (“Defaults and appropriate models to assess human exposure for dipping processes (PT08)”) gives a default value of 4 cycles x 60 min = 240 min for the duration of mechanical or automated dipping which will be used in the assessment.

Applied parameters:

Hands	**1.18 mg/min** (actual, n=19)
Glove penetration	**not considered for actual hand exposure values**
Body	**3.8 mg/min** (potential, value, n=19)
Clothing penetration	**10% (HEEG opinion, 2010**)
Inhalation	**0.539 mg/m³** (potential, n=22)
Inhalation rate	**1.25 m³/h** (default)
Duration	**240 min** (HEEG opinion, 2009)
Body weight	**60 kg** (default)

Estimated Exposure:
The estimated systemic exposure to tebuconazole and IPBC is **0.00755** and **0.00958 mg/kg bw/day**, respectively (Table A3-3).

Table A3-3: Exposure assessment for industrial timber pre-treatment

Solvent-based vacuum timber pre-treatment		
	IPBC	**Tebuconazole**
active substance % (w/w)	0,50%	0,800%
Potential body exposure		
Indicative value mg/min	3,8	3,8
Duration min	240	240
Potential dermal deposit mg	912	912
Clothing type	Coated coveralls	Coated coveralls
Clothing penetration %	10%	10%
Actual dermal deposit [product] mg	91,2	91,2
Hand exposure		
Indicative value mg/min (actual)	1,18	1,18
Duration min	240	240
Hand deposit mg	283,2	283,2
Mitigation by gloves	Not applicable	Not applicable
Actual hand deposit [product] mg	283,2	283,2
Total dermal exposure		
Total dermal deposit [product] mg	374,4	374,4
Active substance mg	1,87	3,00
Dermal absorption %	30%	14,4%
Systemic exposure via dermal route mg	0,5616	0,4313
Exposure by inhalation		
Indicative value mg/m³	0,539	0,539
Duration	240	240
Inhalation rate m^3/h	1,25	1,25
Mitigation by RPE (PF)	1	1
Inhaled [product] mg	2,70	2,70
Systemic exposure via inhalation route mg	0,013	0,022
Systemic exposure		
Total systemic exposure a.s. mg	0,5751	0,4529
Body weight kg	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0,00958**	**0,00755**

2 Indirect exposure as a result of use of the active substance in biocidal product

2.1 Acute phase: Adult – sanding treated wood posts

Inhalation route
A person (non professional) is sanding the surface of treated wood posts (4 cm x 4 cm x 2.5 m, surface area of 4032 cm²) for an outdoor play area. The active substances are in the outer 1 cm layer: The product is applied at a rate of about 135 g/m^2. If 100% retention by the wood is assumed as the ultimate worst case, the wood can contain Accordingly the IPBC content is 135 g/m^2 × 0.5% IPBC = 0,675 g IPBC/m² (0.0675 mg/cm²) and the tebuconazole content is 135 x 0.8% = 1.08 g/m^2 (0.108 mg tebuconazole/cm^2), when applied by superficial treatment (dipping, deluging).

The IPBC concentration in the in outer 1-cm layer would be 0.0675 mg/cm³ and the tebuconazole concentration is 0.108 mg/cm^2) . The density of the wood is assumed to be 0.40 g/cm³ (MOTA, TM08III).

It is not possible to predict how much wood dust an operator would inhale while sanding wood treated with a wood preservative. As a surrogate parameter, it is assumed that the wood dust concentration does not exceed the applicable occupational exposure limits for dust at the workplace.

The Operator Exposure Limit (OEL) of the EU for respirable hardwood dust is 5 mg/m³ (Directive 1999/38/EC). The duration of a sanding task is an estimated one hour.

The results of this exposure estimate are given in Table A3-4. **Systemic exposure estimates** for IPBC and tebuconazole are **2.36×10^{-5} mg/kg bw/day and $3.77\text{x}10^{-5}$ mg/kg bw/day**, respectively, when applied by superficial treatment.

