Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

Induline SW-900 IT

Product type 8

Cypermethrin, IPBC and propiconazole as included in the Union list of approved active substances

Case Number in R4BP: BC-LF017476-43

Evaluating Competent Authority: Denmark

Date: 08. December 2017

With amendments to PAR, latest: Date:

19. June 2023

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Overview of applications

Application type	Ref MS	Case number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation/amendment/renewal)
NA-APP	DK	BC-LF017476-43	8th of December 2017	First authorisation
NA-APP	DK	BC-SG038147-36	15th of May 2018	Additional tradename
NA-MAC	DK	BC-CH045693-44		Additional target organism and change in application rate
NA-ADM And referral	DK	DK-001200-0000 BC-CH045693-44	19th of June 2023	Change of classification to: Repro 1B H360 D And adding of: "Propiconazole meets the exclusion criteria." In the PAR. Addition to SPC 5.2: "Do not use on wood that will come in direct contact with food, animal feed or livestock. Never use this product to treat wood on surfaces in habitable and recreation rooms"

1 CONCLUSION

The Danish CA proposes the authorisation of the biocidal product Induline SW-900 IT as a wood preservative (PT 8) for professional use by brushing, dipping, flow coating and spraying in closed facilities (e.g. spray tunnel) in use classes 2 and 3. The use of top coat is required. The top coat cannot be a film- or a wood preservative.

The biocidal product contains 0.2% w/w of the active substance cypermethrin, 0.8% w/w of the active substance propiconazole and 0.8% w/w of the active substance IPBC.

Together, two long term stability studies showed an acceptable degradation of the active substances, and a claim for 6 months shelf-life can be accepted. The product is a water-based formulation, and extrapolation to all packaging types, apart from metal are supported.

The biocidal product has been documented effective against wood destroying fungi, blue stain, insects and termites with the following application rates:

- Use against fungi and insects, including termites – 150 mL/m²
- Use against fungi and insects, excluding termites – 100 mL/m²

The application rate of 150 mL/m^2 has been applied in the risk assessment for human health and for the environment.

No unacceptable risks were identified in the risk assessment for human health for the product Induline SW-900 IT, for professionals with the correct personel protective equipment. Due to the sentitizing properties of IPBC and propiconacole the product must be labelled with EUH208: Contains 3-Iodo-2-propynylbutylcarbamate (IPBC) and propiconazole. May produce an allergic reaction.

In the environmental risk assessment for the product Induline SW-900 IT no unacceptable risk is identified for secondary poisoning, air and groundwater compartments. However, risk is identified for the aquatic compartment when the product is used for in-situ applications close to water. As a consequence the product may not be applied near bodies of surface water or in the area of water protection zones. A risk is also identified for the soil compartment when the product is used for in-situ applications. As a consequence the ground must be covered during application in-situ and any spillage should be collected. Finally, a risk is also identified during industrial application and storage and as a consequence, the freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing or both to prevent direct losses to soil, sewer or water and that any losses of the product should be collected for reuse or disposal.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
Induline SW-900 IT	Not relevant

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Remmers GmbH
	Address	Bernhard-Remmers-Str. 13 D-49624 Löningen Germany
Authorisation number	DK-0012600-0000	
Date of the authorisation	8 December 2017	
Expiry date of the authorisation	8 December 2027	

2.1.1.3 Manufacturer of the product

Name of manufacturer	Remmers GmbH
Address of manufacturer	Bernhard-Remmers-Str. 13 D-49624 Löningen Germany
Location of manufacturing sites	Please see address above

2.1.1.4 Manufacturers of the active substances

Active substance	**Cypermethrin**
Name of manufacturer	Arysta LifeScience (former Agriphar S.A.)
Address of manufacturer	Rue de Renory 26, 1 B-4102 Ougrée, Belgium
Location of manufacturing sites	Please refer to the confidential annex (confidential for the applicant)

Active substance	**IPBC**
Name of manufacturer	Troy Chemical Company B.V.
Address of manufacturer	8 Vreeland Road 07932 Florham Park, New Jersey, USA
Location of manufacturing sites	Please refer to the confidential annex

Active substance	**Propiconazole**
Name of manufacturer	LANXESS Deutschland GmbH
Address of manufacturer	Kennedyplatz 1, 50569 Köln, Germany
Location of manufacturing sites	Please refer to the confidential annex

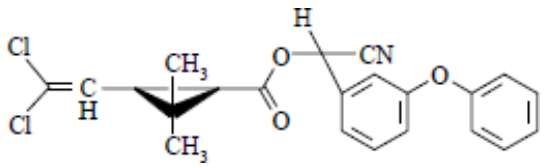
2.1.2 Product composition and formulation

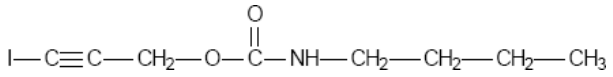
The full composition of the product is according to Annex III Title 1 provided in the confidential annex.

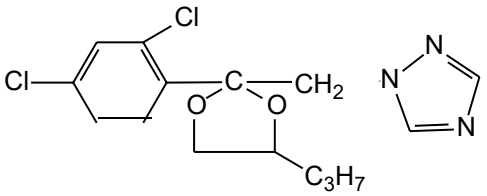
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substances

Main constituent(s)	
ISO name	**Cypermethrin**
IUPAC or EC name	(RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate
EC number	257-842-9
CAS number	52315-07-8
Index number in Annex VI of CLP	607-421-00-4
Minimum purity / content	920 g/kg (from the AR of cypermethrin)
Structural formula	

Main constituent(s)	
ISO name	**IPBC**
IUPAC or EC name	3-Iodo-2-propynylbutylcarbamate
EC number	259-627-5
CAS number	55406-53-6
Index number in Annex VI of CLP	616-212-00-7
Minimum purity / content	980 g/kg (from the AR of IPBC)
Structural formula	

Main constituent(s)	
ISO name	**Propiconazole**
IUPAC or EC name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
EC number	262-104-4
CAS number	60207-90-1
Index number in Annex VI of CLP	613-205-00-0
Minimum purity / content	930 g/kg (from the AR of propiconazole)
Structural formula	

2.1.2.2 Candidate(s) for substitution

Propiconazole meets the exclusion criteria.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Only content of active substances are shown in the table below. A full composition can be found in the confidential annex.

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (% w/w) (pure)**
Propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole	Active substance	60207-90-1	262-104-4	0.80
IPBC	3-Iodo-2-propynylbutyl-carbamate	Active substance	55406-53-6	259-627-5	0.80
Cypermethrin	(RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate	Active substance	52315-07-8	257-842-9	0.2

2.1.2.4 Information on technical equivalence

The sources of active substance were the same as were evaluated for inclusion in the Union list of approved active substances.

2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

2.1.2.6 Type of formulation

EW Emulsion, oil in water

2.1.3 Hazard and precautionary statements

Classification and labelling of the product according to Regulation (EC) No 1272/2008:

Classification	
Hazard category	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H360D: May damage the unborn child. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.
Labelling	
Signal words	Danger
Hazard statements	H360D: May damage the unborn child. H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P273: Avoid release to the environment P280: Wear protective gloves. P308+P313: If exposed or concerned: Get medical advice/attention. P391: Collect spillage P501 - Dispose of contents/container according to local rules
GHS Pictogram	GHS08
Note	EUH208: Contains 3-Iodo-2-propynylbutylcarbamate and propiconazole. May produce an allergic reaction. EUH210: Safety data sheet available on request Keep away from food, drink and animal feedingstuffs. May not be disposed of in sewers, including rainwater canals.

2.1.4 Authorised use(s)

2.1.4.1 Use description, generel

Product Type(s)	PT 8 – Wood preservatives	Product Code
Where relevant, an exact description of the authorised use	The biocidal product is a ready-to-use water-based formulation to protect non-load-bearing softwood timber without ground contact in outdoor areas against wood destroying fungi, blue stain, insects and termites. It is used to protect timber in use classes 2 and 3. A top coat is required. The top coat cannot be a film- or a wood preservative.	E.20 E.30
Target organism (including development stage)	Wood destroying fungi (brown rot, white rot): *Coniophora puteana* *Gloeophyllum trabeum* *Poria placenta* *Coriolus versicolor* Blue stain fungi: *Aureobasidium pullulans spp.* *Sclerophoma pithyophila* Wood destroying insects: *Hylotrupes bajulus* L. Termites: Termites (*Reticulitermes ssp.*) *Note: Since termites of the genus Reticulitermes mainly occur in the southern part of Europe, use against termites will not be needed in all member states. It is up to each member state to decide whether use against termites is relevant to be included.*	G.10 G.11 G.21.2 G.30 G.51
Field of use	Used for softwood timber without ground contact in outdoor use. It is used to protect timber in use classes 2 and 3. A top coat is required. The top coat cannot be a film- or a wood preservative.	B.10 C.10
Application method(s)	Use # 1 Brushing Use # 2 Dipping Use # 3 Flow coating Use # 4 Spraying in closed facilities (e.g. spray tunnel)	F.10 F.14 F.12 F.11
Application rate(s) and frequency	• Use against fungi and insects, including termites – 150 mL/m² • Use against fungi and insects, excluding termites – 100 mL/m² *Note: It is up to each member state to decide whether use against termites is needed and to mention the corresponding application and retention rates on the label.*	
Category(ies) of user(s)	Use-specific, see 2.1.4.2-2.1.4.5.	
Pack sizes and packaging material	Please see the section 2.1.7.	

2.1.4.2 Use-specific description, **Use # 1 Brushing**

Instruction for use	The substrate must be free of grease, wax, soil and dust. The product should be stirred well before use. The biocidal product is ready-to-use and applied by brushing. The application rate is 100-150 mL wood preservative/m². Working temperature is 15 to 30 °C (ambient temperature and surface temperature of the wood substrate). It must be handled only on impermeable ground; treated wood is to be stored until completely dry on an impermeable, hard ground to prevent the ingredients from reaching the soil. The wood is dry after approx. 4 hours at 20 °C and 65% relative humidity. At 30 °C (forced drying) the wood is dry after approx. 3 hours. Use of top coat is required. The top coat cannot be a film- or a wood preservative.
Catergories of users	Professional, Trained Professional (A.30)
Use-specific risk mitigation measures	Coated coveralls is required. Wear protective chemical resistant gloves during product handling phase and for subsequent manual processing of the treated wood (glove material to be specified by the authorisation holder within the product information).

2.1.4.3 Use-specific description, **Use # 2 Dipping**

Instruction for use	Product must only be used in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place including when the treated articles are transported through the dip tank to the draining/drying and storage areas (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until after the treated articles are surface dry. The wood must be dry or semi-dry. Bark and inner bark must be removed. The biocidal product is ready-to-use and should not be diluted. The biocidal product is applied by dipping. The application rate is 100-150 mL wood preservative/m² wood. The wood is initially dry after approx. 12 hours at 20 °C and 65% relative humidity. High humidity and low temperatures delay drying. Treated wood is to be stored until completely dry on an impermeable, hard ground to prevent the ingredients from reaching the soil.Translucent coatings and lacquers can be subsequently applied at the earliest after 24 hours. Use of top coat is required. The top coat cannot be a film- or a

	wood preservative.
Catergories of users	Industrial (A.20)
Use-specific risk mitigation measures	Coated coveralls is required. Wear protective chemical resistant gloves during product handling phase and for subsequent manual processing of the treated wood (glove material to be specified by the authorisation holder within the product information). Induline SW-900 IT must only be used in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place including when the treated articles are transported through the dip tank to the draining/drying and storage areas (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until after the treated articles are surface dry.

2.1.4.4 Use-specific description, **Use # 3 Flow coating**

Instruction for use	The substrate must be free of grease, wax, soil and dust. The product should be stirred well before use. The biocidal product is ready-to-use and applied by flow coating. The application rate is 100-150 mL wood preservative/m². Working temperature is 15 to 30 °C (ambient temperature and surface temperature of the wood substrate). It must be handled only on impermeable ground; treated wood is to be stored until completely dry on an impermeable, hard ground to prevent the ingredients from reaching the soil. The wood is dry after approx. 4 hours at 20 °C and 65% relative humidity. At 30 °C (forced drying) the wood is dry after approx. 3 hours. Use of top coat is required. The top coat cannot be a film- or a wood preservative.
Catergories of users	Industrial (A.20)
Use-specific risk mitigation measures	Impermeable coveralls is required. Wear protective chemical resistant gloves during product handling phase and for subsequent manual processing of the treated wood (glove material to be specified by the authorisation holder within the product information). Wear respiratory protection equipment (FFP1).

2.1.4.5 Use-specific description, **Use # 4 Spraying in closed facilities**

Instruction for use	The substrate must be free of grease, wax, soil and dust. The product should be stirred well before use. The biocidal product is ready-to-use and applied by dipping. The application rate is 100-

	150 mL wood preservative/m². Working temperature is 15 to 30 °C (ambient temperature and surface temperature of the wood substrate). It must be handled only on impermeable ground; treated wood is to be stored until completely dry on an impermeable, hard ground to prevent the ingredients from reaching the soil. The wood is dry after approx. 4 hours at 20 °C and 65% relative humidity. At 30 °C (forced drying) the wood is dry after approx. 3 hours. Use of top coat is required.
Catergories of users	Industrial (A.20)
Use-specific risk mitigation measures	Impermeable coveralls is required. Wear protective chemical resistant gloves during product handling phase and for subsequent manual processing of the treated wood (glove material to be specified by the authorisation holder within the product information). Wear respiratory protection equipment (FFP1).

2.1.4.6 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No use-specific, please refer to 2.1.5.3

No use-specific, please refer to 2.1.5.4

2.1.4.7 Where specific to the use, the instructions for safe disposal of the product and its packaging

2.1.4.8 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

No use-specific, please refer to 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

See use-specific instructions for use, please refer to 2.1.4.2-2.1.4.5

2.1.5.2 Risk mitigation measures

- Wear protective gloves/protective clothing/eye/face protection. Do not get in eyes, on skin, or on clothing.
- Wear protective chemical resistant gloves during product handling phase and for subsequent manual processing of the treated wood (glove material to be

specified by the authorisation holder within the product information).
- Keep children and pets away from treated surfaces until dried.
- In situ application:
  - Cover the ground during application and collect any spillage.
- - Do not apply near bodies of surface water or in the area of water protection zones. Industrial application: Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing or both to prevent direct losses to soil, sewer or water and that any losses of the product should be collected for reuse or disposal.
- Do not apply the product to wood or place treated wood in areas where food/feed, food utensils or food processing surfaces may come into contact with, or be contaminated by the product or treated wood.
- Wash hands after application and use of the product, and before eating, drinking or smoking.
- Do not allow this product to reach aquatic environments, the sewer system or the ground.
- Do not inhale dust when sanding treated wood. When sanding treated wood, wear a respiratory protection mask (P2 filter).
- Do not use on wood that will come in direct contact with food, animal feed and livestock. Never use this product to treat wood surfaces in habitable and recreation rooms.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Particulars of likely direct or indirect effects: Not known if the product is used properly according to the product label.

First aid instructions:
General information: If symptoms occur or in case of doubt, seek medical attention. In case of unconsciousness, do not administer anything orally.
After inhalation: No special requirements.
After skin contact: Remove contaminated clothing. Do not use solvents or thinners! If skin irritation continues, consult a doctor. Pyrethroids and pyrethrines may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice
After eye contact: Rinse opened eye for several minutes under running water.
After swallowing: Keep the person affected quiet. Rinse out mouth and then drink plenty of water.

Emergency measures to protect the environment:
Do not allow to enter the ground/soil. Inform responsible authorities in case product reaches bodies of water or sewage system.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Waste treatment methods
Recommendation:
The given refuse codes are recommendations based upon the intended use of the product. Because of special use and disposal conditions at the user's, other codes may apply under other conditions. Do not dispose of together with household garbage. Do

not allow product to reach sewage system.
European waste catalogue:
03 02 02* - organochlorinated wood preservatives

This material must be disposed of safely as hazardous waste. Any product collected during application that is not re-used must be disposed of safely as hazardous waste.

Do NOT dispose of unwanted product down drains. Dispose of packaging and unused product in accordance with local regulations. If required, consult a professional waste operator or local authority.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

6 months.
Requirements to be met by storerooms and containers: No special requirements.
Information on storage in a common storage facility: Store away from food.
Further information about storage conditions: Store container in a well ventilated position. Do not store the product at temperatures above 20 ºC. Protect from frost.

2.1.6 Other information

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2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Container	20 L	Tin with lining*	Tin	Professional	Yes
Drum	120 L	Blue HDPE**	Blue HDPE	Professional	Yes

* lining: two layer system, the first layer is an epoxy-phenolic resin, top-coat is based on a vinyl resin
** absorbs over 99% of UV radiation

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Find a complete reference list of studies submitted for the product and for the active substance during product authorisation in annex 3.1.

2.1.8.2 Access to documentation

The applicant has submitted letters of access from Agriphar S.P.R.L. (now a part of Arysta Lifescience)(cypermethrin), Lanxess Deutschland GmbH (propiconazole) and Troy Chemical Company B.V. (IBPC). Data access is granted to the dossier that supported the registration of the active substances cypermethrin, propiconazole and IPBC under the Biocidal Product Directive 98/8/EC to get Annex I inclusion.

2.2 Assessment of the biocidal product

2.2.1 Intended uses as applied for by the applicant

Product Type(s)	PT 8
Where relevant, an exact description of the authorised use	The biocidal product is a ready-to-use water-based formulation to protect non-load-bearing softwood timber without ground contact in outdoor areas against blue stain and wood rotting fungi (wood rotting basidiomycetes), insects and termites. It is used to protect timber in use classes 2 and 3.
Target organism (including development stage)	Wood destroying and blue stain fungi: *Aureobasidium pullulans* spp. *Sclerophoma pithyophila* *Coniophora puteana* *Gloeophyllum trabeum* *Poria placenta* *Coriolus versicolor* Wood destroying insects: *Hylotrupes bajulus* L. Termites (Reticulitermes flavipes (formerly R. santonensis))
Field of use	Used for softwood timber without ground contact in outdoor use.
Application method(s)	Use # 1 Brushing Use # 2 Dipping Use # 3 Flow coating Use # 4 Spraying in closed facilities (e.g. spray tunnel)
Application rate(s) and frequency	The application rate is 100 mL/m²*
Category(ies) of user(s)	Professionals
Pack sizes and packaging material	20 L tin containers 120 L plastic drums

* During the assessment, the applicant has agreed to change the application rate for the use against termites to 150 ml/m^2 due to the efficacy assessment.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	IPBC:0.75% Propiconazole: 0.64%* Cypermethrin: 0.22% *see discussion under storage stability	Before and after storage for 2 years at 20 °C: oily emulsion	Affolter, 2012
Colour at 20 °C and 101.3 kPa	Visual inspection	IPBC:0.75% Propiconazole: 0.64%* Cypermethrin: 0.22% *see discussion under storage stability	Before storage: white with yellow-brownish tinge After storage for 2 years at 20 °C: light ivory (RAL 1015)	Affolter, 2012
Odour at 20 °C and 101.3 kPa	Olfactory inspection	IPBC:0.75% Propiconazole: 0.64%* Cypermethrin: 0.22% *see discussion under storage stability	Before and after storage 2 years at 20 °C: typical, strong, like solvent	Affolter, 2012
Acidity / alkalinity	CIPAC MT 75.3 (25 °C)	IPBC:0.75% Propiconazole: 0.64%* Cypermethrin: 0.22% *see discussion under storage stability	pH determination: 7.76 (1% w/v suspension in water) The acidity / alkalinity was not determined as the pH value is between 4 and 10.	Affolter, 2012
Relative density/ Bulk density	National guideline: NF T 20-053 (pycnometer method) *Guideline mentioned in EEC Method A3*	IPBC: 0.81 % Propiconazole: 0.85% Cypermethrin: 0.22%	Density: 1.01 g/mL Determination of the bulk density is not applicable because the biocidal product is liquid.	Legay, 2010

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Storage stability test – **accelerated storage**	National guideline: NF X 41-580-10: 2006 The test was performed in glass flask with PTFE cap. 54 °C for 14 days, 40 °C for 8 weeks	See results	<u>IPBC content</u> 0.81% (w/w) (prior to storage) 0.73% (w/w) (54 °C, 14 days) **(variation - 9.9%)** 0.71% (w/w) (40 °C, 8 weeks) **(variation - 12.3%)** <u>Propiconazole content</u> 0.85% (w/w) (prior to storage) 0.81% (w/w) (54 °C, 14 days) **(variation - 4.7%)** 0.80% (w/w) (40 °C, 8 weeks) **(variation - 5.9%)** <u>Cypermethrin content</u> 0.22% (w/w) (prior to storage) 0.20 % (w/w) (54 °C, 14 days) **(variation - 9.1%)** 0.19 % (w/w) (40 °C, 8 weeks) **(variation - 13.6%)** No significant changes of physicochemical properties were observed. No deposit is observed, but disappears after a light shaking. The variation of all active substance contents did exceed the limit of 5% (up to 13.6%). However the long term storage stability tests is accepted by the rMS, and overrules this result in terms of storage stability in general. The results do however indicate that the product should not be stored above 20 ºC , and this has to be included in the SPC.	Legay, 2010

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Storage stability test – **long term storage at ambient temperature**	Storage stability for 2 years at 20 °C (CIPAC, MT 46) The test was performed in the original vessel (coated tin plate cans). Lining: two layer system, the first layer is an epoxy-phenolic resin, top-coat is based on a vinyl resin	See results	Please find the full assessment of the long term storage stability tests below this table. No significant changes of physical-chemical properties and packaging stability occurred during the tests. No information regarding phase separation was explicitly included in the reports. In an on-going stability study (presented during the MR process) was explicitly reporter that no phase separation was observerd during 13 months storage. When both submitted long term stability studies are included for a full assessment, IPBC has been shown stable for up to 2 years (Affolter, 2012) and propiconazole has been shown stable for up to 6 months (Raphalen, 2016). Cypermethrin has in one study (Affolter, 2012) been shown stable for up to 1 year, while it did not fully fulfill the requirement for stability after 6 months in the second study (Raphalen, 2016); this has been	Affolter, 2012