Table A3-4: Exposure during sanding of treated wood (superficial treatment)

Sanding of treated wood		
	IPBC	**Tebuconazole**
active substance % (w/w)	0,50%	0,800%
Concentration in wood		
Application rate [product] g/m²	135	135
Application rate [a.s.] g/m²	0,675	1,080
area of wood to be sanded surface area m²	0,4032	0,4032
volume of outer layer (layer thickness 1 cm) cm³	3008	3008
Amount in wood [a.s] g	0,272	0,435
Exposure by inhalation		
Concentration of in wood dust a.s mg/cm³	0,090	0,145
Wood dust concentration in air mg/m³	5	5
Exposure duration min	60	60
Inhalation rate m^3/h	1,25	1,25
Mitigation by RPE (PF)	1	1
Retention of a.s. in wood	100%	100%
Density of wood g/cm³	0,40	0,40
Amount dust inhaled in 1 hour (cm³)	0,0156	0,0156
Inhaled [a.s] mg	0,0014	0,0023
Body weight kg	60	60
Systemic exposure mg kg^{-1} day^{-1}	**2,36E-05**	**3,77E-05**

When exposure is estimated for a piece of wood treated by double vacuum, the following result is obtained:

Surface area of the treated wood Volume of wooden post*	(4 x 4 cm x 2.5 m) + (2 x 4 cm x 4 cm) = 4032 cm^2 0.004 m^3
Active substance concentration in dilution	0.5% IPBC 0.8% Tebuconazole
Active substance concentration on the outer 1 cm layer (double vacuum impregnated wood) **	0.25 mg/cm^3 (IPBC) 0.4 mg/cm^3 (Tebuconazole)
Inhalation rate*	1.25 m^3/h
Exposure for wood dust during sanding for 60 min*	5 mg/m^3
Inhaled wood dust amount	1.25 m^3/h x 5 mg/m^3= 6.25 mg
Density of soft wood	0.4 g/cm^3
Volume of wood dust	6.25 mg / 0.4 g/cm^3 = 0.0156 cm^3
Concentration of active substance in the wood dust	0.25 mg/cm^3 x 0.016 cm^3= 0.004 mg (IPBC) 0.4 mg/cm^3 x 0.016 cm^3= 0.0064 mg (tebu)
Inhalation exposure of 60 kg adult	**0.00007 mg a.s./kg bw/day (IPBC)** **0.00011 mg a.s./kg bw/day (tebuconazole)**

* Parameters given in the Technical Notes for Guidance – Human exposure to biocidal products, User Guidance

** Wood absorbs 50 L/m^3 of product in double vacuum pressure process (default value given in User Guidance): 50 L/m^3 x 0.5% x 0.004 m^3 = 1.0 g IPBC per 4000 cm^3 wood = 0.25 mg/cm^3 IPBC and 50 L/m^3 x 0.8% x 0.004 m^3 = 1.6 g tebuconazole per 4000 cm^3 wood = 0.4 mg/cm^3 tebuconazole.

The exposure estimation revealed a systemic exposure of 0.00007 mg IPBC/ kg bw and 0.00011 mg tebuconazole/ kg bw for an adult during sanding of treated wood.

Dermal route (hands – no gloves worn)

The highest concentration on the surface is 13.5 mg b.p../cm². The surface area of both palms of hands is 168 cm² and this is the assumed transfer coefficient per day, with a 100 % contamination as a worst case scenario. The transfer efficiency is 2% for rough sawn wood (TNsG 2007, p.102) and dermal uptake is 30% and 14.4% for IPBC and tebuconazole, respectively.

The results of this exposure estimate are given in Table A3-5. **Systemic exposure estimates** for IPBC and tebuconazole are **0.00113 mg/kg bw/day and 0.00087 mg/kg bw/day**.

Table A3-5: Exposure from dermal contact with treated wood

Touching of dry treated wood		
	IPBC	**Tebuconazole**
active substance % (w/w)	0,50%	0,800%
Wood contamination		
Application rate [product] g/m²	135	135
Application rate [a.s.] mg/cm²	0,068	0,108
Percentage dislodgeable	2%	2%
Dislodgeable residues mg a.s./cm²	0,00135	0,00216
Hand exposure		
Transfer coefficient cm²/day	168	168
Hand deposit mg a.s./day	0,23	0,36
Dermal absorption %	30%	14,4%
Systemic exposure via dermal route mg a.s.	0,0680	0,0523
Body weight kg	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0,00113**	**0,00087**

2.2 Acute phase: Infant chewing treated wood chip

The relevant exposure route is oral. This is an incidental event and exposure duration is therefore best described as acute. This scenario is considered to represent the worst case for secondary oral exposure. For simplification, 100% retention of all active substances in the wood is assumed.
It is assumed that all a.s. is bound in the outermost 1 cm of the timber volume and that this part is accessible to children for chewing. It is further assumed that only a small fraction of the total preservative become released by chewing, as most of it is bound inside of the piece of wood. A reasonable assumption is that 10% may become released. A piece of the size of 16 cm^3 is chewed. An oral bioavailability of 100% is assumed for IPBC.

The results of this exposure estimate are given in table A3-6. **Systemic exposure estimates** for IPBC and tebuconazole are **0.0108 mg/kg bw/day and 0.0173 mg/kg bw/day**.

Table A3-6: Oral exposure via mouthing of treated wood

Mouthing of treated wood	**IPBC**	**Tebuconazole**
active substance % (w/w)	0,50%	0,800%
Concentration in wood		
Application rate [product] g/m²	135	135
Application rate [a.s.] mg/cm²	0,068	0,108
Layer thickness cm	1,00	1,00
Retention of a.s. in wood	100%	100%
Concentration in wood [a.s.] mg/cm³	0,068	0,108
Oral exposure		
Size of the wood chip cm³	16	16
Extraction of active substance when chewing	10%	10%
Extraction from wood mg a.s./day	0,11	0,17
Oral absorption %	100%	100%
Systemic exposure via oral route mg a.s.	0,108	0,173
Systemic exposure		
Body weight kg	10	10
Systemic exposure mg kg^{-1} day^{-1}	**0,0108**	**0,0173**

When exposure is estimated for a piece of wood treated by double vacuum, and assuming the highest use rate of 110 g IPBC / m^3 sapwood and 176 g Tebuconazole / m^3 sapwood, the following result is obtained:

Assumptions:

- Infant (10 kg bw) chewing piece of wood of the following dimensions:
  1 cm × 4 cm × 4 cm (area: $4.8x10^{-3}$ m^2, volume: $1.6×10^{-5}$ m^3)
- IPBC: 110 g/ m^3 sapwood
- Tebuconazole: 176 g/ m^3 sapwood

Results:

- Amount in treated wood:
  IPBC: 110 g /m^3 x $1.6x10^{-5}$ m^3 = 1.76 mg
  Tebuconazole: 176 g /m^3 x $1.6x10^{-5}$ m^3 = 2.82 mg
- Amount extracted by chewing:
  IPBC: 1.76 mg x 10% = 0.176 mg
  Tebuconazole: 2.28 mg x 10% = 0.282 mg
- Systemic dose:
  IPBC: 0.176 mg /10 kg = **0.0176 mg /kg bw**
  Tebuconazole: 0.282 mg /10 kg = **0.0282 mg /kg bw**

The exposure of an infant after oral ingestion of Induline IL-150 via chewing of treated wood is estimated at 0.0176 mg IPBC per kg bw/day and 0.0282 mg Tebuconazole per kg bw/day.

2.3 Chronic phase: Adult – professional sanding

The acute sanding scenario is extrapolated to the chronic situation by assuming that the exposure time is 6 hours per day.