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Storage stability test – **long term storage at ambient temperature, II**	Storage stability for 6 months at 20 ± 2 °C Test is performed in commercial packagings (coated tin plate cans, 2 L). Lining: two layer system, the first layer is an epoxy-phenolic resin, top-coat is based on a vinyl resin	See results	addressed below this table. In conclusion a claim for 6 months shelf-life can be accepted.	Raphalen, 2016 (to be found in IUCLID, under annotations in section 3.4.1)
Storage stability test – **low temperature stability test for liquids**	–	–	The stability after storage at low temperatures must be determined for liquid products. Although the biocidal product is liquid, the low temperature stability does not need to be tested due to the label claim "protect from frost".	–
Effects on content of the active substance and technical characteristics of the biocidal product – **light**	–	–	Not applicable as the packaging is light-proof. Therefore, the formulation is not exposed to light during storage.	–

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	–	–	Not applicable because according to the label instructions the biocidal product has to be stored cool, dry and protected from frost in closed, original containers.	–
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	8 weeks test: glass flask with PTFE cap 2 year test: coated tin plate cans	See results for the storage stability studies	No significant changes of packaging stability occurred during the test for accelerated storage at 40 °C for 8 weeks or during the 2 year stability test at 20 °C.	Legay, 2010 Affolter, 2012
Wettability	–	–	Not applicable as the product is a liquid ready-to-use product.	–
Suspensibility, spontaneity and dispersion stability	–	–	Not applicable as the product is a liquid ready-to-use product	–
Wet sieve analysis and dry sieve test	–	–	Not applicable as the product is a liquid ready-to-use product	–
Emulsifiability, re-emulsifiability and emulsion stability	–	–	Not applicable as the product is a liquid ready-to-use product	–
Disintegration time	–	–	Not applicable as the product is a liquid ready-to-use product	–
Particle size distribution, content of dust/fines, attrition, friability	–	–	Not applicable as the product is a liquid ready-to-use product	–
Persistent foaming	–	–	Not applicable as the product is a liquid ready-to-use product	–

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Flowability/ Pourability/ Dustability	–	–	Not applicable as the product is a liquid ready-to-use product	–
Physical compatibility	–	–	Not applicable as the biocidal product is not intended to be used with other products including other biocidal products.	–
Chemical compatibility	–	–	Not applicable as the biocidal product is not intended to be used with other products including other biocidal products.	–
Degree of dissolution and dilution stability	–	–	Not applicable as the product is a liquid ready-to-use product	–
Surface tension	National guideline NF EN 14370: 2004	IPBC: 0.81 % Propiconazole: 0.85% Cypermethrin: 0.22%	27.16 mN/m at 21 °C (mean value of two determinations) The product is regarded as being surface-active as the measured surface tension is lower than 60 mN/m (according to EEC Method A5)	Legay, 2010
Viscosity	OECD guideline 114, forced ball viscometer (dynamic)	IPBC:0.75% Propiconazole: 0.64%* Cypermethrin: 0.22% *see discussion under storage stability	Dynamic: 1.564 mPa*s at 20.1 °C (kinematic: 1.549 mm^2/s (calculated)) The determination of the kinematic viscosity at 40 °C has been waived by the applicant, as the product contains <10% of hydrocarbon solvent. The determination of the kinematic viscosity at 40 °C is regarded as core data only for products which are not already classified with "Asp. 1 – H304" but do contain > 10 % aliphatic / aromatic hydrocarbon solvents. This explanation has been accepted by rMS.	Affolter, 2012

2.2.2.1 Storage stability test – long term storage at ambient temperature

The results of a 2 year stability study at 20 °C (Affolter, 2012) is presented in the table below. The study was performed in coated tin plate cans.

Long term storage stability study (Affolter, 2012)				
	0 months	**6 months**	**12 months**	**24 months**
pH	7.76	7.42	7.29	7.19
IPBC (%)	0.75 ± 0.04%	0.73 ±0.02% (variation -2.5%)	0.68 ±0.02% (variation -9.7%)	0.82 ±0.02% (variation +9.9%)
Propiconazole (%)	0.64 ± 0.07%	0.74 ± 0.01% (variation **+15.5%)**	0.85 ± 0.01% (variation **+33%)**	0.73 ± 0.00% (variation **+14.6%)**
Cypermethrin (%)	0.22 ± 0.01%	0.21 ± 0.001% (variation -6.3%)	0.21 ± 0.01% (variation -5.8%)	0.19 ± 0.00% (variation **-14.9%)**

According to the GIFAP monograph no. 17 a deviation of 10% active substance content should be applied; hence if the active content decreases by ≤10 % from the measured concentration at t=0 then in general the product can be regarded as stable. For IPBC this requirement is met for 24 months. For cypermethrin the requirement is fulfilled for 12 months. However for propiconazole, the requirement is not met at all. The nominal concentration of propiconazole is 0.8%, and the initial measurement at t=0 is rather lower (0.64%). The deviation from the nominal concentration is 20 %, which is above the acceptable 15 % tolerance given in the FAO/WHO manual[1]; and hence invalids the study from the very beginning. In addition, the standard deviation of the propiconazole measurement at t=0 and the metod variation coefficient of the calibration function at t=0 are high compared to t=6,12 and 24; indicating that there might have been analytical problems with the intial measurement of propiconazole.

[1] Manual on development and use of FAO and WHO specifications for pesticides, 2nd Revision (2010)

The applicant was asked to submit an additional stability study in order to meet the requirement of < 10% deviation and < 15% of the nominal concentration. The applicant has in December 2016 submitted a 6 months study performed at 20 ± 2 °C in commercial packagings (coated tin plate cans, 2 L). The results of this second study (Raphalen, 2016) is presented in the table below.

Long term storage stability study II (Raphalen, 2016)			
	0 months	**3 months**	**6 months**
pH	Not measured		
IPBC (%)	0.80 ± 0.014%	0.79 ±0.008% (variation -1.3%)	0.78 ±0.000% (variation -2.5%)
Propiconazole (%)	0.81 ± 0.011%	0.79 ± 0.005% (variation -2.5%)	0.80 ± 0.005% (variation -1.2%)
Cypermethrin (%)	0.23 ± 0.005%	0.22 ± 0.000% (variation -4.3%)	0.20 ± 0.000% **(variation -13.0%)**

In this second study, the initial measurements of all three active substances were acceptable in compare to the nominal concentrations (<15 % deviation). The deviations following 3 months storage compared with prior to storage were within the accepted range for all three active substances. After 6 months the deviation were within the accepted range for propiconazole and IPBC, while it was slightly exceeding the limit for cypermethrin, where the measured content was decreasing from 0.23% to 0.20%, resulting in a deviation of 13.0%. The presented contents are an arithmetric mean of 6 replicates, and taking the standard deviation into consideration, the results are quite close to the required maximum of 10%.

When both the submitted stability studies are included for a full assessment of the long term stability, IPBC has been shown stable for up to 2 years (Affolter, 2012) and propiconazole has been shown stable for up to 6 months (Raphalen, 2016). Cypermethrin (Affolter, 2012) has in one study been shown stable for up to 1 year, while it was close to but did not fully fulfill the requirement for stability after 6 months in the second study (Raphalen, 2016). Taking both stability studies into consideration, however, rMS can accept a claim for 6 months shelf-life.

Conclusion on the physical, chemical and technical properties of the product
The provided studies for the physical, chemical and technical properties were found acceptable. The product is regarded as being surface-active. The accelerated stability study showed degradation of the active substances at 54°C for 2 weeks and at 40°C for 8 weeks. The degradation exceeded the limit of 5 % for all three active substances. However the long term storage stability tests were accepted and overrules this result in terms of storage stability in general. The results do however indicate that the product should not be stored above 20 ºC , and this has to be included in the SPC. No unacceptable effects on the physical parameters were observed during storage test. Two long term stability studies has been submitted and when both are included for a full assessment of the long term stability, an acceptable degradation of the active substances at room temperature (20°C ± 2 °C) for 6 months has been shown. The product is a water-based formulation, and extrapolation to all packaging types (including lined metal cans), apart from metal, are supported with no further data. A claim for 6 months shelf-life can therefore be accepted.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Explosives	–	–	The biocidal product does not contain components in concentrations which are known to confer explosivity or to enhance explosibility properties. Therefore the biocidal product is incapable of exothermic reaction and rapid decomposition with evolution of gases or release of heat and does not have explosive properties. Since the biocidal product does not present any risk for explosion, explosive properties do not need to be tested.	–
Flammable liquids	National guideline: NF EN 22719: 1994, Pensky-Martens closed cup EN *International relationship with ISO 2719*	IPBC: 0.81 % Propiconazole: 0.85% Cypermethrin: 0.22%	No flash point was detected below 99 °C.	Legay, 2010
Self-reactive substances and mixtures	–	–	There are no ingredients with explosive or self-reactive properties present in the biocidal product. Therefore the formulation is not self-reactive.	–
Pyrophoric liquids	–	–	The study does not need to be conducted as based on experience in handling and use and the chemical structure of product contents, pyrophoric properties are not to be expected.	–
Self-heating substances and mixtures	–	–	There are no ingredients with explosive or self-reactive properties present in the biocidal product. Therefore the formulation is not self-reactive.	–

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Substances and mixtures which in contact with water emit flammable gases	–	–	The biocidal product contains water. Therefore an emission of flammable gases is not expected when the preparation comes in contact with water.	–
Oxidising liquids	–	–	The biocidal product does not contain components which are known to enhance oxidising properties. None of its ingredients is classified as oxidising. Therefore the formulation may not react exothermically with a combustible material and does not have oxidising properties. Since oxidising properties of the biocidal product are unlikely, it is justified not to submit a study for oxidising properties.	–
Organic peroxides	–	–	Since the biocidal product does not contain any organic peroxide, tests do not need to be performed.	–
Corrosive to metals	–	–	The product has been known for many years. It has never been reported any significant corrosion with tank or applicability material which are partially made of metal. Furthermore containers made of carbon steel or aluminium are not recommended.	–
Auto-ignition temperatures of products (liquids)	-	-	The product is a water based formulation. It is a non-flammable liquid that has no flash point up to the boiling point value of ca. 99 °C, which is approximately equal to the normal boiling point of water.	-

Conclusion on the physical hazards and respective characteristics of the product
The liquid product is not flammable, oxidising, self-heating or explosive and should not be classified for physical hazards.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity (r^2)**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Cypermethrin	HPLC-UV (210 nm)	5 concentrations, 20-30 mg/L	0.9950	No interference at the wave length of the active substances to quantifiy or no interference greater than 3% of the active substances to quantify in HPLC-UV.	(conc: 25 mg/L)			Not relevant	Legay, 2010
					97.4% - 99.8%	98.5% (n=12)	0.18%		
IPBC	HPLC-UV (210 nm)	5 concentrations, 80-120 mg/L	0.9972		(conc: 100 mg/L)			Not relevant	Legay, 2010
					98.8%-102.4%	100.4% (n=12)	0.88%		
Propiconazole	HPLC-UV (210 nm)	5 concentrations, 80-120 mg/L	0.9997		(conc: 100 mg/L)			Not relevant	Legay, 2010
					98.9% - 100.4%	99.6% (n=12)	0.40%		

Conclusion on the methods for detection and identification of the product

This method allows for the determination of cypermethrin, IPBC and propconazole in Induline SW-900 IT. The results obtained show that the method is linear, precise, accurate and specific when used for the assay of Induline SW-900 IT.

Analytical methods for the determination of active substance 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.

Furthermore, analytical methods for the determination of active substance residues in/on food or feedstuffs are not required considered the intended use of the biocidal product.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The biocidal product Induline SW-900 IT is used to protect non-load-bearing softwood timber in use classes 2 and 3 against wood destroying fungi and insects (including termites) as well as blue staining fungi. It is a clear, water based impregnation agent. The product is be used by professionals. The use of a topcoat after drying is required.

It contains the fungicidal components propiconazole and IPBC and the insecticidal component cypermethrin.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Induline SW-900-IT shows efficacy against blue stain fungi, wood rotting fungi (brown rot and white rot), wood boring insects (*Hylotrupes bajulus*) and termites.[2]

2.2.5.3 Mode of action

Cypermethrin is a synthetic pyrethroid with contact and stomach action. It acts by preventing the transmission of impulses along the nervous system of the insect. It is thought that this is achieved by blocking the sodium channels in nerve membranes, thus preventing action potentials passing down the nerve axon.

IPBC has a carbamate structure. The target sites of carbamates in fungi are cell membrane permeability and fatty acids (according to the information provided by FRAC (Fungicide Resistance Action Committee).

Propiconazole belongs to the triazole fungicides. Propiconazole inhibits the fungal growth and has no obvious effect on spore germination or penetration of the pathogen. As other triazole fungicides propiconazole inhibits the C14 demethylation step in the ergosterol biosynthesis of fungi. All four isomers of propiconazole provide biological activity. The intrinsic activity of each isomer is different from pathogen to pathogen. The broad spectrum and high level of activity of propiconazole is the result of the combined activity of the single isomers.

2.2.5.4 Efficacy data

Summaries of the efficacy studies and the efficacy assessment can be found in annex 3.5. The efficacy assessment can be found as two separate documents. The two assessment reports were prepared by FCBA and Danish Technological Institute (DTI), respectively. A list of the submitted studies can be found in annex 3.1.

[2] Assessment based on the "Transitional Guidance on Efficacy Assessment for Product Type 8 Wood Preservatives" (dated: March 2015)

The efficacy assessment performed by FCBA gives a positive evaluation of the efficacy of the product towards *Aureobasidium pullulans* spp., *Sclerophoma pithyophila*, *Coniophora puteana*, *Gloeophyllum trabeum*, *Poria placenta* and *Hylotrupes bajulus* at an application rate of 100 ml/m^2. The EN 118 + EN 73 test (Termites) was also given a positive evaluation at an application rate of 150 ml/m^2, while no test at 100 ml/m^2 had been submitted. Two studies concerning white rot (*Coriolus versicolor*) were evaluated with a negative outcome. The applicant has submitted further studies concerning white rot; these two studies are included in the efficacy assessment performed by DTI. Further, the test EN 118 + EN 84 (Termites) was evaluated with a negative outcome. The applicant has submitted another EN 118 + EN 84 study which is included in the efficacy assessment by DTI.

The efficacy assessment performed by DTI gives a positive evaluation of the efficacy of the product towards white rot (*Coriolus versicolor*) at an application rate of 100 ml/m^2. Further a positive evaluation was given for the EN 118 + EN 84 test (Termites) at an application rate of 100 ml/m^2.

Overall the efficacy has been demonstrated for all intended uses at the intended method of application and an application rate of 100 ml/m^2, except for the use against termites for which an application rate of 150 ml/m^2 is needed. Please note, the particular application rate (150 ml/m^2) for termites is due to a missing EN 118 + EN 73 test at the lower application rate. The applicant has informed that a EN 118 + EN 73 test (100 ml/m^2) has been initiated and will be available approximately primo 2017.

Conclusion on the efficacy of the product

The product, Induline SW-900-IT, has been documented efficient as a preventive insecticide and fungicide for superficial application methods on softwood in use classes 2 and 3. A top coat is required.

It has been documented efficient against blue stain fungi, wood destroying fungi and wood boring insects, excluding termites at an application rate of 100 ml/m^2. The product has further been documented efficient against termites at an application rate of 150 ml/m^2.

Since termites of the genus Reticulitermes mainly occur in the southern part of Europe, use against termites will not be needed in all member states. Therefore a distinction is made in the dosing for as either:
- use against fungi and insects, including termites, or
- use against fungi and insects, excluding termites.

It is up to each member state to decide whether use against termites is needed and to mention the corresponding application and retention rates on the label.

2.2.5.5 Occurrence of resistance and resistance management

Cypermethrin: Resistance to pyrethroid insecticides has been reported for a number of pests both in agriculture and public health. Strategies such as alteration of insecticides with different modes of action and avoidance of over frequent use are standard practises in agriculture and should be applied also to biocide uses of cypermethrin.

IPBC: The risk of resistance formation against Carbamate fungicides is regarded to be low to medium by FRAC (Fungicide Resistance Action Committee). This applies to the use of carbamate fungicides in agriculture, where yearly applications to the same fields are possible (even more than one application per season is possible).

With regard to the use of cabamates in wood preservation, resistance formation constitutes an even smaller problem: The number of treatments to wooden structures is generally low (in many cases, only one application is made per lifetime of timber structures), resulting in a low selection pressure. IPBC has been used for many years in wood preservation without the reporting of cases of resistance.

Propiconazole: Resistance to fungicides is a normal phenomenon embodied in the natural process of the evolution of biological systems and all DMIs (demethylation inhibitor) including propiconazole have a similar resistance risk but resistance factors may be different. However, no specific resistance cases to propiconazole have been reported and the activity of all four isomers of propiconazole may reduce the formation of resistance.

2.2.6 Risk assessment for human health

The toxicology of Induline SW- 900 IT was examined according to standard requirements. The product is not identical to any representative product in the EU- review program for inclusion of the any of the three active substances IPBC, propiconazole or cypermethrin in Annex I of Directive 98/8/EC.
The toxicological properties of the active substances are summarised in the respective CA reports:

- Propiconazole – RMS FL, 2007
- IPBC – RMS DK, 2007
- Cypermethrin – RMS BE, 2013

Acute toxicity tests as well as tests for skin or eye irritation and skin sensitisation have been performed on the product Induline SW- 900 IT. The criteria for the classification of mixtures according to the Regulation 1272/2008 (CLP) were followed.
According to the Regulation 1272/2008, Induline SW-900 IT does not need to be classified for acute toxicity, skin or eye irritation, and skin sensitisation.

The basis for the health assessment of the biocidal product is laid out in the following.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation
(*cf.* IUCLID Section 8.1)

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results**	**Remarks**	**Reference**
OECD 404, GLP, RL1	rabbit, Albino New Zealand, female, 3	Induline SW-900 IT / VP 21075, no vehicle, applied dose: 0.5 mL, exposure duration: 4 h	Mean score (24, 48, 72h) per animal: Erythema: 0.7, 0.3, 1.7 Edema: 0.3, 0, 0 fully reversible within 6 days	none	Colas, S. (2010a)

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to skin
Justification for the value/conclusion	In a dermal irritation study according to OECD guideline 404 with the b.p. Induline SW-900 IT, 3 of 3 rabbits showed slight erythema, associated with a very slight to slight oedema on the

	treated area, 1 hour after the patch removal. Very slight to slight erythema where noted at the 24 h reading time point. The oedematous reactions were totally reversible between Day 1 and Day 2 and the erythematous reactions were totally reversible between Day 2 and Day 6.
Classification of the product according to CLP	Not classified.

For skin corrosion and irritation no human data is available.

Eye irritation

(*cf.* IUCLID Section 8.2)

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance ,Dose levels, Duration of exposure**	**Results**	**Remarks**	**Reference**
OECD 405, GLP, RL1	rabbit, New Zealand, female, 3	Induline SW-900 IT / VP 21075, 0.1 mL, 9 days post exposure period	Mean score of 3 animals (24, 48, 72 h): Cornea: 0, 0, 0 Iris: 0, 0, 0 Conjunctivae: 1.3, 1.3, 0.3 Chemosis: 0.7, 0, 0 Reversibility: not applicable	none	Colas, S., (2010b)

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to eyes
Justification for the value/conclusion	The eye irritation potential of the b.p. Induline SW-900 IT was tested in 3 young adult female New Zealand White rabbits according to OECD guideline 405. The ocular conjunctivae reactions observed during the study have been slight to moderate and totally reversible in the three animals: a slight to moderate redness, noted 1 h after the test item installation and totally reversible between Day 2 and Day 9, associated with a slight to moderate chemosis, noted 1 h after the test item installation and totally reversible between day 1 and day 2.
Classification of the product according to CLP	Not classified.

For serious eye damage and irritation no human data is available.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract
Justification for the conclusion	Induline SW-900 IT is neither irritating to eyes nor to the skin. A respiratory tract irritation study with Induline SW-900 IT has not been conducted. Propiconazole is not classified for respiratory tract-irritation. The active substances cypermethrin, IPBC and the co-formulant 1,4-dioxane are classified as irritating to the respiratory system. The concentration of each of the ingredients and also the sum of the ingredients is below 20%. It is therefore concluded that the b.p. has no respiratory tract-irritating potential.
Classification of the product according to CLP	According to CLP, no classification for respiratory tract irritation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The b.p. Induline SW-900 IT is neither irritating to eyes nor to the skin. The toxicity of the active substances (a.s.) and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product (b.p.) can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation 1272/2008 (CLP). Propiconazole is not classified for respiratory tract irritation. The a.s. cypermethrin, IPBC and the co-formulant 1,4-dioxane are classified as irritating to respiratory system as STOT SE 3, H335 (respiratory tract irritation) according to CLP. No specific concentration limits are specified for cypermethrin, IPBC and 1,4-dioxane in Annex VI of Regulation 1272/2008, so that the generic concentration limit of the CLP applies. Since, cypermethrin, IPBC, and 1,4-dioxane are present at a concentration below the concentration limit of 20%, the b.p. product does not need to be classified for respiratory tract irritation.

Skin sensitization
(*cf.* IUCLID Section 8.3)

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
Guinea Pig Maximisation Test, OECD 406, GLP, RL1	guinea pig, Dunkin Hartley, female, 6 (control group), 11 (treated group)	Induline SW-900 IT / VP 21075, Induction: 6.25% intradermal, 100% topical; Challenge: 50% and 100% topical Induction exposure: 48 h (topical) Challenge exposure: 24 h (topical)	Negative control: 0/6 Test group: 0/11	none	Colas, S., (2010c)

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	A study for skin sensitisation in guinea pigs was conducted with the test substance Induline SW- 900 IT / VP 21075 using the guinea pig maximisation test (GPMT) in accordance with OECD Guideline 406 and in compliance with GLP. The test was performed to assess the skin sensitisation potential of the test item Induline SW- 900 IT / VP 21075 in the Dunkin Hartley strain following intradermal and epicutaneous induction and epicutaneous occlusive challenge. Animals were induced on Day 0 (6.25% (w/w or vehicle, intradermal) and Day 7 (100% w/w or vehicle, epicutaneous), whereas control animals were challenged on Day 21 (50%, and 100% (w/w)). Following the challenge phase (at 24 and 48 hours) neither control animals (6 females)

	nor animals of the treated group (11 females) showed no skin sensitization reactions. No macroscopic cutaneous reactions were observed during the examination following the challenge phase in animals of the test group and the control group. Positive controls (alpha-Hexylcinnamaldehyde) were periodically performed and confirmed the sensitivity and validity of the test system. In view of these results, under these experimental conditions, the test item Induline SW-900 IT / VP 21075 is not classified for "Skin sensitisation", in accordance with the Regulation (EC) No 1272/2008.
Classification of the product according to CLP	According to CLP, the biocidal product does not need to be classified with Skin Sens. 1, H317 but needs to be labelled with EUH208 "Contains IPBC and propiconazole. May produce an allergic reaction".