Inhalation route
The inhalation exposure is six times higher than for the one-hour task of an amateur (see Section 2.1). Accordingly, **systemic exposure estimates** for IPBC and tebuconazole are **1.41×10^{-4} mg/kg bw/day and 2.26×10^{-4} mg/kg bw/day, respectively for superficial treatment**.

For treatment by double vacuum, the systemic inhalation exposure for the professional during the sanding task are **4.2×10^{-4} mg/kg bw/day and 6.6×10^{-4} mg/kg bw/day for** IPBC and tebuconazole, respectively.

Dermal route (hands – no gloves worn)
The surface area of both palms of hands is168 cm² and this is the assumed transfer coefficient per day. With this assumption, dermal exposure is independent of the daily exposure duration. **Systemic exposure estimates for IPBC and tebuconazole are 0,00113 mg/kg bw/day and 0.00087 mg/kg bw/day** the same as for the acute scenario.

2.4 Chronic phase: Child – playing on playground structure outdoors and mouthing

A child (10 kg body weight) is playing on playground structure outdoors. The total body surface area of a 10-kg child is 0.467 m² (Bremmer & van Veen, 2000). The hands make up about 5.7% of that surface (US EPA, 2002). The palmar hand surface area is about 50% of the total hand surface. Thus, the exposed hand surface (= transfer coefficient) of a 2-year old is 4670 cm² × 5.7% × 50% = 133 cm² (both hands). With a 100 % contamination, this is considered as a worst case scenario. The concentration of a.s. at the wood surface is 0.0675 mg IPBC /cm² and 0.108 mg tebuconazole/cm^2. The transfer efficiency is taken from the TNsG 2007 (page 102) as 2% for transfer of dried fluid from rough-sawn wood to skin.
In addition, the amount dislodged by the hands would be taken up by hand-to-mouth contact assuming an oral bioavailability of 100% for IPBC and tebuconazole.

Systemic exposure estimates for IPBC and tebuconazole are **0.02334 mg/kg bw/day and 0.03286 mg/kg bw/day**, respectively (Table A3-7).

Table A3-7: Exposure of infants via skin and hand-to-mouth transfer

Touching of dry treated wood and mouthing	**IPBC**	**Tebuconazole**
active substance % (w/w)	0,50%	0,800%
Wood contamination		
Application rate [product] g/m²	135	135
Application rate [a.s.] mg/cm²	0,068	0,108
Percentage dislodgeable	2%	2%
Dislodgeable residues mg a.s./cm²	0,00135	0,00216
Hand exposure		
Transfer coefficient cm²/day	133	133
Hand deposit mg a.s./day	0,18	0,29
Dermal absorption %	30%	14,4%
Systemic exposure via dermal route mg a.s.	0,0539	0,0414
Oral exposure		
Hand deposit mg a.s./day	0,18	0,29
Oral absorption %	100%	100%
Systemic exposure via oral route mg a.s.	0,1796	0,2873
Systemic exposure		
Total systemic exposure a.s. mg	0,2334	0,3286
Body weight kg	10	10
Systemic exposure mg kg^{-1} day^{-1}	**0,02334**	**0,03286**

2.5 Chronic (intermittent): Adults - laundering work clothes at home

Persons at risk are adults. The relevant exposure route is dermal. Exposure duration is acute to short-term. An activity with the potential for some contamination is the laundering of contaminated work clothing (e.g. a coverall). Laundering is assumed to occur mechanically without any exposure risk to humans. Contact with effluent is unlikely to occur. The only likely exposure can occur during handling of the dirty clothing while preparing it for laundry. The exposure route is dermal (mainly to hands) and is dependent on the area concentration of dislodgeable residues on the surface of the clothing and the transfer coefficient to the human skin. For the following it is assumed, that the clothing to be washed is a coverall used by an industrial operator (considered to represent the worst case). The total surface of a medium size coverall was determined to be 22,700 cm². Body contamination (without hands and feet) was calculated to be 912 mg for above described industrial exposure scenarios (see **Fejl! Henvisningskilde ikke fundet.**) are re-expressed as mg a.s./cm².
It is assumed that the coverall is washed after one working week, corresponding to 5 working days, and the total residues accumulate during this time and account for 5 times the daily deposits.
The transfer coefficient (TC) is determined by estimating how many times the coverall is touched with the hands. Assuming that this happens three times, twice with the inner side of both hands and once with the total hands surface, the TC would account for 1640 cm^2 (total surface of both hands = 820 cm^2). As another worst case assumption, 100% of the dislodgeable residues in the touched area are considered to be transferred to the skin. The results of the estimation are given in A3-8.
The **systemic exposure estimate** for **IPBC and tebuconazole** is **0.0041 mg/kg bw/day and 0.0032 mg/kg bw/day**, respectively.

Table A3-8: Exposure during laundry of contaminated clothing

Laundry of contaminated clothing	**IPBC**	**Tebuconazole**
active substance % (w/w)	0,50%	0,800%
Clothing contamination		
Actual dermal deposit [product] mg/day	912	912
Actual dermal deposit [a.s.] mg/day	4,56	7,30
Overall surface cm²	22.700	22.700
Surface concentration mg a.s./cm²/day	2,01E-04	3,21E-04
No of working days before washing	5	5
Percentage dislodgeable	50%	50%
Dislodgeable residues mg a.s./cm²	0,00050	0,00080
Hand exposure		
Transfer coefficient cm²/day	1640	1640
Hand deposit mg a.s./day	0,82	1,32
Percentage transferred to skin	100%	100%
Dermal absorption %	30%	14,4%
Systemic exposure via dermal route mg a.s.	0,2471	0,1898
Body weight kg	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0,00412**	**0,00316**

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

Chronic exposure to wood preservatives may arise from indoor remedial treatment. Exposure through preserved window frames or joists is not considered to be relevant, because the frame or other wood generally is coated and the wood preservative is sealed and cannot evaporate. IPBC and tebuconazole furthermore have a low vapour pressure. Nevertheless, exposure by volatilised residues indoors was calculated.

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

Assumptions:

- Adult: 60 kg bw, residential time 18 hours, inhaling 1.25 m^3 air/h (TNsG on HE, 2007, p 61)
- Child: 15 kg bw, residential time 18 hours, inhaling 0.35 m^3 air/h (TGD, page 274)
- Infant: 10 kg bw, residential time 18 hours, inhaling 0.24 m^3 air/h (TGD, page 274)
- Vapour pressure IPBC : 2.36 x 10^{-3} Pa (at 20°C)
- Vapour pressure Tebuconazole : 1.7 x 10^{-6} Pa (at 20°C)

- Molecular weight of IPBC : 281 g/mol
- Molecular weight of Tebuconazole : 307.8 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 : 2.36×10^{-3} Pa x 1%/101325 x 10^{6} = 2.33×10^{-4} ppm (mL/m^3)
  Tebuconazole : 1.7×10^{-6} Pa x 1%/101325 x 10^{6} = 1.68×10^{-6} ppm (mL/m^3)
- SVC:
  IPBC: 2.33×10^{-4} ppm x 281 g/mol/24.1L = 2.72×10^{-3} mg/m^3
  Tebuconazole: 1.68×10^{-6} ppm x 307.8 g/mol/24.1L = 2.14×10^{-5} mg/m^3
- Systemic dose:
  IPBC
  Adult: 2.72×10^{-3} mg/m^3 x 1.25 m^3/h x 18 h/60 kg bw = 1.02×10^{-3} mg/kg bw/day
  Child: 2.72×10^{-3} mg/m^3 x 0.35 m^3/h x 18 h/15 kg bw = 1.14×10^{-3} mg/kg bw/day
  Infant: 2.72×10^{-3} mg/m^3 x 0.24 m^3/h x 18 h/10 kg bw = 1.18×10^{-3} mg/kg bw/day
  Tebuconazole
  Adult: 2.14×10^{-5} mg/m^3 x 1.25 m^3/h x 18 h/60 kg bw = 8.03×10^{-6} mg/kg bw/day
  Child: 2.14×10^{-5} mg/m^3 x 0.35 m^3/h x 18 h/15 kg bw = 8.99×10^{-6} mg/kg bw/day
  Infant: 2.14×10^{-5} mg/m^3 x 0.24 m^3/h x 18 h/10 kg bw = 9.24×10^{-6} mg/kg bw/day

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

2.7 Exposure to residues in food

Not relevant, as contact with food is not predicted.