For skin sensitisation no human data is available.

Respiratory sensitization (ADS)

(*cf.* IUCLID Section 8.4)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	A respiratory sensitisation test with Induline SW-900 IT has not been conducted. The active substances propiconazole, IPBC, cypermethrin and the co-formulants are not classified for respiratory sensitisation. It is therefore concluded that the b.p. has no potential for respiratory sensitisation.
Classification of the product according to CLP	According to CLP classification for respiratory sensitisation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The toxicity of the active substances (a.s.) and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product (b.p.) can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation 1272/2008 (CLP). The a.s. propiconazole, IPBC, cypermethrin and the co-formulants are not classified for respiratory sensitisation. Therefore, the biocidal product does not need to be classified for respiratory tract sensitisiation.

For respiratory sensitisation no human data is available.

Acute toxicity

Acute toxicity by oral route
(cf. IUCLID Section 8.5.1)

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels Type of administration**	**Signs of toxicity**	**Value LD50**	**Remarks**	**Reference**
OECD 423, GLP RL1	rat, Sprague Dawley, female, 6	Induline SW 900 IT / VP 21075, 2000 mg/kg bw, gavage	No mortality, No clinical signs of toxicity, No macroscopic findings.	> 2000 mg/kg bw	none	Colas, S., (2010d)

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not harmful
Justification for the selected value	In an acute oral toxicity study according to the Acute Toxic Class Method of OECD Guideline 423 (2001), six young female rats (Sprague Dawley), were given a single oral dose, by gavage, of the b.p. Induline SW-900 IT at the limit dose of 2000 mg/kg bw. There were no mortalities or any signs of toxicity, all animals gained the expected weight and no treatment-related macroscopic findings were noted. The oral LD_{50} exceeds 2000 mg/kg bw.
Classification of the product according to CLP	Not classified

For acute oral toxicity no human data is available.

Acute toxicity by inhalation
(cf. IUCLID Section 8.5.2)

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not harmful
Justification for the selected value	Acute toxicity studies with Induline SW-900 IT have not been conducted. Testing of the pure active substance propiconazole revealed no acute inhalation toxicity. The active substances IPBC, cypermethrin and the co-formulant 2-butoxyethanol are classified fo acute inhalation toxicity. Using the conventional method described in the guidance for classifying mixtures under Regulation 1272/2008 (CLP), the biocidal product does not need to be classified for acute inhalation toxicity.
Classification of the product according to CLP	According to CLP, no classification for acute inhalation toxicity is necessary.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The toxicity of the active substances (a.s.) and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product (b.p.) can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Testing of the pure a.s. propiconazole revealed no acute inhalation toxicity. The a.s. cypermethrin and the co-formulant 2-butoxyethanol are classified as Acute Tox. 4, H332 according to CLP. The a.s. IPBC is classified as Acute Tox. 3, H331 according to CLP. Specific concentration limits are not specified for cypermethrin, IPBC, and 2-butoxyethanol in Annex VI of Regulation 1272/2008, so that the generic concentration limit of the CLP applies. According to CLP, the concentration of cypermethrin and 2-butoxyethanol is below the concentration limit of 1%. Thus the ingredients do not need to be taken into consideration for the purpose of classification. The concentration of IPBC is not below the concentration limit of 0.1%. Thus IPBC does need to be taken into account when determining the classification of the biocidal product. In order to classify the biocidal product, the acute toxicity estimate (ATE) of a mixture was estimated. Since the estimated ATE_{mix} does not fall within a CLP acute inhalation toxicity category, the b.p. does not need to be classified for inhalation toxicity.

For acute inhalation toxicity no human data is available.

Acute toxicity by dermal route
(cf. IUCLID Section 8.5.3)

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity**	**LD50**	**Remarks**	**Reference**
OECD 402, GLP RL1	rat, Sprague Dawley, male and female, 5	Induline SW 900 IT / VP 21075, 2000 mg/kg bw, at least 10% of body surface	none	>2000 mg/kg bw	none	Colas, S., (2010e)

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not harmful
Justification for the selected value	In an acute dermal toxicity study according to OECD Guideline 402, rats were exposed to the b.p. Induline SW-900 IT in a limit test. No mortalities or signs of overt toxicity were observed; all animals gained the expected weight. The dermal LD_{50} for male and female rats exceeds 2000 mg/kg bw.
Classification of the product according to CLP	Not classified

For acute dermal toxicity no human data is available.

Information on dermal absorption

(cf. IUCLID Section 8.6)

No dermal absorptions studies with Induline SW-900IT has been conducted. However, information on dermal penetration is available from the CARs on IPBC, Propiconazole and Cypermethrin, respectively.

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Propiconazole	IPBC	Cypermethrin
Value	2%	30%	13%
Justification for the selected value	The dermal absorption from the available studies was re-evaluated in the propiconazole CAR for PT7 (RMS FI, 2014). Using human/rat ratios of absorbed fraction the dermal absorption values of 4, 7 and 9 % were reached for the a.i. concentrations of 25 %, 0.06 % and 0.006 %, respectively. However, in the CAR the highest value of 9 % is proposed to be taken forward to the exposure calculations for a concentration range between 0.3 – 10 % a.i. as a worst case, which is used in the evaluation of SW-900IT. (RMS FI, 2014).	Dermal absorption of IPBC, determined *in vitro* through human skin using a solvent-based formulation containing 0.6% IPBC, has been found to be 30%. This absorption value is valid in a concentration range of 0.5-2.4% (RMS DK, 2007).	The dermal absorption of cypermethrin determined in rats *in vivo* resulted in an absorption of 7.6% and 12.7% of the applied dose for the concentrate (50%) and an aqueous spray dilution (0.0025%; RMS BE, 2013). For the assessment of the human internal dermal exposure, a value of 13% is derived.

Data waiving	
Information requirement	Other justification
Justification	Dermal absorption studies with Induline SW-900 IT have not been

	conducted. As dermal absorption is inversely proportional to the concentration, bridging to a higher concentration of active substance is acceptable. Induline SW-900 IT is not a skin irritant and does not contain a high content in solvents and surfactants affecting dermal absorption. Also as organic solvents enhances dermal absorption, using data from a solvent based product in the evaluation of a water based product reflects a concervative approach, which is acceptable. • For IPBC a dermal absorption value of 30% was proposed by the applicant. Solvent-based solutions containing 0.6% IPBC, a dermal absorption value of 30% has been set in the CAR (RMS Denmark, 2008). For IPBC, a dermal absorption value of 30% is therefore, accepted and used for this evaluation of the biocidal product Induline SW-900 IT containing 0,8% IPBC. • For propiconazole, a dermal absorption value of 2% was proposed by the applicant since the formulation Induline SW-900 IT contains 0.8% propiconazole within the concentration ranges used in the dermal absorption studies in the PT8 CAR. However the dermal absorption from the available studies was re-evaluated in the PT7 CAR for propiconazole (RMS FI, 2014) resulting in a dermal absorption value of 9 % for a concentration range between 0.3 – 10 % a.i. as a worst case. The test formulation of the dermal absorption studies submitted for Annex I inclusion is the solvent based thus the evaluation of a water based product (Induline SW-900IT) reflects a concervative approach. From these points an adaption of the dermal absorption value of 9% derived during Annex I inclusion is accepted and used for this evaluation of the biocidal product Induline SW-900 IT containing 0.8% propiconazole. • For cypermethrin a dermal absorption value of 13% was proposed by the applicant for the evaluation of the b.p. Induline SW-900 IT containing 0.2% cypermethrin. Following the DK eCA assessment we agree on the setting of the Dermal Absorption of 13% agreed in the CAR for cypermethrin (2013) for Induline SW-900 IT Please refer to Annex 4 for further justifications.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

The biocidal product (b.p.) contains no non-active substances that are classified in Annex I of Directive 67/548/EEC or in Annex VI of Regulation 1272/2008, respectively at concentrations leading to a classification of the b.p.

Available toxicological data relating to a mixture

Toxicological data relating to a mixture that a substance of concern is a component of are not required.

Other

Other test(s) related to the exposure to humans are not available for the proposed biocidal use pattern. Exposure estimates and risk characterisations are given for the formulation, use and post application in the human risk assessment. The risk characterisation, showed no concern when the b.p. is handled and applied or when humans are indirectly exposed to residues of the active substances (post-application exposure). Therefore no other test related to the exposure to humans is necessary.

The biocidal product is not intended for direct application to foods or feedingstuff or to surfaces and areas where foods or feedingstuff are prepared or stored. Hence, an exposure of food and feeding stuff to a.s. can be excluded when applied according to the recommended uses. Additional food or feedingstuffs studies are not required. The biocidal product should not be used on wood that will come in direct contact with food, animal feed or livestock.

2.2.6.2 Exposure assessment

The biocidal product contains the active substances IPBC, propiconazole and cypermethrin. Human exposure evaluation relates to the production and use phases of the product and cover primary and secondary exposure.

The following, primary exposure of professionals performing the different tasks related to the different methods of application of the product. Induline SW-900 IT is a ready-to-use water-based wood preservative for non-load-bearing softwood timber without ground contact in outdoor areas (industrial use). It is intended for the preventive treatment of timber used in situations in which the wood-based product is under cover and not exposed to the weather particularly no persistent wetting can occur (Use Class 2 of the European Standard EN 335:2013). It is also used in situations in which the wood-based product is either continually exposed to the weather or is protected from the weather but subject to wetting (Use Class 3). Use of top coat is required.

Timber treatment is conducted by brushing, dipping, flow-coating or automated spraying (spray tunnel). The product Induline SW- 900 IT is applied with the following application rates: 100-150 mL wood preservative/m² wood. Therefore as a worstcase the exposure assessment of Induline SW-900IT was performed using 150 mL/m^2 corresponding to 151.5 g/m^2 at maximum considering a product density of 1.01 g/mL at 20°C.

Exposure of industrial professional workers to the active substances while handling Induline SW-900 IT is estimated. Induline SW-900 IT is not intended or sold for the treatment of wood surfaces in habitable and recreation rooms.

A high standard of occupational hygiene has to be observed: e.g. do not eat, drink or smoke when working with Induline SW-900 IT; avoid contact with eyes and skin; do not inhale vapour; unprotected persons, children, animals, domestic pets, wildlife, etc. should be kept away from products and freshly treated surfaces until dry, maintaining ventilation at a maximum.

During and after the application of Induline SW-900 IT, operator exposure could theoretically occur by dermal and inhalation routes. 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 (propiconazole: 5.6 x 10^{-5} Pa at 25°C (CAR, RMS FL, 2007); IPBC: 4.5 x 10^{-3} Pa at 25°C (CAR, RMS DK, 2007); cypermethrin: 2.3 x 10^{-7} Pa at 20°C (CAR, RMS BE,

2013)) low energy application techniques which do not result in aerosol formation (spraying occurs in closed facilities only).
Post-application exposure can occur to professionals handling treated wood.

Secondary exposure of residents will not be significant because of the application of the b.p. onto wood that is not used in interior spaces.
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).
The b.p. is not used on wood with direct exposure to living areas. Furthermore, it is only used on wood exposed to weather, including wooden playground structures, when the treated wood is coated after drying. Children and infants may be exposed via residues in playground structures, and infants in addition through accidential ingestion of a piece of wood cut-off.

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	yes	n.a.	n.a.	yes	yes	n.a.
Dermal	n.a.	yes	n.a.	n.a.	yes	yes	n.a.
Oral	n.a.	no	n.a.	n.a.	no	yes	n.a.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Brush application	Primary exposure, Brush application of water-based wood preservative	Professionals
2.	Cleaning the brush	Primary exposure, Cleaning of the brush after application	Professionals
3.	Industrial dipping	Primary exposure, Post-application exposure during manual handling of treated wood	Professionals
4.	Professional deluging/flowc oat/autospray	Primary exposure, Post-application exposure during manual handling of treated wood	Professionals
5.	Acute: sanding of treated wood, amateur	Secondary exposure, Sanding the surface of treated wood posts	Non-professionals
6.	Chronic: sanding of treated wood, professional	Secondary exposure, Sanding the surface or treated wood posts	Professionals
7.	Handling treated wood	Acute secondary exposure, Adult handling treated wood after application	Non-Professionals
8.	Infant touching wet treated wood	Acute secondary exposure, Infant touching freshly treated surface	General public
9.	Infant chewing wood-chip	Acute secondary exposure, Infant chewing on a treated piece of wood	General public
10.	Child or toddler playing on playground structure	Chronic secondary exposure, Child or toddler playing on playground structure treated with wood preservative	General public
11.	Inhalation of residues, indoors	Chronic secondary exposure, Adult, child and toddler exposed to volatilised residues indoors from remedial treatment	General public

Induline SW-900 IT is supplied as a ready-to-use formulation. Therefore, there is not mixing and loading process for the brushing/rolling applications.

Industrial exposure

The risk characterisation of industrial dipping, flow-coating and automated spraying is reported in the section for professional workers.

Professional exposure

Scenario [1]

Brush application

Description of Scenario [1]		
According to "Biocides Human Health Exposure Methodology, p. 120" the scenario on professional brushing based on the Summary Report - Human Exposure to Wood Preservatives, the following assumptions are considered in the used model: Application area: 31.6 m² The application area is calculated using the median work rate of 7.6 min/m² (acc. to TNsG 2002 "Consumer product painting Model 3" and the exposure duration of 240 min. Calculation: 1/7.6 min/m² *240 min = 31.6 m² The indicative values are normalized to 1% active substance and are referring to the exposure when brushing an area of 1 m² (acc. to Summary Report - Human Exposure to Wood Preservatives, Lingk, W.; Reifenstein, H.; Westphal, D.; Plattner, E., BfR Wissenschaft, 2006). As propiconazole and IPBC are skin sensitizers, professionals are expected to wear coveralls which would provide a higher reduction of exposure of the body. Also, professionals will wear gloves, in order to avoid dermal exposure. No futher refinement of the scenario was considered necessary. For details on the exposure assessment please refer to Appendix 3.2.		
	Parameters	Value
Tier 1	Frequency	1/week
	Application area	31.6 m^2
	Dermal absorption IPBC	30%
	Dermal absorption propiconazole	9%
	Dermal absorption cypermethrin	13%

	Indicative values[1]	Hands: 0.5417 mg/m² (normalized to 1% a.s.) Body: 0.2382 mg/m² (normalized to 1% a.s.) Inhalation (non-volatile compounds): 0.0016 mg/m² (normalized to 1% a.s.)
	Inhalation rate[2]	1.25 m³/h
	Body weight, adult[2]	60 kg
Tier 2	Clothing, reduction factor[3]	90%

[1] Consumer painting Model 3, Biocides Human Health Exposure Methodology, page 120
[2] HEEG opinion 17, default human factor values
[3] HEEG opinion 9, coated coverall liquid light challenge, 90% protection factor

Scenario [2]

Cleaning the brush

Description of Scenario [2]		
A post-application task which may lead to some degree of exposure is cleaning of the brush. Cleaning of the equipment (brush) by professionals after the application event lasts for no more than 15 min. It might result in some exposure to hands. The exposure during cleaning is not covered by any of the proposed TNsG models and water-based formulations might be removed under a water stream. That would render the cleaning task to be negligible with regard to dermal exposure. However as worst case, the exposure of professional and non-professional workers is assessed using the General Exposure Calculator for Washing out Of Brushes of the annex to HEEG Opinion 11. Cleaning a brush used for water-based formulations may be done by repeated dipping and swaying it in a vessel containing clean water. 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 no mitigation by gloves occurs. For details on the exposure assessment please refer to Appendix 3.2.		
	Parameters	Value
Tier 1	Brush size : 10 x 10 x 2 cm[1]	200 mL
	Volume of residual solution in brush[1]	1/8 of brush volume = 25mL
	Volume of each washing solution[1]	at least 400 mL
	Remaining residues in brush after each washing step[1]	10%
	Remaining residues in brush after each squeezing[1]	50%
	Penetration through cleaning cloth during squeezing[1]	10%
	Body weight[2]	60 kg
	Dermal absorption IPBC	30%
	Dermal absorption propiconazole	9%

	Dermal absorption cypermethrin	13%
Tier 2	Gloves, reduction factor	90%

[1] HEEG opinion 11, Exposure model –washing of a brush
[2] HEEG opinion 17, default human factor value

Scenario [3]
Water based fully automated industrial dipping

Description of Scenario [3]
Application: The application process itself occurs in a large tank or in a spray tunnel, 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 or flow-coating 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 during dipping 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 also cover potential exposure during the treatment process itself. This model may be best described as "intermittent contact with wet objects" Handling of treated wood: Post-application exposure to the product may occur during manual contact during handling of treated (damp) 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. Exposure calculations are given according to aggreements made at TM III 2009 where HEEG agreed that for automated dipping processes using a fork-lift it is appropriate to use Handling Model 1 (Biocides Human Health Exposure Methodology page 197 TNsG Human Exposure to Biocidal Products 2002, Part 2 p162, and the User Guidance, 2004, p26 & p.41) to predict exposure. This conclusion was based on the findings of a German exposure study, which observed qualitatively that the dermal exposure pattern of automated dipping is comparable to that of the vacuum-pressure process, i.e. exposure occurs through the intermittent handling of wet-preserved timber. Exposure will primarily be via the dermal route. This is a long-term exposure scenario. Hand exposure is actual hand exposure inside gloves. Storage of treated timber at dipping sites is usually outdoors or in open-sided structures to ensure good ventilation while the timber is drying and the preservative is fixing in the wood. Consequently, exposure via inhalation is considered insignificant. In accordance with the Manual Of Technical Agreements 4.2.9.8 HEEG Opinion TM III 2009 4 dipping cycles of 60 minutes per cycle are assumed per day.

Furthermore according to the HEEG OPINION 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping the biocidal product must only be used in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place including when the treated articles are transported through the dip tank to the draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until the treated articles are surface dry". The untreated wood may only be lowered by a separate lifting unit into the dipping tank. The latter statement excludes the use of fork lift trucks for lowering the wood into the dipping tank. Due to these restrictions the exposure is decreased by a factor of 4 in Tier 2.

	Parameters	Value
Tier 1	Hands[3]	1080 mg/cycle
	Body[3]	8570 mg/cycle
	Body weight[2]	60 kg
	Duration[1]	4 cycles
	Dermal absorption IPBC	30%
	Dermal absorption propiconazole	9%
	Dermal absorption cypermethrin	13%
Tier 2	Factor 4 reduction[1]	

[1]HEEG opinion 8, Defaults and appropriate models to assess human exposure for dipping processes (PT 8)

[2] HEEG opinion 17, default human factor values

[3] HEEG opinion 18, For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping

Scenario [4]

Professional deluging/flow-coat/automated spraying

Description of Scenario [4]
During the flow-coat process (also known as deluge process), the timber, usually window frames, is passed automatically through an enclosed tunnel. The wood preservative is applied to it by flooding the timber during passage through the tunnel. The treatment-solution is retained automatically for recycling. Operator exposure is assumed to be low during application phase although it might be possible that the operator is exposed during handling the wet treated wood. The possibility of generation of spray droplets which could be inhaled is considered to be very low because the wood is flooded not sprayed. If droplets are generated their size is large and they cannot be respired. Two flow-coat applications are assumed per day, each with a duration of 30 minutes. The TNsG on Human Exposure provides no exact model for exposure assessment for flow-coat use of IPBC. Dipping model 1 "Dipping wooden articles in tanks and coating with fluid by pouring and scrubbing" is considered to be appropriate for calculation of operator exposure because it is not only for dipping process, but also for automated spraying. The operator exposure during dipping process is considered to be far higher when compared to exposure during flow-coat process due to the automated nature of flow-coat application. The use of dipping model 1 would therefore be justified.

	Parameters	Value
Tier 1	Hands in gloves[1]	25.7 mg/min
	Body[1]	178 mg/min
	Inhalation[1]	1 mg/m^3
	Body weight[2]	60 kg
	Duration[1]	60 min
	Dermal absorption IPBC	30%
	Dermal absorption propiconazole	9%
	Dermal absorption cypermethrin	13%
Tier 2	Impermeable coveralls[3]	95%
	RPE (PFP1)[4]	25%

[1]Dipping model 1, Professional manual dipping of wooden articles (application)
[2] HEEG opinion 17, default human factor values
[3] HEEG opinion 9, default protection factors for protective clothing and gloves
[4] TNsG on Human Exposure to Biocidal Products from June 2002

Scenario [6]

Chronic: sanding of treated wood, professional

Description of Scenario [6]
This scenario is relevant for amateurs (acute axposure) and for professionals (chronic exposure). The acute sanding scenario [5] (for details please refer to the Non-professional exposure scenarios) is extrapolated to the chronic situation by assuming that the exposure time is 6 hours per day. The professional user is instructed to wear a respiratory protection mask when sanding treated wood. As worst case scenario inhalation exposure without respiratory protection will be six times higher than for the one-hour task of an amateur (see Scenario [5]). The surface area of both palms of hands is 420 cm² and this is the assumed transfer coefficient per day. With this assumption, dermal exposure is independent of the daily exposure duration duration and is thus equal to the acute sanding scenario [5]. For details on the exposure assessment please refer to Appendix 3.2.