Annex 4: Leaching calculations

A semi-field leaching study for Induline IL-150 was conducted in accordance with NT Build 509 (approved 2005-03) "Leaching of active components from preservative treated timber – semi-field testing".

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:

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

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

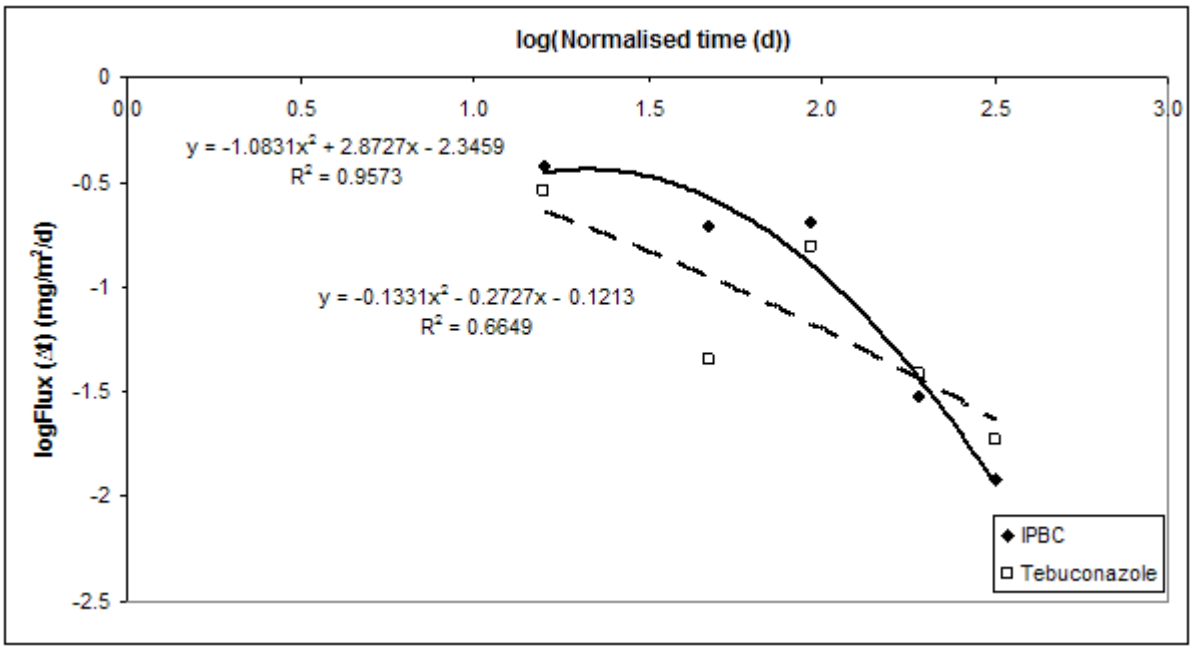

Figure 1 Fitted daily FLUX(Δt) of IPBC and tebuconazole versus time

Once the parameter a, b and c are determined the experimental FLUX(t) = f(t) curve can be recalculated by using the following equation.

$$FLUX(t) = 10^a * t^b * t^{clogt}$$

With the aid of the second equation leaching rates for the short–term risk assessment (TIME 1, 30 days) can be derived. For this purpose daily leaching rates for day 1 up to day 30 are summed up and divided by 30. With this approach the following short-term leaching rate is derived:

IPBC: 0.280 mg/m^2/day ((8.40 mg/m^2))/30 days)

Tebuconazole: 0.284 mg/m^2/day ((8.53 mg/m^2))/30 days)

A correction factor of 1.00 has to be adopted, because it is intended to apply higher amounts of the product than in the leaching study. The maximum intended applied amount of the product is 135.3 g/m^2 and in the leaching study only 135 g product was applied per m^2. The values are also applied with an assessment factor of 10 as a top coat was used in the study, for further explanation see Annex 5.