Calculations for Scenario [1, 2, 3, 4, 6]

Propiconazole

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [1]	1 / none	0.00084	0.0296	-	0.0304
Scenario [1]	2 / PPE	0.00084	0.00296	-	0.0038
Scenario [2]	1 / none	-	0.0016	-	0.0016
Scenario [3]	1 / none	-	0.463	-	0.463
Scenario [3]	2 / PPE	-	0.0232	-	0.0232
Scenario [4]	1 / none	0.00017	0.147	-	0.147
Scenario [4]	2 / PPE	0.00067	0.0249	-	0.0249
Scenario [6]	1 / none	0.000254	0.0015	-	0.0018

IPBC

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [1]	1 / none	0.00084	0.0986	-	0.0994
Scenario [1]	2 / PPE	0.00084	0.00986	-	0.0107
Scenario [2]	1 / none	-	0.0053	-	0.0053
Scenario [3]	1 / none	-	1.54	-	1.54
Scenario [3]	2 / PPE	-	0.077	-	0.077
Scenario [4]	1 / none	0.00017	0.489	-	0.489
Scenario [4]	2 / PPE	0.00067	0.083	-	0.083
Scenario [6]	1 / none	0.000254	0.0051	-	0.0053

Cypermethrin

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [1]	1 / none	0.000002	0.0107	-	0.0107
Scenario [1]	2 / PPE	0.000002	0.00107	-	0.00107
Scenario [2]	1 / none	-	0.0006	-	0.0006
Scenario [3]	1 / none		0.167	-	0.167
Scenario [3]	2 / PPE		0.0084	-	0.0084

Scenario [4]	1 / none	0.00004	0.0529	-	0.0529
Scenario [4]	2 /PPE	0.00017	0.009	-	0.0090
Scenario [6]	1 / none	0.000064	0.0006	-	0.0006

Combined scenarios

As a conservative approach a combined exposure for scenario 1+2+8 has been performed: professional brushing, professional cleaning brushes, and adult handling treated wood after application was preformed.

Propiconazole

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
	mg/kg bw/day			
Scenarios [1,2,8] tier 1	0.00084	0.0335	-	0.0343
Scenarios 1 (Tier 2),2 (Tier 1), 8	0.00084	0.0054	-	0.0063

IPBC

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
	mg/kg bw/day			
Scenarios [1,2,8] tier 1	0.00084	0.111	-	0.112
Scenarios 1 (Tier 2),2 (Tier 1), 8	0.00084	0.0054	-	0.0063

Cypermethrin

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
	mg/kg bw/day			
Scenarios [1,2,8] tier 1	0.0000017	0.0121	-	0.0121
Scenarios 1 (Tier 2),2 (Tier 1), 8	0.0000017	0.0020	-	0.0020

Non-professional exposure

Scenario [5]

Acute: sanding of treated wood, amateur

Description of Scenario [5]
Inhalation route: A person (non-professional) is sanding the surface of treated wood (4 cm x 4 cm x 2.5 m, surface area of 4032 cm²) (TNsG 2002, Part 3, p.50). The active substances are in the outer 1 cm layer. The product is applied at a rate of about 150 mL/m² (at a relative b.p. density of about 1.01 g/cm³: 151.5 g/m²). If 100% retention by the wood is assumed as the ultimate worst case, the wood can contain: Propiconazole: 151.5 g/m² × 0.80% = 1.212 g/m² (0.1212 mg /cm²) IPBC: 151.5 g/m² × 0.80% = 1.212 g/m² (0.1212 mg /cm²) Cypermethrin: 151.5 g/m² × 0.2% = 0.303 g/m² (0.0303 mg /cm²) The ultimate worst case of 100% retention of the active substances in the wood is assumend: Propiconazole: 0.1212 mg /cm² IPBC: 0.1212 mg /cm² Cypermethrin: 0.0303 mg /cm² The density of the wood is assumed 0.5 g/cm³. 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 2004/37/EC). The duration of a sanding task is an estimated one hour. *Dermal route (hands – no gloves worn):* The highest concentration on the surface is 10 mg b.p./cm². The surface area of both palms of hands is 420 cm² and this is the assumed transfer coefficient per day. The transfer efficiency is 2% for rough sawn wood (BPR guidance: Volume III Human Health, Part B Assessment, p.315). For details on the exposure assessment please refer to Appendix 3.2.

	Parameters	Value
Tier 1	Concentration of a.s. in the outer 1 cm layer	IPBC: 0.1212 mg /cm²
		Propiconazole: 0.1212 mg /cm²
		Cypermethrin: 0.0303 mg /cm²
	The density of the wood	0.4 g/cm³
	Wood dust concentration[1]	5 mg/m³
	Task duration	1 h
	Inhalations rate	1.25 m³/h

	Surface area of palms of hands	420 cm^2
	Transfer efficiency[2]	2%

[1]Directive 2004/37/EC and TnSG 2002, part 3 p. 50

[2]Biocides Human Health Exposure Methodology 2015 p.171

Scenario [7]
Non-professional handling treated wood after application

Description of Scenario [7]		
A non-professional is likely to handle the treated wood after application, either by mounting the wood to form a structure or moving the treated wood to the intended place. The wood-preservative is assumed completely dry at the time of handling. For details on the exposure assessment please refer to Appendix 3.2.		
	Parameters	Value
Tier 1	Concentration of a.s. on the surface[1]	IPBC: 0.1212 mg /cm^2
		Propiconazole: 0.1212 mg /cm^2
		Cypermethrin: 0.0303 mg /cm^2
	Adult hand surface (palms)[2]	420 cm^2
	Percentage dislodgeble[3]	3 %

[1]Calculated for scenario [6]
[2] HEEG opinion –Default protection factors for protective clothing and gloves

[3]Biocides Human Health Exposure Methodology 2015 p.171

Calculations for Scenario [5,7]

Propiconazole

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [5]	1 / none	0.000042	0.0015	-	0.0016
Scenario [7]	1 / none	-	0.00229	-	0.00229

IPBC

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [5]	1 / none	0.000042	0.0051	-	0.0051
Scenario [7]	1 / none	-	0.00764	-	0.00764

Cypermethrin

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [5]	1 / none	0.000011	0.0006	-	0.0006
Scenario [7]	1 / none	-	0.00083	-	0.00083

Exposure of the general public

Scenario 8- Toddler touching freshly treated wood

Description of Scenario [8]		
It is assumed that infants play nearby persons (non-professionals) who are treating wood using Induline SW-900 IT. Contact with treated surfaces is assumed to be of short duration, as parents will remove the product from hands as soon as the "accident" is observed. However all of the palm of the hand will be covered and the transfer coefficient is set to 20%, as Induline SW-900 IT is a product intended to penetrate the wood, it cannot be expected to be transfered to the hand All of the hand deposit is considered for mouthing and exposure via the oral route. For details on the exposure assessment please refer to Appendix 3.2.		
	Parameters	Value
Tier 1	Concentration of a.s. on the surface[1]	IPBC: 0.1212 mg /cm^2
		Propiconazole: 0.1212 mg /cm^2
		Cypermethrin: 0.0303 mg /cm^2
	Toddler hand surface (palm)[2]	115.2 cm^2
	Transfer coefficient of paint from treated surface to hand[2]	50%
	Proportion of palms of hand in contact with the paint[2]	100 %
	Transferable fraction of paint from hand to mouth for wet paint[2]	10 %
	Toddler body weight[2]	10 kg
	Oral absorption[3]	IPBC: 100%
		Propiconazole: 86%
		Cypermethrin: 57%

[1] Calculated for scenario [3]
[2] Recommondation no. 5 Non-professional use of antifouling paints: exposure assessment for a toddler
[3] CAR's of IPBC (RMS DK 2007), Propiconazole (RMS FI 2007), Cypermethrin (RMS BE 2007)

Scenario [9]- Infant chewing wood-chip

Description of Scenario [9]		
It is assumed that an infant plays nearby persons who are handling and sawing Induline SW-900 IT pre-treated wood. The infant chews on one of the pieces of wood. Exposure of infants resulting from chewing of treated wood was estimated using the example calculation provided in the TNsG, 2002, part 3 (worked examples, page 50). This scenario is considered to represent the worst case for secondary oral exposure. This is an incidental event and exposure duration is therefore best described as acute. For simplification, 100% retention of all active substances in the wood is assumed. It is also assumed that all a.s. is bound in the outermost 1 cm of the timber volume and that this part is accessible to infants 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. The full calculations are presented in appendix 3.2.		
	Parameters	Value
Tier 1	Concentration of a.s. on the surface[1]	IPBC: 0.1212 mg /cm^2
		Propiconazole: 0.1212 mg /cm^2
		Cypermethrin: 0.0303 mg /cm^2
	Wood chip size[2]	16cm^3
	Extraction percentage[2]	10%
	Body weight of infant	8 kg
	Oral absorption[4]	IPBC: 100%
		Propiconazole: 86%
		Cypermethrin: 57%

[1] Calculated for scenario [3]
[2] TnSG 2002 part 3 p.50
[3] HEEG opinion: Default human factors values for use in exposure assessment for biocidal products
[4] CAR's of IPBC (RMS DK 2007), Propiconazole (RMS FI 2007), Cypermethrin (RMS BE 2007)

Scenario 10 – Toddler or child playing on playground structure

Description of Scenario [10]		
This scenario describes a toddler or child playing on playground structure outdoors was estimated using the example calculation provided in the TnSG 2002, part 3. The toddler is representing a worst case scenario and is used in the calculation. Only the palm of the hands will be exposed, which is an area of 50% of the default value for hand surface area (230.4 cm^2). It is assumed that 20% of the hand is contaminated at 100% surface concentration. For details on the exposure assessment please refer to Appendix 3.2.		
	Parameters	Value
Tier 1	Concentration of a.s. on the surface[1]	IPBC: 0.1212 mg /cm^2
		Propiconazole: 0.1212 mg /cm^2
		Cypermethrin: 0.0303 mg /cm^2
	Body weight[2]	10 kg
	Toddler hand surface (palm)[2]	115.2 cm^2
	Transfer efficency[3]	20%
	Oral absorption[4]	IPBC: 100%
		Propiconazole: 86%
		Cypermethrin: 57%

[1] Calculated for scenario [3]
[2] HEEG opinion: Default human factors values for use in exposure assessment for biocidal products
[3] TNsG 2002 part 3 p. 50
[4] CAR's of IPBC (RMS DK 2007), Propiconazole (RMS FI 2007), Cypermethrin (RMS BE 2007)

Scenario [11] – Inhalation of volatised residues, indoors

Description of Scenario [11]			
Chronic exposure to wood preservatives may arise from infoor remedial treatment. As a worst case, inhalation exposure was taken as 100% of the saturated vapour pressure/concentration (SVC) according to HEEG opinion 13[1]. SVC = vp (pa) x mw (g/mol) // 8.31 (gas constant) x Temp (K) The calculation is highly concervative and is designed as a screeing tool for identifying a risk. Preserved window frames or joists are required to be coated and hence the wood preservative is sealed and cannot evaporate. Furthermore the vapour pressures of IPBC , propiconazole and cypermethrin are in the generelly considered to be low (<0.5 kPa). In TNsG 2002[2], a similar exposure model was presented using 1% of SVC for a room of moderate ventilation and considering the arguments above, this is regarded a more realistic scenario for induline SW-900 IT. The toddler is presented as the worst case in the output tables below, since the ratio between body weight and inhatation rate is highest for the toddler. For details on the exposure calculations please refer to Appendix 3.2.			
	Parameters		Value
Tier 1	Vapour pressure	Propiconazole	5.6 x 10^{-5} Pa (at 25°C)
		IPBC	4.5 x 10^{-3} Pa (at 20°C)
		Cypermethrin	2.3 x 10^{-7} Pa (at 20°C)
	Molecular weight	Propiconazole	342.2 g/mol
		IPBC	281 g/mol
		Cypermethrin	416.3 g/mol
	Adult	Body weight	60 kg
		Inhalation rate	16 m^3/day
	Child	Body weight	23.9 kg
		Inhalation rate	12 m^3/day
	Toddler	Body weight	10 kg
		Inhalation rate	8 m^3/day

[1]HEEG opinion 13, Assessment of inhalation exposure of volatilised biocide active substance
[2] TNsG 2002, part 3 p.50

Calculations for Scenario [8,9,10,11]

Propiconazole

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake mg/kg bw/d**	**Estimated oral uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Scenario [8]Toddler touching wet treated wood	1/No PPE	-	0.063	0.060	0.123
Scenario [9] Toddler chewing wood	1/No PPE	-	-	0.0208	0.0208
Scenario [10] Toddler playing on play-ground structure	1/No PPE	-	0.0008	0.00016	0.0009
Scenario [11] Inhalation of volatised residues, indoors	1/No PPE	Adult: 0.000021 Child: 0.000040 Toddler: 0.000063	-	-	Adult: 0.000021 Child: 0.000040 Toddler: 0.000063

IPBC

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake mg/kg bw/d**	**Estimated oral uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Scenario [8]Toddler touching wet treated wood	1/No PPE	-	0.201	0.0698	0.279

Scenario [9] Toddler chewing wood	1/No PPE	-	-	0.0242	0.0242
Scenario [10] Child playing on play-ground structure	1/No PPE	-	0.0025	0.00018	0.0027
Scenario [11] Inhalation of volatised residues, indoors	1/No PPE	Adult: 0.0014 Child: 0.0026 Toddler: 0.0042	-	-	Adult: 0.0014 Child: 0.0026 Toddler: 0.0042

Cypermethrin

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake mg/kg bw/d**	**Estimated oral uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Scenario [8]Toddler touching wet treated wood	1/No PPE	-	0.0227	0.0099	0.033
Scenario [9] Toddler chewing wood	1/No PPE	-	-	0.0035	0.0035
Scenario [10] Child playing on play-ground structure	1/No PPE	-	0.00027	0.00002	0.0003
Scenario [11] Inhalation of volatised residues, indoors	1/No PPE	Adult: 1.05 x 10^-7 Child: 1.97 x 10^-7 Toddler: 3.15 10^-7	-	-	Adult: 1.05 x 10^-7 Child: 1.97 x 10^-7 Toddler: 3.15 10^-7

Monitoring data

No further information on surveys or studies with the actual product or with a surrogate were submitted.

Dietary exposure

Food, drinking water or livestock exposure by propiconazole, IPBC and cypermethrin can be excluded when applied according to the recommended uses.

Information of non-biocidal use of the active substance

Propiconazole

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	plant protection products	MRL range of different crops and products of animal origin	0.01 – 6 mg/kg[1]

Cypermethrin

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	veterinary use	Fat (Bovine, Porcine)	200 µg/kg[2]
		Fat (Chickens)	50 µg/kg[2]
		All ruminants	20 µg/kg (muscle, liver, kidney)[3]
			200 µg/kg fat[3]
		Milk	20 µg/kg[2]
2.	plant protection products	MRL range of different crops and products of animal origin	0.05 – 30 mg/kg[4]

No area of other (non-biocidal) use of IPBC is known.

1 Products to which MRLs apply, (Part A of Annex I to Reg. 396/2005), propiconazole
2 Council Directive 93/57/EC
3 Committee for veterinary Medicinal Products, Cypermethrin, Summary Report, 2004 http://www.ema.europa.eu/ema/index.jsp?curl=search.jsp&q=cypermethrin&btnG=Search&mid=WC0b01ac058023eff0
4 Products to which MRLs apply (Part A of Annex I to Reg. 396/2005); Cypermethrin http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=pesticide.residue.CurrentMRL&language=EN&pestResidueId=65

Estimating Livestock Exposure to Active Substances used in Biocidal Products
Food, drinking water or livestock exposure by propiconazole, IPBC and cypermethrin can be excluded when applied according to the recommended uses.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)
Food, drinking water or livestock exposure by propiconazole, IPBC and cypermethrin can be excluded when applied according to the recommended uses.

Estimating transfer of biocidal active substances into foods as a result of non-professional use
Food, drinking water or livestock exposure by propiconazole, IPBC and cypermethrin can be excluded when applied according to the recommended uses.

Exposure associated with production, formulation and disposal of the biocidal product
Exposure during the production of the b.p. should be addressed under other EU legislation (e.g. REACh) and not repeated under Regulation (EU) 528/2012. The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance was not required, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for propiconazole, IPBC and cypermethrin which are existing biocidal active substances within the EU.

Aggregated exposure
The aggregated exposure and assessment is addressed in the risk characterisation for mixtures.

Summary of exposure assessment

Propiconazole

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake** (mg/kg bw/day)
1.	Professionals	1 / none	0.030
1.	Professionals	2 / PPE	0.004
2.	Professionals	1 / none	0.0016
3.	Professionals	1 / none	0.463
3.	Professionals	2 / PPE	0.023
4.	Professionals	1 / none	0.147
4.	Professionals	2 / PPE	0.025
5.	Non-professionals (adults)	1 / none	0.0016
6.	Professionals	1 / none	0.0018
7.	Non-professionals (adults)	1 / none	0.00229
8.	General public	1 / none	0.1228
9.	General public	1 / none	0.0208
10.	General public	1 / none	0.0009
11.	General public	1 / none	Adult: 0.00002 Child: 0.00004 Toddler: 0.00006

IPBC

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake** (mg/kg bw/day)
1.	Professionals	1 / none	0.0994
1.	Professionals	2 / PPE	0.0107
2.	Professionals	1 / none	0.0053
3.	Professionals	1 / none	1.54
3.	Professionals	2 / PPE	0.077
4.	Professionals	1 / none	0.489
4.	Professionals	2 / PPE	0.083
5.	Non-professionals (adults)	1 / none	0.0051

6.	Professionals	1 / none	0.0053
7.	Non-professionals (adults)	1 / none	0.0076
8.	General public	1 / none	0.279
9.	General public	1 / none	0.0242
10.	General public	1 / none	0.0027
11.	General public	1 / none	Adult: 0.0014 Child: 0.0026 Toddler: 0.0042

Cypermethrin

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake** (mg/kg bw/day)
1.	Professionals	1 / none	0.0107
1.	Professionals	2 / PPE	0.00107
2.	Professionals	1 / none	0.0006
3.	Professionals	1 / none	0.167
3.	Professionals	2 / PPE	0.0084
4.	Professionals	1 / none	0.0530
4.	Professionals	2 / PPE	0.0090
5.	Non-professionals (adults)	1 / none	0.0006
6.	Professionals	1 / none	0.0006
7.	Non-professionals (adults)	1 / none	0.0008
8.	General public	1 / none	0.0326
9.	General public	1 / none	0.0035
10.	General public	1 / none	0.0003
11.	General public	1 / none	Adult: 1.05 x 10^-7 Child: 1.97 x 10^-7 Toddler: 3.15 x 10^-7

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

The rationale for setting the AELs of the active substances propiconazole, IPBC and cypermethrin can be found in the respective CA reports. The reference doses and the relevant NOAEL-values from which they are derived are summarised in the following tables.

Propiconazole

Reference	Study	NOAEL	AF[1]	Correction for oral absorption	Value
AEL_{acute}	developmental toxicity rat study	30 mg/kg bw/day	100	No[2]	0.3 mg/kg bw/day
$AEL_{medium\text{-}term}$	2-generation rat study	8 mg/kg bw/day	100	No[2]	0.08 mg/kg bw/day
$AEL_{long\text{-}term}$	2 year rat study	3.6 mg/kg bw/day	100	No[2]	0.04 mg/kg bw/day

[1] compensating for inter/intra species variations

[2] IPBC: >90% oral absorption. Propiconazole: 86% oral absoption within 48 h.

IPBC

Reference	Study	NOAEL	AF[1]	Correction for oral absorption	Value
$AEL_{short\text{-}term}$	90-day gavage rat study	35 mg/kg bw/day	100	No[2]	0.35 mg/kg bw/day
$AEL_{long\text{-}term}$	2-year feeding rat study	20 mg/kg bw/day	100	No[2]	0.2 mg/kg bw/day

[1] compensating for inter/intra species variations

[2] IPBC: >90% oral absorption. Propiconazole: 86% oral absoption within 48 h.

Cypermethrin

Reference	Study	NOAEL	AF[1]	Correction for oral absorption	Value
$AEL_{short\text{-}term}$	acute delayed neurotoxicity rat study	20 mg/kg bw/day	100	44 %	0.088 mg/kg bw/day
$AEL_{medium\text{-}term}$	90-day feeding dog study	12.5 mg/kg bw/day	100	44 %	0.055 mg/kg bw/day
$AEL_{long\text{-}term}$	2-year feeding rat study	5 mg/kg bw/day	100	44 %	0.022 mg/kg bw/day

[1] compensating for inter/intra species variations

Specific reference value for groundwater
No specific reference value for groundwater was established. Thus, the European standard value of 0.1 µg/L for the maximum admissible concentration of pesticides in drinking water (Council Directive 98/83/EC) does apply.

Risk for industrial users

The risk characterisation of industrial dipping, flow coating and automated spraying is reported in the section for professional workers.

Risk for professional users

In the present risk assessments the systemic exposure estimates are compared to the corresponding AEL (exposure / AEL ratio = %AEL).

Propiconazole

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
[1] Brush application	1	3.6	0.04	0.0304	76	Yes
[1] Brush application	2	3.6	0.04	0.0038	9.5	Yes
[2] Cleaning the brush	1	3.6	0.04	0.0016	4	Yes
[3] Industrial dipping	1	3.6	0.04	0.463	1158	No
[3] Industrial dipping	2	3.6	0.04	0.0232	58.1	Yes
[4] Deluging/Flowcoat/Automated spraying	1	3.6	0.04	0.147	367	No
[4] Deluging/Flowcoat/Automated spraying	2	3.6	0.04	0.0249	62.3	Yes
[6] Chronic: sanding of treated wood, professional	1	3.6	0.04	0.0018	0.6	Yes

Combined scenarios

Scenarios combined	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
Scenarios [1,2,8]	1	3.6	0.04	0.0343	86	Yes
Scenarios [1,2,8]	1+2	3.6	0.04	0.0063	16	Yes

IPBC

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
[1] Brush application	1	20	0.2	0.0994	50	Yes
[1] Brush application	2	20	0.2	0.0107	5.4	Yes
[2] Cleaning the brush	1	20	0.2	0.0053	3	Yes
[3] Industrial dipping	1	20	0.2	1.544	772	No
[3] Industrial dipping	2	20	0.2	0.0775	38.7	Yes
[4] Deluging/Flowcoat/Automated spraying	1	20	0.2	0.489	244.4	No
[4] Deluging/Flowcoat/Automated spraying	2	20	0.2	0.0830	41.5	Yes
[6] Chronic: sanding of treated wood, professional	1	20	0.2	0.0053	2.7	Yes

Combined scenarios

Scenarios combined	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
Scenarios [1,2,8]	1	20	0.2	0.112	56	Yes
Scenarios [1,2,8]	1+2	20	0.2	0.019	9	Yes

Cypermethrin

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
[1] Brush application	1	5	0.022	0.0107	49	Yes
[1] Brush application	2	5	0.022	0.00107	4.9	Yes
[2] Cleaning the brush	1	5	0.022	0.0006	2.6	Yes
[3] Industrial dipping	1	5	0.022	0.167	760.3	No
[3] Industrial dipping	2	5	0.022	0.0084	38.2	Yes
[4] Deluging/Flowcoat/Automated spraying	1	5	0.022	0.0530	241	No
[4] Deluging/Flowcoat/Automated spraying	2	5	0.022	0.0090	41	Yes
[6] Chronic: sanding of treated wood, professional	1	5	0.022	0.0006	2.8	Yes

Combined scenarios

Scenarios combined	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
Scenarios [1,2,8]	1	5	0.022	0.0121	55	Yes
Scenarios [1,2,8]	1+2	5	0.022	0.0020	9	Yes

Local effects
The b.p. is not classified for local effects. Therefore, risk characterisation for local effects is not required

Conclusion
Professional users involved in wood treatment by brushing, dipping, flow-coating or automated spraying are not exposed to critical doses of either a.s.

Risk for non-professional users

Secondary exposure may occur in the course of sanding treated wood. This affects only adults.
Since the exposure due to amateur sanding is an acute scenario, the scenario is assessed using the respective short-term AEL.
The %AEL values are less than 100%.

Propiconazole

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
[5] Acute: sanding of treated wood, amateur	1	30	0.3	0.0016	0.5	Yes
[7] Acute, Adult handling treated wood after application	1	30	0.3	0.0023	0.8	Yes

IPBC

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
[5] Acute: sanding of treated wood, amateur	1	35	0.35	0.0051	1.5	Yes
[7] Acute, Adult handling treated wood after application	1	35	0.35	0.00764	2.2	Yes

Cypermethrin

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
[5] Acute: sanding of treated wood, amateur	1	20	0.088	0.0006	0.6	Yes
[7] Acute, Adult handling treated wood after application	1	20	0.088	0.00083	0.9	Yes

Combined scenarios
No combined exposure is foreseen.

Local effects
The b.p. is not classified for local effects. Therefore, risk characterisation for local effects is not required.

Risk for the general public

Propiconazole

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
[8] Acute secondary exposure, Toddler touching freshly treated surface	1	30	0.3	0.123	41	Yes
[9] Acute secondary exposure, Infant chewing on a treated piece of wood	1	30	0.3	0.0208	6.9	Yes
[10] Chronic secondary exposure, Child or toddler playing on playground structure treated with wood preservative	1	3.6	0.04	0.0009	2.3	Yes
[11] Inhalation of volatised residues, indoors, toddler*	1	3.6	0.04	0.000063	0.16	Yes

***Toddler as worst case assumption**

IPBC

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
[8] Acute secondary exposure, toddler touching freshly treated surface	1	35	0.35	0.279	80	Yes
[9] Acute secondary exposure, Infant chewing on a treated piece of wood	1	35	0.35	0.0242	6.9	Yes
[10] Chronic secondary exposure, Child or toddler playing on playground structure treated with wood preservative	1	20	0.2	0.0027	1.35	Yes
[11] Inhalation of volatised residues, indoors, toddler*	1	20	0.2	0.0042	2.1	Yes

***Toddler as worst case assumption**

Cypermethrin

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/ AEL** (%)	**Acceptable** (yes/no)
[8] Acute secondary exposure, Toddler touching freshly treated surface	1	20	0.088	0.033	37	Yes
[9] Acute secondary exposure, Toddler chewing on a treated piece of wood	1	20	0.088	0.0035	3.9	Yes
[10] Chronic secondary exposure, Child or toddler playing on playground structure treated with wood preservative	1	5	0.022	0.0003	1.36	Yes
[11] Inhalation of volatised residues, indoors, toddler*	1	5	0.022	3.15 x 10^-7	0.0014	Yes

***Toddler as worst case assumption**

Risk for consumers via residues in food

Food, drinking water or livestock exposure by propiconazole, IPBC and cypermethrin can be excluded when applied according to the recommended uses. Therefore no unacceptable risk to consumer health via residues in food needs to be expected.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

The methodology from BPR guidance Vol III Part B+C has been applied. Tier I has been presented in the sections above, and tier II by calculating the HQ Hazard Quotient (HQ), defined by the ratio of internal exposure and AEL, for each active substance and summing them to the hazard index, Hazard Index (HI), being the sum of the HQ's for each substance.

Scenarios	Propiconazole	IPBC	Cypermethrin	Conclusion
Scenario [1] Professional brushing				
Without PPE				
Tier I % AEL	76.0	49.7	48.6	Not acceptable
Tier II HQ	0.76	0.497	0.486	Not acceptable
	HI= 1.743			
With gloves and coated coveralls				
Tier I % AEL	9.50	5.35	4.86	Acceptable
Tier II HQ	0.0950	0.0535	0.0486	Acceptable
	HI = 0.197			
Scenario [2] Professional cleaning brush/roller				
Without PPE				
Tier I %AEL	3.99	2.66	2.62	Acceptable
Tier II HQ	0.0399	0.0266	0.0262	Acceptable
	HI= 0.093			
Scenario [3] Professional dipping				
Without PPE				
Tier I %AEL	1158.0	772.0	760.3	Not acceptable
Tier II HQ	11.58	7.72	7.603	Not acceptable
	HI=26.90			
Factor 4 reduction (HEEG opinion no. 18), Coated coveralls and gloves				
Tier I %AEL	58.1	38.7	38.2	Acceptable
Tier II HQ	0.581	0.387	0.382	Not acceptable
	HI= 1.350			
Scenario [4] Professionel deluging/flow-coat/auto spray				
Without PPE				
Tier I %AEL	366.7	244.4	240.7	Not acceptable
Tier II HQ	3.667	2.444	2.407	Not acceptable
	HI= 8.52			
With impearmeble coveralls, gloves and RPE				

Tier I %AEL	62.3	41.5	40.9	Acceptable
Tier II HQ	0.623	0.415	0.409	Not acceptable
Scenario [5] Non-professional sanding				
Without PPE				
Tier I %AEL	0.52	1.47	0.64	Acceptable
Tier II HQ	0.0052	0.0147	0.0064	Acceptable
	HI= 0.03			
Scenario [6] Professional sanding				
Without PPE				
Tier I %AEL	0.59	2.67	2.80	Acceptable
Tier II HQ	0.0059	0.0267	0.028	Acceptable
	HI= 0.060			
Scenario [7] Adult handling wood				
Without PPE				
Tier I %AEL	0.76	2.18	0.94	Acceptable
Tier II HQ	0.0076	0.0218	0.0094	Acceptable
	HI= 0.04			
Scenario [8] Toddler touching wet treated wood				
Without PPE				
Tier I %AEL	40.96	79.78	37.09	Not acceptable
Tier II HQ	0.4096	0.7978	0.3709	Not acceptable
	HI= 1.58			
Scenario [9] Infant chewing wood				
Without PPE				
Tier I %AEL	6.95	6.93	3.93	Acceptable
Tier II HQ	0.0695	0.0693	0.0393	Acceptable
	HI= 0.18			
Scenario [10] Toddler playing on playground structure				
Without PPE				
Tier I %AEL	2.28	1.35	1.36	Acceptable
Tier II HQ	0.0228	0.0135	0.0136	Acceptable
	HI=0.0499			
Scenario [11] Inhalation of volatised residues, indoors, toddler				
Without PPE				
Tier I %AEL	0.16	2.1	0.0014	Acceptable
Tier II HQ	0.0016	0.021	0.000014	Acceptable
	HI=0.0226			

An unacceptable risk has been identified for the combined scenario 3 for professionel dipping and deluging/flow-coat/auto spray, hence an assessment of combined exposure to mixture by dose addition is considered in the following. The assessment will be performed with the same parameters as in the first tier. Hazard Quotients (HQ) for propiconazole, IPBC, and cypermethrin will be used to calculate the Hazard Indez (HI) for b.p. Induline SW-900 IT according to the following:

HI= Σ HQ a.s.

TIER IIIa

Target organ/ Mode of Action	**Propiconazole** NOAEL (AEL)	**IPBC** NOAEL (AEL)	**Cypermethrin** NOAEL (AEL)
Liver (chronic)	10 mg/kg bw/day (0.1 mg/kg bw/day)	35 mg/kg bw/d (0.35 mg/kg bw/d)	5mg/kg bw/d (0.022 mg/kg bw/d)
Kidney (chronic)	N.A	35 mg/kg bw/d (0.35 mg/kg bw/d)	5 mg/kg bw/d (0.022 mg/kg bw/d)
Stomach (chronic)	N.A	20 mg/kg bw/d (0.2 mg/kg bw/d)	N.A.
Salvery glands (chronic)	N.A	20 mg/kg bw/d (0.2 mg/kg bw/d)	N.A.
Adreal glands (chronic)	3.6 mg/kg bw/day (0.04 mg/kg bw/day)	N.A.	N.A
Iron concentration ↓ (acute)	N.A	35 mg/kg bw/d (0.35 mg/kg bw/d)	N.A
Neurotoxicity (acute)	N.A.	N.A.	20 mg/kg bw/d (0.088 mg/kg bw/d)
Malformation (acute)	30 mg/kg bw/day (0.3 mg/kg bw/day)	N.A.	N.A.

TIER IIIb professionel dipping

Scenario [4]	**Propiconazole - HQ**	**IPBC - HQ**	**Cypermethrin -HQ**	**HI**	**Conclusion**
Liver	0.232	0.221	0.382	0.835	Acceptable
Kidney	N.A	0.221	0.382	0.603	Acceptable
Stomach	N.A	0.387	N.A	0.387	Acceptable
Salvery glands	N.A	0.387	N.A	0.387	Acceptable
Adreal glands	0.581	N.A	N.A	0.581	Acceptable
Neurobehavioural	N.A	N.A	N.A	0.095	Acceptable
Iron concentration ↓	N.A	0.221	N.A	0.221	Acceptable
Neurotoxicity	N.A	N.A	0.409	0.409	Acceptable

TIER IIIb professionel deluging/flowcoat/auto-spraying

Scenario [4]	Propiconazole - HQ	IPBC - HQ	Cypermethrin -HQ	HI	Conclusion
Liver	0.249	0.237	0.409	0.895	Acceptable
Kidney	N.A	0.199	0.343	0.542	Acceptable
Stomach	N.A	0.210	N.A	0.210	Acceptable
Salvery glands	N.A	0.210	N.A	0.210	Acceptable
Adreal glands	0.623	N.A	N.A	0.623	Acceptable
Neurobehavioural	N.A	N.A	N.A	0.627	Acceptable
Iron concentration ↓	N.A	0.210	N.A	0.210	Acceptable
Neurotoxicity	N.A	N.A	0.409	0.409	Acceptable

Conclusion
As a result of the assessment of the combined exposure for scenario 3, professionel dipping, by dose addition and considering the organ specific AELs in tier IIIB the risk for professionals using coated coveralls and gloves during dipping process is considered acceptable.
As a result of the assessment of the combined exposure for scenario 4, professionel deluging/flow-coat/auto spraying, by dose addition and considering the organ specific AELs in tier IIIB, the risk for professionals using impermeable coated coveralls, RPE (FFP1) and gloves during dipping /deluging/flow-coat/auto spray process can be considered acceptable.

For scenario 9 the AEL is reached and exceeded, where a toddler accidentally touches freshly treated wood. However, considering that Induline SW 900-IT is for professional use only and that it is reasonable to expect that toddlers should not be present at workplaces, and therefore will not have access/contact with freshly treated wood, the RMS is of the opinion that the following risk mitigation measure is be comprehensive and should be stated on the label: "Keep away from children during application and drying".
For the remaining scenarios the AEL is neither reached nor exceeded by the estimated exposures. Hence, it can be concluded that the use of wood treated with Induline SW-900 IT does not pose an acute or chronic health risk for humans.

2.2.7 Risk assessment for animal health

Food, drinking water or livestock exposure by propiconazole, IPBC and cypermethrin can be excluded when applied according to the recommended uses. Therefore no unacceptable risk to consumer health via residues in food needs to be expected.

2.2.8 Risk assessment for the environment

Induline SW-900 IT is a ready to use water based wood preservative. It contains the active substances propiconazole at 0.8% w/w, IPBC at 0.8% w/w and cypermethrin at 0.2% w/w. The product is used for wood outdoors in use classes 2 and 3. The modes of application include brushing, spraying in closed facilities, automated dipping and flow coating. Induline SW-900 IT should only be applied by professionals. Use of top coat is required.

The product Induline SW-900 IT is applied with the following application rates

- Use against fungi and insects, including termites – 150 mL/m²
- Use against fungi and insects, excluding termites – 100 mL/m²

The application rate of 150 mL/m^2 has been applied in the environmental risk assessment.

The environmental risk assessment focusses on the use in class 3 as relevant emissions to environmental compartments might occur when industrially and in-situ treated wooden structures are exposed to frequent wetting outdoors, or outdoor in-situ treatment leads to losses to soil and/or surface water during the application.

2.2.8.1 Effects assessment on the environment

The assessment is based on the active substances, including relevant metabolites, as there has not been submitted any effect studies regarding the product, and as there is no substance of concern in the product.

There has not been submitted any new data regarding the active substances. The PNEC values for IPBC/PBC have been taken from the Assessment Reportfor PT 8 and also including updates in the Assessment Report for PT13. For cypermethrin the PNEC values have been taken from the Assessment Report for PT8. However, a revised $PNEC_{soil}$, a new $PNEC_{water}$ and corresponding $PNEC_{sed}$ were decided on WG-IV-2016 when assessing the draft CAR for PT18; these new values are used in the present assessment. For propiconazole/1,2,4-triazole the PNEC values have been taken from the Assessment Report for propiconazole in PT9 (December 2013), because new data has been included compared to the Assessment Report for propiconazole in PT8 (December 2007).

Summary table on PNEC values for active ingredients			
Compartment	**PNEC**		
	Propiconazole	**IPBC**	**Cypermethrin**
STP	100.0 mg/L	0.44 mg/L	1.63 mg/L
Surface water	6.8 µg/L	0.50 µg/L	0.004 µg/L
Sediment	0.054 mg/kg wwt	Covered by surface water	0.005 mg/kg wwt
Soil	0.1 mg/kg wwt	0.0043 mg/kg wwt	0.07 mg/kg wwt

Summary table on PNEC values for metabolites			
Compartment	**PNEC**		
	1,2,4-triazole	**PBC**	**Iodine/Iodate/Iodide**
STP	Not relevant, 1,2,4-triazole is a soil metabolite	The one for IPBC is used as a worst case	2900 / - / - (µg iodine/L)
Surface water	Not relevant, 1,2,4-triazole is a soil metabolite	41.3 µg/L	0.59 / 58.5 / 0.83 (µg iodine/L)
Sediment	Not relevant, 1,2,4-triazole is a soil metabolite	Covered by surface water	Covered by surface water
Soil	0.01 mg/kg wwt	0.149 mg/kg wwt	0.0118 / 0.304 / 0.0043 (mg iodine/kg wwt)

Beside PBC another transformation product from IPBC is iodine which is not a xenobiotic substance but an essential dietary trace element and is ubiquitously present in the environment. Because of iodine's natural presence in the environment, background values have to be taken into account in the environmental risk assessment. An overview on the background concentrations of iodine in the relevant environmental compartments is given in the table below. This has been taken from the Assessment Report for iodine (PT1,3,4,22), December 2013.

Background concentration of iodine in the environment	
Compartment	**Background level (as iodine)**
Soil	Typically 0.5 - 20 mg/kg dw but with extremes up to 98 mg/kg Global mean value of 5 mg/kg
Groundwater	Mean concentration: 1 µg/l Range: < 1-70 µg/l with extremes up to 400 µg/l
Freshwater (river and lake)	0.5 - 20 µg/l

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

Harmonised environmental classification of the active substances
The environmental classification of the active substances are the following:

Harmonised env. classification for the active substances			
Substance	**Env. classification**	**M-factor**	**Concentration of a.s. in the product (%)**
Cypermethrin	H400, H410	M=1000[1]	0.2
IPBC	H400, H410	M(chronic)=1, M=10	0.8
Propiconazole	H400, H410	M=1 (chronic)[2] M=1 (acute)[3]	0.8

[1] According to the harmonised classification. (Note:In the Assessment Report for cypermethrin, PT18 (2016) a proposed classification is included as well (M=100 (acute), M=1000 (chronic))
[2] No m-factor was shown in the harmonised classification, but the m-fator noted here is based on NOEC (100d) = 0.068 mg/L
[3] No m-factor was shown in the harmonised classification, but the m-fator noted here is based on a based on LC_{50} = 0.51mg/L

Environmental classification of the substance(s) of concern
The biocidal product does not contain any other substances which influence the environmental classification.

Environmental classification of the biocidal product
Regarding the ecotoxicological properties, the formulation is very toxic to aquatic organisms. According to Regulation (EC) No 1272/2008 the product is classified as Aquatic Acute 1 (H400: Very toxic to aquatic life)/Aquatic Chronic 1 (H410: Very toxic to aquatic life with long lasting effects) with the signal word "Warning".

Foreseeable routes of entry into the environment on the basis of the use envisaged

Industrial application of the biocidal product and storage of the wood
Emissions to the environment can occur during industrial application of the wood preservative and subsequent storage of the treated structures. In general, emissions to sewage water during applications in joineries and carpentry shops 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. The revised ESD for PT 8 confirms that the release of wood preservatives from treatment installations to the drain connected to an STP is not permitted in EU countries. Nevertheless, this scenario is going to be considered in this risk assessment. The same applies to the storage of treated commodities. According to the revised ESD for PT 8 it can be assumed, that most storage places are sealed and run-off from storage places will be collected and disposed of safely.

Outdoor in-situ applications

Outdoor in-situ applications of Induline SW-900 IT by brushing will only be undertaken by professionals experienced in wood preservation. Product losses can occur due to spills and drips and will end-up in the soil (and groundwater) or the surface water (incl. sediment), if treated commodities are located close to surface water bodies.

In-service life

Emissions may take place due to leaching from constructions being in-situ treated with Induline SW-900 IT or built from industrially treated wood.

During the Arona Leaching Workshop in June 2005[5], it was agreed that a long-term assessment of in-service uses of wood should be carried out. For brushing treatments an assessment of cumulative leaching from treated wood in-service over a 5 year period was applied. For other superficially treated wood (e.g., by dipping or automated spraying) a service life of 15 years is applied. Hence, the assessment times are 30 days (TIME 1) for short term consideration and the respective service life for the longer time period (TIME 2). If a risk is identified for TIME 1, a further TIME 2 value of 365 days is calculated as well (not used for decision making, but sent to ECHA) as agreed by the Environment Working Group.

No special Emission Scenario for the industrial process of flow-coating is foreseen by the revised ESD for product type 8 however, this mode of application is covered by the scenarios under consideration.

Please refer to section "Fate and distribution in exposed environmental compartments" for further details.

Leaching behaviour

The leaching of propiconazole, IPBC/PBC and cypermethrin, a.i. of Induline SW-900 IT, from treated timber was investigated in a semi-field study (point 10.3: Wegner, R., 2011a, Wegner, R., 2011b; Wegner, R. 2013; Wegner, R., 2015a and Wegner R., 2015b) at Wald Campus of FH Eberswalde, Germany. The study is evaluated and leaching rates for the emission calculation have been calculated, see annex 3.6.1 for details. The leaching rates are based on a yearly rain amount of 700 mm. The data available comprises of nearly 5 years of leaching.

The test design is in accordance with NT Build 509, developed by the Nordic Innovation Centre (approved 2005-03). Application was superficial treatment (brushing), and the application was followed by spraying the topcoat (2 x 125 ml/m²) twice. The timber received an end sealant by brushing three times with a transparent silicon system.

For the risk assessment the leaching rates are shown below. The leaching rates are calculated based on the semi-field leaching study.

Cypermethrin could not be detected in any leachate above the limit of detection. To ensure that this was not due to stability or analytical problems, a stability study of cypermethrin

5 Report of the Arona Leaching Workshop (open session). Arona, Italy, 13 and 14 June 2005. European Commission Joint Research Centre, EUR 21878

in leachate was assessed (at different temperatures and +/- sunlight); reasonable recoveries were found. In addtion the validation of the determination of cypermethrin in leachate water samples was assessed, showing good recoveries (100.6% +/- 2.6 %). These studies did not give any reason to question the finding of no cypermethrin in the leachate.

For cypermethrin, the semi-field leaching test did not yield concentrations in the leachate above the limits of detection of 0.3 (before 22 Nov.2013) and 0.1 µg/L (after 22 Nov.2013). As a worst case assumption, concentrations of 0.3 µg/L (until 22 Nov 2013) and 0.1 (from 22 Nov. 2013 on), representing the limits of detection, were assumed for each sampling point. Taking the wooden surface and the volume of collected leachates in to consideration, concentrations in mg/m^2 wood and FLUX rates have been calculated.