The following corrected short-term leaching rate is used as input parameter for the different exposure scenarios:

Day 1-30: used for storage assessment (3 and 15 days) and for short-term consideration (TIME 1: 30 days assessment)

IPBC: **2.80 mg/m^2/day** ((8.40 mg/m^2) / 30 days x 1.00 x 10)
Tebuconazole: **2.85 mg/m^2/day** ((8.53 mg/m^2) / 30 days x 1.00 x 10)

Leaching rates for the long-term risk assessment (TIME 2; 5 and 15 years) is derived using the same equation. For this purpose daily leaching rates for day 31 to day 1825 or 5475 are summed up and divided by TIME2-30 days. The values are corrected according to the same method as for the short term leaching.

For the long term risk assessment the following leaching rates were used:

Day 31-1825: used for long-term leaching TIME 2 (service life of 5 years)

IPBC: **0.141 mg/m^2/day** ((25.3 mg/m^2) / (1825-30 days) x 1.00 x 10)
Tebuconazole: **0.152 mg/m^2/day** ((27.3 mg/m^2) / (1825-30 days) x 1.00 x 10)

Day 31-5475: used for long-term leaching TIME 2 (service life of 15 years)

IPBC: **0.0467 mg/m^2/day** ((25.3 mg/m^2) / (5475-30 days) x 1.00 x 10)
Tebuconazole: **0.0627 mg/m^2/day** ((34.1 mg/m^2) / (5475-30 days) x 1.00 x 10)

Double vacuum treatment

No leaching study was submitted for the double vacuum treatment and the leaching rates are then calculated with 100 % leaching during the service life based on the highest application level from the efficacy evaluation (22 kg/m^3).

The amount of product applied to the wood is recalculated from kg/m^3 to g/m^2 using the worst case situation were the planks used in the study for the superficial treatment is fully impregnated with the product.

Volume of the plank:

$$V_{plank} = 0.76m \times 0.1m \times 0.025m = 0.0019\ m^3$$

Surface area of the plank:

$$A_{plank} = (0.76m \times 0.1m) + 2 \times (0.76m \times 0.025m) = 0.114\ m^2$$

Volume to surface ratio:

V_{plank}/A_{plank} = 0.0019 m^3 / 0.114 m^2 = 0.0167 m^3/m^2

Induline IL-150: 22 kg/m^3 x 0.0167 m^3/m^2 = 0.367 kg/m^2

IPBC: 0.367 kg/m^2 x 0.50% x 10^6 = 1833 mg/m^2
Tebuconazole: 0.367 kg/m^2 x 0.80% x 10^6 = 2933 mg/m^2

Day 1-30: used for storage assessment (35 days) and for short-term consideration (TIME 1: 30 days assessment)

IPBC: **61.1 mg/m^2/day** ((1833 mg/m^2) / 30 days)
Tebuconazole: **97.8 mg/m^2/day** ((2933 mg/m^2) / 30 days)

Day 0-7300: used for long-term leaching TIME 2 (service life of 20 years)

IPBC: **0.251 mg/m^2/day** ((1833 mg/m^2) / 7300 days)
Tebuconazole: **0.402 mg/m^2/day** ((2933 mg/m^2) / 7300 days)

Annex 5: Additional information about the calculation of leaching rates

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(Δt)=*f(t)* curve using a polynomial regression of second order:

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

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

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

Top coats

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

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

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

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

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

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

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

Available leaching study	Claim on the biocidal product	How to perform emission calculations?	Requirement regarding top coat
No study	No top coat or any top coat	Use: 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