Leaching rates for Induline SW-900 IT with assessment factors (mg/m^2/day)			
	TIME1 (30 days)	TIME 2 (5 years)	TIME2 (15 years)
IPBC/PBC	0.168	0.0146 (AF=1)*	0.0730 (AF=5)*
Propiconazole	0.0630	0.0205 (AF=1)*	0.103 (AF=5)*
Cypermethrin	4.32E-05**	4.32E-05**	4.32E-05**

*Assessment factors was chosen in accordance with the conclusions taken at the follow-up leaching workshop in Varese (held 12th June 2013). AF=1 (5 years) was chosen, because the current study comprised nearly 5 years of leaching.
** No assessment factors were assigned, since real leaching rates could not be derived from the test.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT8
Assessed scenarios	**Scenario 1: Industrial application**: • **A:** Automated dipping of wooden articles • **B:** Automated spraying of wooden articles **Scenario 2: Industrial storage:** • **A:** Automated dipping wooden articles • **B:** Automated spraying of wooden articles **Scenario 3: In-situ brush application by professional users:** • Bridge over pond • Timber cladded house **Scenario 4: In-service leaching from treated wood** • Bridge over pond • Timber cladded house • Noise barrier (This scenario is included in order to evaluate the possible risk for STP, though it is not

	mandatory according to the ESD)
ESD(s) used	ESD for PT 8: Revised Emission Scenario Document for Wood Preservatives (OECD series No. 2, 2013)
Approach	Scenarios 1-4: Average consumption
Distribution in the environment	Calculated based on Vol. IV, Part B
Groundwater simulation	For groundwater simulations, please refer to the modelling carried out in the Assessment Reports. In the Assessment Report for IPBC used as in-can preservative (Product Type 6), FOCUS-PEARL-3.3.3 groundwater modelling was carried out for the degradation product **iodine** using a worst-case scenario of 35 simultaneously treated wooden houses per hectare. In the Assessment Report for **propiconazole** used as wood preservative (Product Type 8), FOCUS-PEARL-3.3.3 groundwater modelling was carried out using a worst-case scenario of 35 simultaneously treated wooden houses per hectare. In the Assessment Report for propiconazole used as film perservative (PT 7) FOCUS-PEARL 4.4.4 revised groundwater modelling for three different scenarios was carried out for the degradation product **1,2,4-triazole** because of the new half-life value of the metabolite in soil. In the modelling the house number of 16 and the fraction of house surface exposed to weather (0.5) were applied according to the revised OECD ESD for wood preservatives
Confidential Annexes	No
Life cycle steps assessed	Scenarios 1-4 Production: No Formulation No Use: Yes Service life: Yes
Remarks	No remarks

Emission estimation

Input parameters for calculating the local emission		
Input	**Value**	**Unit**
Scenario 1B: Automated spraying of wooden articles **Scenario 2B:** Automated spraying of wooden articles **Scenario 3:** Bridge over pond, Timber cladded house **Scenario 4:** Bridge over pond, Timber cladded house, Noise barrier		
Application rate of biocidal product		
	150*	mL/m^2
Concentration of active substance in the product		
Propiconazole	1212	mg/m²
IPBC	1212	mg/m²
Cypermethrin	303	mg/m²
Scenario 1A: Automated dipping of wooden articles **Scenario 2A:** Automated dipping of wooden articles		
Application rate of biocidal product		
	6060	g/m^3
Concentration of active substance in the product		
Propiconazole	48.48	g/m^3
IPBC	48.48	g/m^3
Cypermethrin	12.12	g/m^3

* corresponding to 151.5 g/m^2 at maximum considering a product density of 1.01 g/mL at 20°C

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway							
Scenario		**Air**	**STP**	**Soil**	**Ground-water**	**Surface water**	**Biota**
1:Industrial application	Dipping, spraying	(+)	+	-	-	+	+/(+)[2]
2:Storage	Dipping, spraying	(+)	-	+	(+)	+	+/(+)[2]
3:In-situ application	Brushing: Bridge over pond	(+)	-	-	-	+	(+)
	Brushing: House	(+)	-	+	(+)	-	(+)
4:Service life	Bridge over pond	(+)	-	-	-	+	(+)
	House	(+)	-	+	+/(+)[1]	-	(+)
	Noise barrier	(+)	+	+	(+)	+	(+)

[1] For iodine (metabolite of IPBC) and 1,2,4-triazole (metabolite of propiconazole) a groundwater assessment has been made, for all other compounds this is not relevant

[2] For cypermethrin an assessment for secondary poisioning has been made, for all other compound this is not relevant

The compartments marked with '+' are those of concern for which predicted emissions and local concentrations have been determined for the active substances as well as the metabolites. The compartments marked with '(+)' are those that might in principle be relevant, but not in the case of IPBC/PBC, propiconazole and/or cypermethrin because of their substance-specific properties.

In the table below the relevant parameters from the active substance dossiers of all three active substances are presented. For a general assessment of the environmental fate and behaviour of all three active substances refer to theactive substance dossier.

Input parameters (only set values) for calculating the fate and distribution in the environment				
Input	**Unit**	**Propiconazole**	**IPBC**	**Cypermethrin**
Molecular weight	g/mol	342.2	281.1	416.3
Vapour pressure	Pa	5.6E-05 (25°C)	2.36-4.5E-03 (25°C)	6E-07 (25°C)
Water solubility	mg/l	100 (pH 6.9, 20°C)	168 (pH 7, 20°C)	4E-03**
Log Octanol/water	Log 10	3.72 (20°C)	2.81 (25°C)	5.45

partition coefficient				
Organic carbon/water partition coefficient (Koc)	L/kg	944	113.25 198.1*	575000
Henry's Law Constant	$Pa/m^3/mol$	9.2E-05	3.38-6.45E-03 (25°C)	2.4E-02 (20°C)
Biodegradability		Not readily	Not readily	Not readily
Inherently biodegradable		-	primary biodegradable	No
DT_{50} for biodegradation in surface water	d (12ºC)	DT_{50} water: 6.4 (*for calculation of PEC_{sw}*) DT_{50}: 1206 (*for calculation of PEC_{sed}*)	0.129 31.2*	DT_{50} water: 0.95 (*for calculation of PEC_{sw}*) DT_{50}: 18.5 (*whole system, for calculation of PEC_{sed}*)
DT_{50} for hydrolysis in surface water	d (12ºC)	stable	not relevant under environ-mental conditions	DT_{50} (12°C) 98.9 (pH 7)
DT_{50} for photolysis in surface water	d	stable	Stable	DT_{50}:12.4–14.8 (pH 4)
DT_{50} for degradation in soil	d (12ºC)	82*** (geomean) 115.5*	0.196 9.5*	17.2 (geomean)
DT_{50} for degradation in air	Hr	10.2 - 42	15 (24-h day)	17.99 (OH radical reaction) 49 (ozone reaction)
Distribution in STP		90.0% water 10.0% sludge	IPBC is complete-ly degraded into PBC in the STP PBC****: 0.935% air 96.7% water 2.41 sludge	9.15% water***** 90.9% sludge
BCF fish	L/kg	180	-	373.4 (exp.) 417 L/kg(QSAR)

- not relevant
** value for degradation product (PBC/1,2,4-triazole)*
***value taken for the risk assessment, the measured value is < 0.009 mg/L*
**** From doc IIa of the CAR for propiconazole in PT9 (December 2013). This value has been checked with Finland (eCA for propiconazole).*
***** Results taken from the CAR for PT6 (document IIB, p. 111)*
****** Calculated by EUSES 2.12*

Relevant degradation products

For **cypermethrin**, the major degradation pathway in water, soil, plants, insects, birds and fish consists in the cleavage of cypermethrin into a cyclopropane carbonic acid and dibenzyl (3-phenoxybenzoic acid) moiety (3PBA). In these degradation studies, DCVC acid ((2,2-dichlorovinyl)- 2,2- dimethylcyclopropanecarboxylic acid) accounted for up to 40% of the applied dose in water, 17.4% in soil and 33.4% in plants (as conjugate in this latter

case). In the assessment report (doc IIa) it is considered that its toxicity is covered by the studies on cypermethrin with such high concentrations of DCVC acid rapidly found in the various metabolism studies.

As the Assessment Report for cypermethrin does neither contain further environmental risk assessment for the metabolites nor a request for submitting it at product authorisation level; an environmental risk assessment for the metabolites is therefore not considered to be relevant.

Degradation of **IPBC** yields the primary degradate propargyl butyl carbamate (PBC) as well as iodine. PEC values have been calculated for PBC when relevant. Regarding iodine, IPBC emissions into the environmental compartments surface water and soil, respectively, have been converted to iodine (applying a molecular weight correction) and concentrations have been calculated when relevant. The resulting iodine concentrations have been compared to background concentrations found in the environment. Please refer to annex 3.6.3 for details.

The decomposition of **propiconazole** in aerobic soil proceeds via the formation of CGA 118245 and 1,2,4-triazole (both occurring at amounts > 10%). CGA 118 245 is degraded in soil faster than propiconazole. According to the CAR (PT7) PECs of this compound is not assumed to exceed PEC of propiconazole in soil and therefore PEC of propiconazole in soil could be used as the worst case assumption in the risk assessment of this degradation product.

During the work with the CA report of propiconazole in PT7 1,2,4-triazole's bi-phasic behaviour in soils (fast and slow degradation phases) the DT_{50} is 1.68 d for the fast fraction (48.9%) and 60.5 days for the slow fraction (51.1%) was discussed. It was decided by the BPC Working Group on environmental issues that instead of the previous value of 12 days the DT_{50} of 60.5 days (converted to 115.5 d at 12 ºC) from the slow fraction, being the worst-case, should be used in PEC soil calculations. For groundwater assessment a bi-phasic approach including a fast phase as well as a slow phase degradation should be employed according to FOCUS guidance. Hence, PEC_{soil} has been calculated and a groundwater assessment has been performed.

Calculated PEC values

The Predicted Environmental Concentration (PEC) calculations follow the available guidance documents (Revised Emission Scenario Document for Wood Preservatives (OECD, 2013); Guidance on the BPR: Volume IV Environment, Part B Risk Assessment (active substances) (2015)).

The PECs for cypermethin, IPBC, and propiconazole (including relevant metabolites when relevant) in the environmental compartments derived in the following sections are calculated on the basis of the emission scenarios available for Product Type 8, taking into account degradation processes and/or dilution (where applicable). The PEC values presented in the following tables are rounded values from EXCEL spread sheets. The calculations for the different PECs within EXCEL are always carried out with unrounded values.

Cypermethrin	**PEC_{STP} (µg/L)**	**$PEC_{surface\ water}$ (µg/L)**	**$PEC_{sediment}$ (mg/kg wwt)**	**PEC_{soil} (mg/kg wwt)**
Industrial application				
Spraying (small plant)	2.77E-03	1.49E-04	1.86E-03	-
Spraying (big plant)	2.77E-02	1.49E-03	1.86E-02	-
Dipping	5.54E-03	2.98E-04	3.72E-03	-
Industrial storage				
Spraying (30 days – small plant)	-	3.58E-07	4.47E-06	2.91E-06
Spraying (20 years – small plant)	-	3.58E-07	4.47E-06	6.90E-06
Spraying (30 days – big plant)	-	3.58E-06	4.47E-05	2.91E-05
Spraying (20 years – big plant)	-	3.58E-06	4.47E-05	6.90E-05
Dipping (30 days)	-	3.17E-06	3.96E-05	2.91E-06
Dipping (20 years)	-	3.17E-06	3.96E-05	6.90E-06
In-situ treatments				
House (prof. - day 0) brush	-	-	-	5.14E-02
Bridge over pond (prof. - day 0) brush	-	9.09E-02	-	-
In-service				
Noise Barrier (30 days)	4.15E-06	2.23E-07	2.79E-06	9.53E-07
Noise Barrier (15 years)	4.15E-06	2.23E-07	2.79E-06	2.26E-06
House (30 days)	-	-	-	2.55E-06
House (5 years)	-	-	-	6.01E-06
House (15 years)	-	-	-	6.05E-06
Bridge over pond (30 days)	-	5.64E-07	5.76E-05	-
Bridge over pond (5 years)	-	5.90E-07	1.42E-04	-
Bridge over pond (15 years)	-	5.91E-07	4.31E-04	-
Blue colored cells: Cells including degradation ($PEC_{sediment}$ is without degradation, but calculated based on $PEC_{surfacewater}$ with degradation included)				

IPBC/PBC	PEC_{STP} (µg/L)	$PEC_{surface\ water}$ (µg/L)	PEC_{soil} (mg/kg wwt)
Industrial application			
Spraying (small plant)	36.4	1.9 (*)	-
Spraying (big plant)	3.64E+02	19.4 (*)	-
Dipping	72.7	3.9 (*)	-
Industrial storage			
Spraying (30 days – small plant)	-	4.28E-04	3.05E-04
Spraying (20 years – small plant)	-	4.28E-04	3.07E-04
Spraying (30 days – big plant)	-	4.28E-03	3.05E-03
Spraying (20 years– big plant)	-	4.28E-03	3.07E-03
Dipping (30 days)	-	3.79E-03	3.05E-04
Dipping (20 years)	-	3.79E-03	3.07E-04
In-situ treatments			
House (prof. - day 0) brush	-	-	0.21
Bridge over pond (prof. - day 0) brush	-	0.36	-
In-service			
Noise Barrier (30 days)	0.18	9.42E-03 (*)	9.97E-05
Noise Barrier (15 years)	7.67E-02	4.09E-03 (*)	4.37E-05
House (30 days)	-		2.66E-04
House (5 years)	-		2.34E-05
House (15 years)			1.17E-04
Bridge over pond (30 days)	-	3.11E-04	
Bridge over pond (5 years)	-	3.54E-03 (*)	
Bridge over pond (15 years)		1.80E-02 (*)	

Blue colored cells: Cells including degradation ($PEC_{sediment}$ is without degradation, but calculated based on $PEC_{surfacewater}$ with degradation included)

(*) PBC

Propiconazole	PEC_{STP} (µg/L)	$PEC_{surface\ water}$ (µg/L)	$PEC_{sediment}$ (mg/kg wwt)	PEC_{soil} (mg/kg wwt)
Industrial application				
Spraying (small plant)	16.3	1.6	3.46E-02	-
Spraying (big plant)	162.7	16.2	0.35	-
Dipping	32.5	3.2	6.92E-02	-
Industrial storage				
Spraying (30 days – small plant)	-	5.28E-04	1.12E-05	5.63E-03
Spraying (20 years – small plant)	-	5.28E-04	1.12E-05	4.71E-02
Spraying (30 days – big plant)	-	5.28E-03	1.12E-04	5.63E-02
Spraying (20 years – big plant)	-	5.28E-03	1.12E-04	0.47
Dipping (30 days)	-	4.67E-03	9.96E-05	5.63E-03
Dipping (20 years)	-	4.67E-03	9.96E-05	4.71E-02
In-situ treatments				
House (prof. - day 0) brush	-	-	-	0.21
Bridge over pond (prof. - day 0) brush	-	0.36	-	-
In-service				
Noise Barrier (30 days)	5.92E-02	5.91E-03	1.26E-04	1.84E-03
Noise Barrier (15 years)	9.65E-02	9.64E-03	2.05E-04	2.52E-02
House (30 days)	-	-	-	4.92E-03
House (5 years)	-	-	-	1.32E-02
House (15 years)	-	-	-	6.74E-02
Bridge over pond (30 days)	-	4.09E-03	2.00E-04	-
Bridge over pond (5 years)	-	1.89E-03	2.86E-03	-
Bridge over pond (15 years)		9.47E-03	2.64E-02	

Blue colored cells: Cells including degradation ($PEC_{sediment}$ is without degradation, but calculated based on $PEC_{surfacewater}$ with degradation included)

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).

In the Assessment Report for **IPBC**, the influent concentration is considered to be relevant in order to assess predicted environmental concentrations in sewage treatment plants. Further emissions to surface water are estimated from PBC concentrations in the STP effluent. For **propiconazole** and **cypermethrin**, the STP effluent concentrations represent predicted environmental concentrations for this compartment.

A risk assessment for soils being target for propiconazole, IPBC or cypermethrin emissions via sewage sludge is not considered to be necessary as it is covered by the direct soil emission assessed in the house scenario.

PEC surface water
For industrial applications the removal via STP is taken into account. For automated enclosed spraying the calculations are carried out for two plants of different sizes. Refinement of the calculated concentrations due to adsorption of the active substances on suspended matter in the surface water (according to equation 45, p. 77, Vol IV, Part B) was done.

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

During outdoor service life PECs for industrial pre-treated wood and in-situ treated wood are calculated. The target compartments are pond water (scenario "bridge over pond") and surface water (scenario "noise barrier"). Further refinements of the initial PECs for surface water were done (only for direct emissions to the surface water) taking into account degradation of the active ingredients.

For the **iodine** risk assessment the bridge over pond scenario has been chosen as a worst case since it represents an intake into a static water body. Iodine as an inorganic compound is not biodegradable so it was assumed, that the whole IPBC emissions might accumulate. Please refer to Annex 3.6.3 for the detailed calculation. For a 15 years service life period a this results in an concentration of 1.79 µg/L iodine (3.98 µg/L IPBC). This value is well within the background concentration of iodine of 0.5 – 20 µg/L.

PEC sediment
In the Assessment Report for **IPBC** the reported PNEC for the sediment was derived using the equilibrium method. So the risk of the sediment compartment is the same as that assessed for surface water. Therefore, the calculation of $PEC_{sediment}$ values is not considered necessary.

For **propiconazole** and **cypermethrin**, $PEC_{sediment}$ values are calculated for relevant application and storage scenarios and for the "bridge over pond" scenario and the "noise barrier" scenario taking into account degradation/dissipation in the water phase. Unless otherwise noted, the sediment values are based on surface water values including degradation.

PEC soil
Emissions into soil are assumed to occur during outdoor storage of the treated wood. It is assumed in the OECD models that emissions from the storage place reach the soil directly. For use class 3 outdoor service life the OECD models "timber house" and "noise barrier" are used. Further refinements of the initial PECs for soil were done taking into account degradation of the active ingredients (OECD 2013; eq. 3.7 and 3.8).

For soil, the PECs for **1,2,4-triazole** are calculated on similar basis, only for the worst case exposure situation of soil (house), taking into account the degradation processes of 1,2,4-triazole, using the rate constant from the slow phase of biphasic degradation at 12 C (k=0.006) as described in the CAR from PT 7.

In the calculations, an instant transformation of propiconazole to 1,2,4-triazole upon release to the soil has been assumed (mw corrected); this is a very worst case, as the DT_{50} for propiconazole in soil is 82 days. For Tier 1 a 100 % transformation of

propiconazole to 1,2,4-triazole is assumed. In the CAR from PT 7 a $F_{peak,occurrence}$ of 43.2% is found after 120 days; hence for refinement in Tier 2 a 43.2% transformation is used.

1,2,4-triazole (soil)				
	Tier 1 (100% transformation)		Tier 2 (43.2% transformation)	
PEC_{soil}	**PEC (mg/kg ww)**	**PEC/PNEC**	**PEC (mg/kg ww)**	**PEC/PNEC**
Application	4.11E-2	4.11	1.78E-2	**1.78**
In service, house	-	-	-	-
30 days	1.01E-3	0.10	4.35E-4	4.35E-2
5 year	3.61E-3	0.36	1.56E-3	0.16
15 years	1.88E-2	1.88	8.09E-3	0.81

With reference to the **iodine** risk assessment for soil, the same procedure as for surface water has been followed, taking the house scenario and a service life of 15 years. Accumulated IPBC emissions over 15 years yields 1.03 mg iodine/kg wwt (2.6 mg IPBC /kg dwt). This value is well within the background concentration of 0.5 – 20 mg/kg dwt. Please refer to Annex 3.6.3 for further details.

PEC groundwater

The Assessment Report for **cypermethrin** does neither contain a calculation of ground/porewater concentrations nor a request for submitting them at product authorisation level. Since the active substance is strongly adsorbed to soil as well as sediment, a transport to aquifers is not indicated. A calculation of groundwater concentrations is therefore not considered to be relevant.

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. Thus, the calculation of potential concentrations in groundwater is not considered relevant for the proposed used pattern (cf. Assessment Report for IPBC).

However, **iodine** might reach groundwater. The FOCUS-PEARL-3.3.3 groundwater modelling carried out in the Assessment Report for IBPC used as in-can preservative (Product Type 6, 2013) covers the level of IPBC releasd from Induline SW-900 IT. The calculated concentrations of iodide and iodate in the leachate are well within the background concentration. Please refer to annex 3.6.3 for further details.

In the Assessment Report for **propiconazole** used as wood preservative (Product Type 8), FOCUS-PEARL-3.3.3 groundwater modelling was carried out using a worst-case scenario of 35 simultaneously treated wooden houses per hectare. The calculations were undertaken for a propiconazole release of 1000 mg/m^2 treated wood over a period of 5 years. The 80th percentile leachate concentrations at 1 m soil depth were lower than the legal Drinking Water Limit of 0.1 µg/l in all FOCUS PEARL scenarios. Thus for the intended use of Induline SW-900 IT groundwater concentrations below 0.1 µg/l can be expected since

the estimated maximum total propiconazole release is less than that investigated in the Assessment Report.

In the Assessment Report for propiconazole used as film perservative (PT 7) FOCUS-PEARL 4.4.4 revised groundwater modelling for three different scenarios was carried out for the degradation product **1,2,4-triazole** because of the new half-life value of the metabolite in soil. In the modelling the house number of 16 and the fraction of house surface exposed to weather (0.5) were applied according to the revised OECD ESD for wood preservatives (2013). The leaching rate input in Scenario 2b is comparable to the one for Induline SW-900 IT (see table below), and the conclusions from Scenario 2b can thus be used for Induline SW-900 IT too. The evaluated groundwater concentrations of 1,2,4-triazole based on the available field-leaching data are considerably below the legal drinking water limit of 0.1 µg/l.

Comparison of input values		
Values used for	FOCUS-PEARL 4.4.4 revised groundwater modelling for 1,2,4-triazole, **Scenario 2b (CAR PT 7)**	**Induline SW-900 IT**
Propiconazole in paint (% w/w)	0.3	0.8
Paint application rate (g/m^2)	250	151.5
Total propiconazole (g/m^2)	0.75	1.21
Leaching rate, 5 y ($mg/m^2/day$)	**0.0201**	**0.0205**

PEC for atmosphere
The vapour pressure of **cypermethrin** is very low (6×10^{-7} Pa at 25°C) and emissions to the air compartment are therefore of no relevance. Furthermore, the results of an EPIWIN calculation indicate that the compound is prone to photolysis and will not be accumulated. The assessment report for cypermethrin contains a calculation of PEC values for air, yielding very low concentrations ($< 10^{-6}$ mg/m^3). Since the concentration and application amount for Cypermethrin in Induline SW-900 IT is lower than those used in the Assessment Report, potential air concentrations will even be lower in this case. A risk assessment for the atmosphere is therefore of no relevance.

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

Based on the vapour pressure (5.6×10^{-5} Pa×m^3 at 25°C) and the Henry`s Law constant (9.5×10^{-5} Pa×m³/mol), volatilisation of **propiconazole** can be regarded as negligible.

Therefore, the 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.

Primary and secondary poisoning

Primary poisoning
The product is a wood preservative (Product Type 8). The product is ready to use and is applied in liquid form by brushing, spraying in closed facilities, dipping and flow coating. A direct uptake of the product is unlikely.

Secondary poisoning
According to Vol. IV, Part B 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 indicating that the risk for bioaccumulation of the substance to man via the food chain is low.

Although the log K_{ow} of **propiconazole** (log K_{ow} = 3.7) reveals a slight potential for bioaccumulation, the assessment of secondary poisoning is not requested according to the active substance Assessment Report for the use of propiconazole in wood preservatives.

According to the assessment report for **cypermethrin** a risk for secondary poisoning will have to be performed at product authorisation based on the formulation and the envisaged used. The detailed calculations of $PEC_{oral,\ predator}$ can be found in annex 3.6.2.

For assessment via the aquatic food chain, the PEC_{water} value from the scenario "Industrial application, spraying (big plant)" has been used (1.49E-03 µg/L), as this was the second largest (the highest concentration from the scenario "In situ treatment, bridge over pond" is not used, as this scenario is not a part of the final authorisation). This results in a maximal $PEC_{oral,predator}$ (water) of 1.71E-01 mg/kg wet fish.

For assessment via the terrestrial food chain the PEC soil value from the scenario "Industrial storage, big plant, 15 years" has been used as this was the second largest (the highest concentration from the scenario "In situ treatment, house" is not used, this scenario is not a part of the final authorisation). This results in a $PEC_{oral,predator}$ (soil)=3.3E- 05 mg/kg wet earthworm.

All values and risk quotients are summarized below. Risk characterization is based on the max. calculated PEC values for soil and water.

Cypermethrin Secondary Poisoning			
Model Scenario	**Time 3 (day 1825)**		
	PEC [mg/kg_{wwt}]	**PNEC *** [mg/kg_{food}]	$\frac{PEC}{PNEC}$
Scenario related to brushing (UC 3)			
Aquatic food chain			
Birds	1.71E-01	33	5.18E-03
Mammals		3.3	5.18E-02
Terrestrial food chain			
Birds	3.28E-05	33	9.9E-07
Mammals		3.3	9.9E-06

* PNEC values for birds and mammals from the CAR of Cypermethrin (2013).

According to the calculated risk quotients above, the risk of Cypermethrin for birds and mammals via secondary poisoning is acceptable.

2.2.8.3 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. 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. As stated in section 2.2.8.2, air is not regarded as compartment of concern for this product with the proposed use patterns; also, there are no concerns of secondary poisoning or for the groundwater compartment.

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

Calculated PEC/PNEC values are summarised below.

Cypermethrin	PEC/ $PNEC_{STP}$	PEC/ $PNEC_{surface\ water}$	PEC/ $PNEC_{sediment}$	PEC/ $PNEC_{soil}$
Industrial application				
Spraying (small plant)	1.70E-03	0.04	0.37	-
Spraying (big plant)	1.70E-02	0.37	**3.72**	-
Dipping	3.40E-03	0.07	0.74	-
Industrial storage				
Spraying (30 days – small plant)	-	8.94E-05	8.94E-04	4.16E-05
Spraying (20 years– small plant)	-	8.94E-05	8.94E-04	9.86E-05
Spraying (30 days – big plant)	-	8.94E-04	8.94E-03	4.16E-04
Spraying (20 years – big plant)	-	8.94E-04	8.94E-03	9.86E-04
Dipping (30 days)	-	7.92E-04	7.92E-03	4.16E-05
Dipping (20 years)	-	7.92E-04	7.92E-03	9.86E-05
In-situ treatments				
House (prof. - day 0) brush	-	-	-	0.73
Bridge over pond (prof. - day 0) brush	-	**22.725**	-	-
In-service				
Noise Barrier (30 days)	2.55E-06	5.57E-05	5.57E-04	1.36E-05
Noise Barrier (15 years)	2.55E-06	5.57E-05	5.57E-04	3.23E-05
House (30 days)	-	-	-	3.64E-05
House (5 years)	-	-	-	8.59E-05
House (15 years)		-	-	8.64E-05
Bridge over pond (30 days)	-	1.41E-04	1.15E-02	-
Bridge over pond (5 years)	-	1.48E-04	2.84E-02	-
Bridge over pond (15 years)		1.48E-04	8.61E-02	
Blue colored cells: Cells including degradation ($PEC_{sediment}$ is without degradation. but calculated based on $PEC_{surfacewater}$ with degradation included)				

IPBC/PBC	PEC/ $PNEC_{STP}$	PEC/ $PNEC_{surface\ water}$	PEC/ $PNEC_{soil}$
Industrial application			
Spraying (small plant)	8.26E-02	4.70E-02 (*)	-
Spraying (big plant)	0.83	0.47 (*)	-
Dipping	0.17	9.40E-02 (*)	-
Industrial storage			
Spraying (30 days – small plant)	-	8.56E-04	7.02E-02
Spraying (20 years – small plant)	-	8.56E-04	7.08E-02
Spraying (30 days – big plant)	-	8.56E-03	0.70
Spraying (20 years – big plant)	-	8.56E-03	0.71
Dipping (30 days)	-	7.58E-03	7.02E-02
Dipping (20 years)	-	7.58E-03	7.08E-02
In-situ treatments			
House (prof. - 0 day) brush	-	-	**47.4**
Bridge over pond (prof. - 0 day) brush	-	0.73	-
In-service			
Noise Barrier (30 days)	4.01E-04	2.28E-04 (*)	2.30E-02
Noise Barrier (15 years)	1.74E-04	9.91E-05 (*)	1.01E-02
House (30 days)	-	-	6.14E-02
House (5 years)	-	-	5.39E-03
House (15 years)	-	-	2.69E-02
Bridge over pond (30 days)	-	6.23E-04	-
Bridge over pond (5 years)	-	8.57E-05 (*)	-
Bridge over pond (15 years)	-	4.36E-04 (*)	-

Blue colored cells: Cells including degradation ($PEC_{sediment}$ is without degradation. but calculated based on $PEC_{surfacewater}$ with degradation included)

(*) PBC

Propiconazole	**PEC/ PNEC$_{STP}$**	**PEC/ PNEC$_{surface\ water}$**	**PEC/ PNEC$_{sediment}$**	**PEC/ PNEC$_{soil}$**
Industrial application				
Spraying (small plant)	1.63E-04	0.24	0.64	-
Spraying (big plant)	1.63E-03	**2.39**	**6.41**	-
Dipping	3.25E-04	0.48	**1.28**	-
Industrial storage				
Spraying (30 days – small plant)	-	7.76E-05	2.08E-04	5.63E-02
Spraying (20 years – small plant)	-	7.76E-05	2.08E-04	0.47
Spraying (30 days – big plant)	-	7.76E-04	2.08E-03	0.56
Spraying (20 years – big plant)	-	7.76E-04	2.08E-03	**4.71**
Dipping (30 days)	-	6.87E-04	1.84E-03	5.63E-02
Dipping (20 years)	-	6.87E-04	1.84E-03	0.47
In-situ treatments				
House (prof. - day 0) brush	-	-	-	**2.06**
Bridge over pond (prof. - day 0) brush	-	5.35E-02	-	-
In-service				
Noise Barrier (30 days)	5.92E-07	8.69E-04	2.33E-03	1.84E-02
Noise Barrier (15 years)	9.65E-07	1.42E-03	3.80E-03	0.25
House (30 days)	-	-	-	4.92E-02
House (5 years)	-	-	-	1.32E-01
House (15 years)	-	-	-	0.67
Bridge over pond (30 days)	-	6.02E-04	3.70E-03	-
Bridge over pond (5 years)	-	2.78E-04	5.31E-02	-
Bridge over pond (15 years)	-	1.39E-03	0.49	-
Blue colored cells: Cells including degradation (PEC$_{sediment}$ is without degradation. but calculated based on PEC$_{surfacewater}$ with degradation included)				

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 = Σ (PEC/PNEC)individual substances] for each environmental compartment

(PEC/PNEC)product values for each environmental compartment of concern are summarised below.

Induline SW-900 IT	PEC/ $PNEC_{STP}$	PEC/ $PNEC_{surface\ water}$	PEC/ $PNEC_{sediment}$	PEC/ $PNEC_{soil}$
Industrial application				
Spraying (small plant)	0.08	0.32 (*)	1.01	-
Spraying (big plant)	0.84	**3.23 (*)**	**10.13**	-
Dipping	0.17	0.65 (*)	**2.03**	-
Industrial storage				
Spraying (30 days – small plant)	-	1.02E-03	1.10E-03	0.13
Spraying (20 years – small plant)	-	1.02E-03	1.10E-03	0.54
Spraying (30 days – big plant)	-	1.02E-02	1.10E-02	**1.26**
Spraying (20 years – big plant)	-	1.02E-02	1.10E-02	**5.42**
Dipping (30 days)	-	9.06E-03	9.77E-03	0.13
Dipping (20 years)	-	9.06E-03	9.77E-03	0.54
In-situ treatments				
House (prof. - day 0) brush	-	-	-	**50.18 (49.9)**
Bridge over pond (prof. - day 0) brush	-	**23.51**	-	-
In-service				
Noise Barrier (30 days)	4.05E-04	1.15E-03 (*)	2.89E-03	4.14E-02
Noise Barrier (15 years)	1.78E-04	1.57E-03 (*)	4.36E-03	0.26
House (30 days)	-	-	-	0.11 (0.11)
House (5 years)	-	-	-	0.14 (0.17)
House (15 years)	-	-	-	0.70 (0.84)
Bridge over pond (30 days)	-	1.37E-03	1.52E-02	-
Bridge over pond (5 years)	-	5.11E-04 (*)	8.15E-02	-
Bridge over pond (15 years)	-	1.98E-03 (*)	0.58	-

Blue colored cells: Cells including degradation ($PEC_{sediment}$ is without degradation, but calculated based on $PEC_{surfacewater}$ with degradation included)

(*) PBC values included in stead of IPBC

Results in backets: 1,2,4-triazole values included in stead of propiconazole

Sewage treatment plant (STP)

The requirements for acceptable risk according to Vol. IV, part B are met for all scenarios and each single substance as well as considering ecotoxicity addition of propiconazole, IPBC and cypermethrin.

Aquatic compartment

The storage and in-service scenarios yield PEC/PNEC ratios below one for all scenarios and the single substances as well as the mixture of active substances, indicating acceptable risk for surface water organisms.

The industrial processes of spraying in large plants however provide elevated PEC/PNEC ratios for propiconazole and hence also for the mixture of the three active substances. The

revised ESD for PT 8 confirms that the release of wood preservatives from treatment installations to the drain connected to an STP is not permitted in EU countries, and the calculation was only performed for completeness.

A risk to surface water could also be identified for in-situ applications for the bridge over pond scenario. This risk is due to the high toxicity of cypermethrin to aquatic organisms. To avoid unacceptable losses to surface water (streams, lakes etc.), do not apply near bodies of surface water or in the area of water protection zones.

Sediment

For the sediment, the industrial processes of spraying in large plants and dipping provided elevated PEC/PNEC ratios as for surface water. The same risk mitigation measures as for the surface water apply and a risk for sediment organisms due to the use of Induline SW-900 IT is not indicated.

Terrestrial compartment

For the soil, the industrial storage scenario provided elevated PEC/PNEC ratios. According to the revised ESD for PT 8 it can be assumed, that most storage places are sealed and run-off from storage places will be collected and disposed of safely – this is not taken into account in the calculations. To avoid losses to the soil the freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing or both to prevent direct losses to soil, sewer or water and that any losses of the product should be collected for reuse or disposal..

An unacceptable risk for soil organisms could be identified for in-situ applications for the house scenario. To avoid unacceptable release to soil during application in-situ, the ground must be covered and any spillage should be collected.

In summary, a risk for soil organisms due to the use of Induline SW-900 is not indicated in practice.

Conclusion

Overall conclusion on the risk assessment for the environment of the product
The overall conclusion of the environmental risk assessment for the product Induline SW-900 IT is that no unacceptable risk is identified for secondary poisoning, air and groundwater compartments. However, risk is identified for the aquatic compartment when the product is used for in-situ applications close to water. As a consequence **the product may not be applied near bodies of surface water or in the area of water protection zones**. A risk is also identified for the soil compartment when the product is used for in-situ applications. As a consequence **the ground must be covered during application in-situ and any spillage should be collected.** Finally, a risk is also identified during industrial application and storage and as a consequence, the **freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing or both to prevent direct losses to soil, sewer or water and that any losses of the product should be collected for reuse or disposal.**

2.2.9 Measures to protect man, animals and the environment

2.2.9.1 Recommended methods and precautions

Handling: Use only in well ventilated areas. Information about protection against explosions and fires: No special requirements.
In situ application: Cover the ground during application and collect any spillage. Do not apply near bodies of surface water or in the area of water protection zones.
Industrial application: Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing or both to prevent direct losses to soil, sewer or water and that any losses of the product should be collected for reuse or disposal.

Storage: Requirements to be met by storerooms and containers: No special requirements.
Information on storage in a common storage facility: Store away from food.
Further information about storage conditions:
Store container in a well ventilated position. Protect from frost.

Disposal:
Waste treatment methods
Recommendation:
The given refuse codes are recommendations based upon the intended use of the product. Because of special use and disposal conditions at the user's, other codes may apply under other conditions. Do not dispose of together with household garbage. Do not allow product to reach sewage system.
European waste catalogue:
03 02 02* - organochlorinated wood preservatives

This material must be disposed of safely as hazardous waste. Any product collected during application that is not re-used must be disposed of safely as hazardous waste.

Do NOT dispose of unwanted product down drains. Dispose of packaging and unused product in accordance with local regulations. If required, consult a professional waste operator or local authority.

Transport:
UN-Number: UN 3082
UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (cypermethrin cis/trans +/-40/60)
Packing group: III
Transport hazard class: Class: 9 Miscellaneous hazardous substances and articles; Label: 9
Marine pollutant: Yes

Fire:
Suitable extinguishing agents: CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
Advice for firefighters: Protective equipment: Wear self-contained breathing apparatus. Wear chemical protective clothing.
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.

2.2.9.2 Identity of relevant combustion products in cases of fire

Special hazards arising from the substance or mixture: May be released in case of fire
carbon monoxide (CO)
carbon dioxide
further harmful conflagration gases and fumes
formaldehyde (traces)

2.2.9.3 Specific treatment in case of an accident

General information: If symptoms occur or in case of doubt, seek medical attention. In case of unconsciousness, do not administer anything orally.
After inhalation: No special requirements.
After skin contact: Remove contaminated clothing. Do not use solvents or thinners! If skin irritation continues, consult a doctor.
After eye contact: Rinse opened eye for several minutes under running water.
After swallowing: Keep the person affected quiet. Rinse out mouth and then drink plenty of water.
Indication of any immediate medical attention and special treatment needed: symptomatic treatment

2.2.9.4 Possibility of destruction or decontamination following release

Soil: Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

2.2.10 Assessment of a combination of biocidal products

The product is not intended to be authorised for the use with other biocidal products.

3 ANNEXES

3.1 List of studies for the biocidal product

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Affolter, O.	2012	Determination of the storage stability of Induline SW 900 IT / VP 21075 at room temperature. Date: 2012-10-29	Laus GmbH, Kirrweiler, D-67489 Germany	10021603G001	No	No	Yes	Remmers Baustoff-technik GmbH, Löningen, Germany	3.1 3.2 3.4.1 3.9
Ansard, D. & Paulmier, I.	2009	Determination of the preventive action against European termites of the genus Reticulitermes according to NF EN 118 with NF EN 84. Date: 2009-12-14	FCBA Entomology laboratory, Pôle des Laboratoires Bois, Bordeaux, France	401/09/108F/1/ a,b,c-e	No	No	Yes	Remmers Baustoff-technik GmbH, Löningen, Germany	6.7
Colas, S.	2010a	Induline SW 900 IT / VP 21075 Assessment of acute dermal irritation	Phycher Bio Développement, France	IC-OCDE-PH-10/0070	Yes	No	Yes	Remmers Baustoff-technik GmbH, Löningen, Germany	8.1
Colas, S.	2010b	Induline SW 900 IT / VP 21075 Assessment of acute eye irritation	Phycher Bio Développement, France	IO-OCDE-PH-10/0070	Yes	No	Yes	Remmers Baustoff-technik GmbH, Löningen, Germany	8.2

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Colas, S.	2010c	Induline SW 900 IT / VP 21075 Assessment of sensitising properties on albino guinea pigs - Maximisation test according to Magnusson and Kligman	Phycher Bio Développement, France	SMK-PH-10/0070	Yes	No	Yes	Remmers Baustoff-technik GmbH, Löningen, Germany	8.3
Colas, S.	2010d	Induline SW 900 IT / VP 21075 Evaluation of acute oral toxicity in rats	Phycher Bio Développement, France	TAO423-PH-10/0070	Yes	No	Yes	Remmers Baustoff-technik GmbH, Löningen, Germany	8.5.1
Colas, S.	2010e	Induline SW 900 IT / VP 21075 Evaluation of acute dermal toxicity in rats	Phycher Bio Développement, France	TAD-PH-10/0070	Yes	No	Yes	Remmers Baustoff-technik GmbH, Löningen, Germany	8.5.3
Fennert, E-M. and Wessely, S.	2014a	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with leaching procedure according to EN 84 (1997)	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany	32/13/9731/01	No	No	Yes	Remmers Baustoff-technik GmbH, Löningen, Germany	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Fennert, E-M. and Wessely, S.	2014b	Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with evaporative ageing procedure according to EN 73 (1988)	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany	32/13/9731/02	No	No	Yes	Remmers Baustoff-technik GmbH, Löningen, Germany	6.7
Legay, S.	2010	Physico-chemical tests on an aqueous emulsion (ready-to-use) preservative (VP21075). Date: 2010-03-18	Chemistry Laboratory, Laboratoire de Chimie-Ecotoxicologie, Institut Technologique FCBA, France	402/09/108F-e	Yes	No	Yes	Remmers Baustoff-technik GmbH, Löningen, Germany	3.2 3.3 3.4.1 3.8 3.9 4.2 5
Plarre, R. and Klutzny, K.	2009a	Determination of the protective efectiveness of VP 21075 against wood destroying basidiomycetes– determination of toxic values in combination with DIN EN 84: 1997 – accelerated ageing tests of treated wood prior to biological testing – leaching procedure. Date: 2009-12-02	BAM, Bundesanstalt für Materialforschung und –prüfung, Berlin, Germany	IV.1/8222 Ba A	No	No	Yes	Troy Chemie GmbH, Seelze, Germany	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Plarre, R. and Klutzny, K.	2009b	Determination of the protective efectiveness of VP 21075 against wood destroying basidiomycetes– determination of toxic values in combination with DIN EN 73: 1990– accelerated ageing tests of treated wood prior to biological testing–evaporative ageing. Date: 2009-12-02	BAM, Bundesanstalt für Materialforschung und –prüfung, Berlin, Germany	IV.1/8222 Ba B	No	No	Yes	Troy Chemie GmbH, Seelze, Germany	6.7
Raphalen, E.	2016	24 weeks stability at room temperature on a ready-to use wood preservative INDULINE SW-900 IT	FCBA Laboratoire de Chimie-Ecotoxicologie, Pôle des Laboratoires Bois, Bordeaux, France	402/16/1110F-e	No	No	Yes	Remmers Baustofftechnik GmbH, Löningen, Germany	To be found as an annotation in section 3.4.1
Schumacher, P. and Fennert, E-M.	2009a	Determination of the protective effectiveness of VP 21075 against blue stain according to EN 152 part 1 (08/89) after 4 weeks of artificial weathering. Date: 2009-03-12	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany	32/08/9197/01-02	No	No	Yes	Troy Chemie GmbH, Seelze, Germany	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Schumacher, P. and Fennert, E-M.	2009b	Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46 - 1 (06/05) after leaching procedure according to EN 84 (05/97). Date: 2009-03-06	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany	32/08/9197/03	No	No	Yes	Troy Chemie GmbH, Seelze, Germany	6.7
Schumacher, P. and Fennert, E-M.	2009c	Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46 - 1(06/05) after evaporative ageing procedure according to EN 73 (04/90). Date: 2009-04-16	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany	32/08/9197/04	No	No	Yes	Troy Chemie GmbH, Seelze, Germany	6.7
Schumacher, P. and Fennert, E-M.	2009d	Determination of the toxic values against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 47 - (06/2005) in combination with leaching procedure according to EN 84 (05/97). Date: 2009-02-11	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany	32/08/9197/05	No	No	Yes	Troy Chemie GmbH, Seelze, Germany	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Schumacher, P. and Fennert, E-M.	2009e	Determination of the toxic values against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 47 (06/2005) in combination with evaporative ageing procedure according to EN 73 (04/90). Date: 2009-03-31	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany	32/08/9197/06	No	No	Yes	Troy Chemie GmbH, Seelze, Germany	6.7
Schumacher, P. and Fennert, E-M.	2009f	Determination of toxic values against Reticulitermes santonensis de Feytaud according to EN 117 (06/2005) in combination with leaching procedure according to EN 84 (05/97). Date: 2009-04-17	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany	32/08/9197/07	No	No	Yes	Troy Chemie GmbH, Seelze, Germany	6.7
Schumacher, P. and Fennert, E-M.	2009g	Determination of toxic values against Reticulitermes santonensis de Feytaud according to EN 117 (06/2005) in combination with evaporative ageing procedure according to EN 73 (04/1990). Date: 2009-06-29	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany	32/08/9197/08	No	No	Yes	Troy Chemie GmbH, Seelze, Germany	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Schumacher, P. and Fennert, E-M.	2009h	Determination of the preventive action against Reticulitermes santonensis de Feytaud according to EN 118 (06/2005) in combination with leaching procedure according to EN 84 (05/97). Date: 2009-04-16	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany	32/08/9197/09	No	No	Yes	Troy Chemie GmbH, Seelze, Germany	6.7
Schumacher, P. and Fennert, E-M.	2009i	Determination of the preventive action against Reticulitermes santonensis de Feytaud according to EN 118 (06/2005) in combination with evaporative ageing procedure according to EN 73 (04/90). Date: 2009-07-09	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany	32/08/9197/10	No	No	Yes	Troy Chemie GmbH, Seelze, Germany	6.7
Schumacher, P. & Wegner, R.	2010	Determination of active substances in test product VP-21075 (biological test, MPA report 32/08/9197/01-10). Date: 2010-03-01	MPA Eberswalde, Materialprüfanstalt Brandenburg GmbH – Holz und Holzschutz, Eberswalde, Germany	31/10/1377/05	No	No	Yes	Troy Chemie GmbH, Seelze, Germany	6.7

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Wegner, R.	2011a	NT Build 509 "Leaching of active ingredients from preservative-treated timber - Semi-field testing" (Approved 2005-03)	Materialprüfanstalt Brandenburg GmbH, Eberswalde, Germany	31/09/1326/02	No	No	Yes	Remmers Baustofftechnik GmbH, Löningen, Germany	10.3
Wegner, R.	2011b	NT Build 509 "Leaching of active ingredients from preservative-treated timber - Semi-field testing" (Approved 2005-03)	Materialprüfanstalt Brandenburg GmbH, Eberswalde, Germany	31/09/1326/02 B	No	No	Yes	Remmers Baustofftechnik GmbH, Löningen, Germany	10.3
Wegner, R.	2013	NT Build 509 "Leaching of active ingredients from preservative-treated timber - Semi-field testing" (Approved 2005-03)	Materialprüfanstalt Brandenburg GmbH, Eberswalde, Germany	31/09/1326/02 C	No	No	Yes	Remmers Baustofftechnik GmbH, Löningen, Germany	10.3
Wegner, R.	2015a	NT Build 509 "Leaching of active ingredients from preservative-treated timber - Semi-field testing" (Approved 2005-03)	Materialprüfanstalt Brandenburg GmbH, Eberswalde, Germany	31/09/1326/02 D	No	No	Yes	Remmers Baustofftechnik GmbH, Löningen, Germany	10.3
Wegner, R.	2015b	NT Build 509 "Leaching of active ingredients from preservative-treated timber - Semi-field testing" (Approved 2005-03)	Materialprüfanstalt Brandenburg GmbH, Eberswalde, Germany	31/09/1326/02E	No	No	Yes	Remmers Baustofftechnik GmbH, Löningen, Germany	10.3

3.2 Output tables from exposure assessment tools

Scenario 1: Brush application

Professionel Brushing - water-based product			
Tier I	**propiconazole**	**IPBC**	**cypermethrin**
Active substance % (w/w)	0,80%	0,80%	0,20%
Potential body exposure			
Indicative value mg/m2 (Normalized to1% a.s.)	0,238	0,238	0,238
Indicative value (corrected, a.s.) mg/m2	0,191	0,191	0,048
Application area m2	31,6	31,6	31,6
Potential dermal deposit mg (corrected) a.s	6,022	6,022	1,505
Clothing type	none	none	none
Clothing penetration %	100%	100%	100%
Actual dermal deposit a.s.	6,022	6,022	1,505
Hand exposure			
Indicative value mg/m2 (normalized to 1% a.s.)	0,542	0,542	0,542
Indicative value mg/m2 (corrected, a.s.)	0,433	0,433	0,108
Application area m2	31,600	31,600	31,600
Hand deposit mg a.s	13,694	13,694	3,424
Glove penetration %	100%	100%	100%
Actual hand deposit a.s.	13,694	13,694	3,424
Total dermal exposure			
Total dermal deposit a.s mg	19,716	19,716	4,929
Dermal absorption %	9%	30%	13%
Systemic exposure via dermal route mg	1,774	5,915	0,641
Systemic dermal exposure mg kg^{-1} day^{-1}	0,0296	0,0986	0,0107
Exposure by inhalation			
Indicative value mg/m2	0,002	0,002	0,002
Indicative value (corrected a.s.) mg/m2	0,001	0,001	0,000003
Application area m2	31,6	31,6	31,6
Mitigation by RPE (PF)	100,00%	100,00%	100,00%
Systemic exposure via inhalation route mg a.s	0,051	0,051	0,00010
Systemic exposure via inhalation mg kg^{-1} day^{-1}	0,00084	0,00084	0,000002
Systemic exposure			
Total systemic exposure a.s. mg	1,825	5,965	0,641
Body weight kg	60,0	60,0	60,0
Systemic exposure mg kg^{-1} day^{-1}	**0,0304**	**0,0994**	**0,0107**
AEL mg kg^{-1} day^{-1}	**0,04**	**0,2**	**0,022**
% AEL	76,0%	49,7%	48,6%

Professionel Brushing - water-based product			
Tier II	**propiconazole**	**IPBC**	**cypermethrin**
Active substance % (w/w)	0,80%	0,80%	0,20%
Potential body exposure			
Indicative value mg/m2 (normalized to 1% a.s.)	0,238	0,238	0,238
Indicative value (corrected, a.s.) mg/m2	0,191	0,191	0,048
Application area m2	31,6	31,6	31,6
Potential dermal deposit mg (corrected) a.s	6,022	6,022	1,505
Clothing type	Coated coveralls	Coated coveralls	Coated coveralls
Clothing penetration %	10%	10%	10%
Actual dermal deposit a.s.	0,602	0,602	0,151
Hand exposure			
Indicative value mg/m2 (normalized to 1% a.s.)	0,542	0,542	0,542
Indicative value mg/m2 (corrected, a.s.)	0,433	0,433	0,108
Application area m2	31,600	31,600	31,600
Hand deposit mg a.s	13,694	13,694	3,424
Glove penetration %	10%	10%	10%
Actual hand deposit a.s.	1,369	1,369	0,342
Total dermal exposure			
Total dermal deposit a.s mg	1,972	1,972	0,493
Dermal absorption %	9%	30%	13%
Systemic exposure via dermal route mg	0,177	0,591	0,064
Systemic dermal exposure mg kg^{-1} day^{-1}	0,00296	0,00986	0,00107
Exposure by inhalation			
Indicative value mg/m2	0,002	0,002	0,002
Indicative value (corrected a.s.) mg/m2	0,001	0,001	0,000003
Application area m2	31,6	31,6	31,6
Mitigation by RPE (PF)	100,00%	100,00%	100,00%
Systemic exposure via inhalation route mg a.s	0,051	0,051	0,0001
Systemic exposure via inhalation mg kg^{-1} day^{-1}	0,000843	0,000843	0,000002
Systemic exposure			
Total systemic exposure a.s. mg	0,228	0,642	0,064
Body weight kg	60,000	60,000	60,000
Systemic exposure mg kg^{-1} day^{-1}	**0,0038**	**0,0107**	**0,0011**
AEL mg kg^{-1} day^{-1}	**0,04**	**0,2**	**0,022**
% AEL	9,50%	5,35%	4,86%

Scenario 2: Cleaning the brush

General Exposure Calculator For Washing Out Of Brushes **The systemic dermal exposure is calculated as follows:**				
Activity and Parameters	**Propiconazole No gloves**	**IPBC No gloves**	**Cypermethrin No gloves**	**Units**
Volume of brush	**200**	**200**	**200**	**ml**
Volume of paint remaining on brush after painting ($^1/_8$ of 200 ml = 25 ml)	25	25	25	ml
Density of paint	**1,01**	**1,01**	**1,01**	**g/ml**
Weight of paint on brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	25,25	25,25	25,25	g
Concentration of a.s. in paint	**0,80**	**0,80**	**0,20**	**% w/w**
A. Weight of a.s. on brush after painting	202,0000	202,0000	50,5000	mg
B. Residues of a.s. on brush after 1st washing (10% of A)	20,2000	20,2000	5,0500	mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	181,8000	181,8000	45,4500	mg
C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	10,1000	10,1000	2,5250	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of C)	1,0100	1,0100	0,2525	mg
Penetration of a.s. through gloves	**100**	**100**	**100**	**%**
Weight of a.s. on hand	1,01000	1,01000	0,25250	mg
Dermal absorption of a.s.	**9,00**	**30,00**	**13,00**	**%**
Weight of a.s. entering the body	0,09090	0,30300	0,03283	mg
D. Weight of a.s. left on the brush after 1st wash and squeezing (B – C)	10,1000	10,1000	2,5250	mg
E. Residues of a.s. on brush after 2nd washing (10% of D)	1,0100	1,0100	0,2525	mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	9,0900	9,0900	2,2725	mg
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	0,5050	0,5050	0,1263	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of F)	0,0505	0,0505	0,0126	mg
Penetration of a.s. through gloves	100	100	100	%
Weight of a.s. on hand	0,05050	0,05050	0,01263	mg
Dermal absorption of a.s.	9,00	30,00	13,00	%
Weight of a.s. entering the body	0,00455	0,01515	0,00164	mg
G. Weight of a.s. left on the brush after 2nd wash and squeezing (**E** – **F**)	0,5050	0,5050	0,1263	mg

H. Residues of a.s. on brush after 3rd washing (10% of G)	0,0505	0,0505	0,0126	mg
Amount of a.s. removed from the brush into the cleaning fluid (G – H)	0,4545	0,4545	0,1136	mg
I. Weight of a.s. squeezed out from a brush onto a cloth (50% of H)	0,0253	0,0253	0,0063	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of I)	0,0025	0,0025	0,0006	mg
Penetration of **a.s.** through gloves	100	100	100	%
Weight of a.s. on hand	0,00253	0,00253	0,00063	mg
Dermal absorption of a.s.	9,00	30,00	13,00	%
Weight of a.s. entering the body	0,00023	0,00076	0,00008	mg
Total weight of a.s. entering the body *(to 4 decimal places)*	**0,0957**	**0,3189**	**0,0345**	**mg**
Body weight	**60**	**60**	**60**	**kg**
TOTAL SYSTEMIC DERMAL DOSE OF ACTIVE SUBSTANCE *(to 4 decimal places)*	**0,0016**	**0,0053**	**0,0006**	**mg a.s./kg bw**
AEL mg kg-1 day-1	**0,0400**	**0,2000**	**0,0220**	
%AEL	**3,99%**	**2,66%**	**2,62%**	**%**

Scenario 3: Industrial dipping

Water-based fully automated dipping, industrial			
Tier I Automated dipping, handling model 1	**Propiconazole**	**IPBC**	**Cypermethrin**
Active substance % (w/w)	0,80%	0,80%	0,20%
Potential body exposure			
Indicative value mg/cycle	8570	8570	8570
Duration cycles	4	4	4
Potential dermal deposit mg	34280	34280	34280
Clothing type	None	None	None
Clothing penetration %	100%	100%	100%
Actual dermal deposit [product] mg	34280	34280	34280
Hand exposure			
Indicative value mg/cycle (In gloves, actual)	1080	1080	1080
Duration cycles	4	4	4
Hand deposit mg	4320	4320	4320
Mitigation by gloves	Not applicable	Not applicable	Not applicable
Actual hand deposit [product] mg	4320	4320	4320
Total dermal exposure			
Total dermal deposit [product] mg	38600	38600	38600
Active substance mg	308,80	308,80	77,20
Dermal absorption %	9%	30%	13%
Systemic exposure via dermal route mg	27,7920	92,6400	10,0360
Systemic exposure			
Total systemic exposure a.s. mg	27,7920	92,6400	10,0360
Body weight kg	60	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0,46320**	**1,54400**	**0,16727**
AEL mg kg^{-1} day^{-1}	**0,04**	**0,2**	**0,022**
% AEL	1158,0%	772,0%	760,3%

Water-based fully automated dipping, industrial			
Tier II Automated dipping, handling model 1	**Propiconazole**	**IPBC**	**Cypermethrin**
Active substance % (w/w)	0,80%	0,80%	0,20%
Potential body exposure			
Indicative value mg/cycle	8570	8570	8570
Duration cycles	4	4	4
Potential dermal deposit mg	34280	34280	34280
Clothing type	Coated coveralls	Coated coveralls	Coated coveralls
Clothing penetration %	10%	10%	10%
Actual dermal deposit [product] mg	3428	3428	3428
Hand exposure			
Indicative value mg/cycle (In gloves, actual)	1080	1080	1080
Duration cycles	4	4	4
Hand deposit mg	4320	4320	4320
Mitigation by gloves	Not applicable	Not applicable	Not applicable
Actual hand deposit [product] mg	4320	4320	4320
Total dermal exposure			
Total dermal deposit [product] mg	7748	7748	7748
Active substance mg	61,98	61,98	15,50
Dermal absorption %	9%	30%	13%
Systemic exposure via dermal route mg	5,5786	18,5952	2,0145
Systemic exposure			
Total systemic exposure a.s. mg	5,5786	18,5952	2,0145
Body weight kg	60	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0,09298**	**0,30992**	**0,03357**
Factor 4 reduction (HEEG opinion no 18)	**0,02324**	**0,07748**	**0,00839**
AEL mg kg^{-1} day^{-1}	**0,04**	**0,2**	**0,022**
% AEL	58,1%	38,7%	38,2%

Scenario 4: Professionel deluging/flow-coat/auto spray

Professionel deluging/flow-coat/auto spray			
TIER I Automated dipping, dipping model 1	**Propiconazole**	**IPBC**	**Cypermethrin**
Active substance % (w/w)	0,80%	0,80%	0,20%
Potential body exposure			
Indicative value mg/min	178	178	178
Duration min	60	60	60
Potential dermal deposit mg	10680	10680	10680
Clothing type	None	None	None
Clothing penetration %	100%	100%	100%
Actual dermal deposit [product] mg	**10680**	**10680**	**10680**
Hand exposure			
Indicative value mg/min (In gloves, actual)	25,7	25,7	25,7
Duration min	60	60	60
Hand deposit mg	1542	1542	1542
Mitigation by gloves	Not applicable	Not applicable	Not applicable
Actual hand deposit [product] mg	**1542**	**1542**	**1542**
Total dermal exposure			
Total dermal deposit [product] mg	12222	12222	12222
Active substance mg	97,78	97,78	24,44
Dermal absorption %	9%	30%	13%
Systemic exposure via dermal route mg	8,7998	29,3328	3,1777
Systemic exposure via dermal route mg kg^{-1} day^{-1}	**0,1467**	**0,4889**	**0,0530**
Exposure by inhalation			
Indicative value mg/m³	1	1	1
Duration	60	60	60
Inhalation rate m^3/h	1,25	1,25	1,25
Mitigation by RPE (PF)	1	1	1
Inhaled [product] mg	1,25	1,25	1,25
Systemic exposure via inhalation route mg	0,010	0,010	0,003
Systemic exposure via inhalation route mg kg^{-1} day^{-1}	**0,00017**	**0,00017**	**0,00004**
Systemic exposure			
Total systemic exposure a.s. mg	8,7998	29,3328	3,1777
Body weight kg	60	60	60

Systemic exposure mg kg^{-1} day^{-1}	**0,14666**	**0,48888**	**0,05296**
AEL mg kg^{-1} day^{-1}	**0,04**	**0,2**	**0,022**
% AEL	366,7%	244,4%	240,7%

Professionel deluging/flow-coat/auto spray			
Tier II; Automated dipping, dipping model 1	**Propiconazole**	**IPBC**	**Cypermethrin**
Active substance % (w/w)	0,80%	0,80%	0,20%
Potential body exposure			
Indicative value mg/min	178	178	178
Duration min	60	60	60
Potential dermal deposit mg	10680	10680	10680
Clothing type	Impermeable coveralls	Impermeable coveralls	Impermeable coveralls
Clothing penetration %	5%	5%	5%
Actual dermal deposit [product] mg	**534**	**534**	**534**
Hand exposure			
Indicative value mg/min (In gloves, actual)	25,7	25,7	25,7
Duration min	60	60	60
Hand deposit mg	1542	1542	1542
Mitigation by gloves	Not applicable	Not applicable	Not applicable
Actual hand deposit [product] mg	**1542**	**1542**	**1542**
Total dermal exposure			
Total dermal deposit [product] mg	2076	2076	2076
Active substance mg	16,61	16,61	4,15
Dermal absorption %	9%	30%	13%
Systemic exposure via dermal route mg	1,4947	4,9824	0,5398
Systemic exposure via dermal route mg kg^{-1} day^{-1}	0,0249	0,0830	0,0090
Exposure by inhalation			
Indicative value mg/m^3	1	1	1
Duration	60	60	60
Inhalation rate m^3/h	1,25	1,25	1,25
Mitigation by RPE (PF) (FFP1)	25%	25%	25%
Inhaled [product] mg	5,00	5,00	5,00
Systemic exposure via inhalation route mg	0,040	0,040	0,010

Systemic exposure via inhalation route mg kg^{-1} day^{-1}	0,001	0,001	0,0002
Systemic exposure			
Total systemic exposure a.s. mg	1,4947	4,9824	0,5398
Body weight kg	60	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0,02491**	**0,08304**	**0,00900**
AEL mg kg^{-1} day^{-1}	**0,04**	**0,2**	**0,022**
% AEL	62,3%	41,5%	40,9%

Scenario 5: Acute: sanding of treated wood, amateur

Non-professionel sanding the surface of treated wood posts			
Active Substance	**Propiconazole**	**IPBC**	**Cypermethrin**
Concentration of a.s. %(w/w)	0,80%	0,80%	0,20%
Concentration in wood			
Application rate [product] g/m²	151,5	151,5	151,5
Application rate [a.s.] mg/cm²	0,1212	0,1212	0,0303
Area of wood to be sanded surface area cm² (4 x 4cm x 250cm + 2 x 4cm x 4cm)	4032	4032	4032
Volume of outer layer cm³ (4 x 3cm x 249cm x 1cm + 2 x 3cm x 3cm x 1cm)	3008	3008	3008
Amount in wood [a.s] mg	488,678	488,678	122,170
Exposure by inhalation			
Concentration of in wood dust a.s mg/cm³	0,162	0,162	0,041
Wood dust concentration in air mg/m³	5	5	5
Exposure duration h	1	1	1
Inhalation rate m^3/h	1,25	1,25	1,25
Mitigation by RPE (PF)	1	1	1
Retention of a.s. in wood	100%	100%	100%
Density of wood g/cm³	0,40	0,40	0,40
Amount dust inhaled in 1 hour (cm³)	0,0156	0,0156	0,0156
Inhaled [a.s] mg	0,0025	0,0025	0,0006
Body weight kg	60	60	60
Systemic exposure (inhalation) mg kg^{-1} day^{-1}	**0,000042**	**0,000042**	**0,000011**
Dermal exposure			
Concentration on the wood surface mg/cm^2	0,1212	0,1212	0,0303
Transfer coefficient (%)	2%	2%	2%
Surface of palm of hand cm^2	420	420	420
Dermal absorption (%)	9%	30%	13%
Body weight kg	60	60	60
Systemic exposure (dermal) mg kg-1 day-1	**0,0015**	**0,0051**	**0,0006**
Total systemic exposure			
Systemic exposure mg kg-1 day-1	**0,0016**	**0,0051**	**0,0006**
AEL mg kg^{-1} day^{-1}	**0,3**	**0,35**	**0,088**
% AEL	0,52%	1,47%	0,64%

Scenario 6: Chronic: sanding of treated wood, professional

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

Inhalation rate

The professional user is instructed to wear a respiratory protection mask when sanding treated wood. As worst case scenario inhalation exposure without respiratory protection will be six times higher than for the one-hour task of an amateur (see Scenario [5]).

Accordingly, systemic exposure estimates are:
Propiconazole 0.000254mg/kg bw/day
IPBC: 0.000254mg/kg bw/day
Cypermethrin: 0.000064 mg/kg bw/day

Dermal route (hands – no gloves worn)

The surface area of both palms of hands is 420 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 are (the same as for the acute scenario):
Propiconazole: 0.0015mg/kg bw/day
IPBC: 0,0051mg/kg bw/day
Cypermethrin: 0.0006mg/kg bw/day

Professional sanding of the surface of treated wood posts			
Active Substance	**Propiconazole**	**IPBC**	**Cypermethrin**
Concentration of a.s. %(w/w)	0,80%	0,80%	0,20%
Concentration in wood			
Application rate [product] g/m²	151,5	151,5	151,5
Application rate [a.s.] mg/cm²	0,1212	0,1212	0,0303
area of wood to be sanded surface area cm² (4 x 4cm x 250cm + 2 x 4cm x 4cm)	4032	4032	4032
volume of outer layer cm³ (4 x 3cm x 249cm x 1cm + 2 x 3cm x 3cm x 1cm)	3006	3006	3006
Amount in wood [a.s] mg	488,678	488,678	122,170
Exposure by inhalation			
Concentration of in wood dust a.s mg/cm³	0,163	0,163	0,041
Wood dust concentration in air mg/m³	5	5	5
Exposure duration h	6	6	6
Inhalation rate m^3/h	1,25	1,25	1,25
Mitigation by RPE (PF)	1	1	1

Retention of a.s. in wood	100%	100%	100%
Density of wood g/cm³	0,40	0,40	0,40
Amount dust inhaled in 6 hour (cm³)	0,0938	0,0938	0,0938
Inhaled [a.s] mg	0,0152	0,0152	0,0038
Body weight kg	60	60	60
Systemic exposure (inhalation) mg kg^{-1} day^{-1}	**0,000254**	**0,000254**	**0,000064**
Dermal exposure			
Concentration on the wood surface mg/cm^2	0,1212	0,1212	0,0303
Transfer coefficient (%)	2%	2%	2%
Surface of palm of hand cm^2	420	420	420
Dermal absorption (%)	9%	30%	13%
Body weight kg	60	60	60
Systemic exposure (dermal) mg kg-1 day-1	**0,0015**	**0,0051**	**0,0006**
Total systemic exposure			
Systemic exposure mg kg-1 day-1	**0,0018**	**0,0053**	**0,0006**
AEL mg kg^{-1} day^{-1}	**0,3**	**0,2**	**0,022**
% AEL	0,59%	2,67%	2,80%

Scenario 7: Acute secondary exposure, Adult handling treated wood after application

Adult handling treated wood after application			
	Propiconazole	**IPBC**	**Cypermethrin**
Concentration a.s. % (w/w)	0,80%	0,80%	0,20%
Wood contamination			
Application rate [product] g/m²	151,5	151,5	151,5
Application rate [a.s.] mg/cm²	0,121	0,121	0,030
Percentage dislodgeable	3%	3%	3%
Dislodgeable residues mg a.s./cm²	0,00364	0,00364	0,00091
Hand exposure			
Surface of palm of hands cm²	420	420	420
Hand deposit mg a.s./day	1,53	1,53	0,38
Dermal absorption %	9%	30%	13%
Systemic exposure via dermal route mg a.s.	0,1374	0,4581	0,0496
Body weight kg	60	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0,00229**	**0,00764**	**0,00083**
AEL mg kg^{-1} day^{-1}	**0,3**	**0,35**	**0,088**
% AEL	0,76%	2,18%	0,94%

Scenario 8: Acute secondary exposure, toddlertouching freshly treated surface

Toddler touching freshly treated surface and mouthing			
	Propiconazole	**IPBC**	**Cypermethrin**
Concentration a.s. % (w/w)	0,80%	0,80%	0,20%
Wood contamination			
Application rate [product] g/m²	151,5	151,5	151,5
Application rate [a.s.] mg/cm²	0,121	0,121	0,030
Percentage dislodgeable	50%	50%	50%
Dislodgeable residues mg a.s./cm²	0,06060	0,06060	0,01515
Hand exposure			
Hand surface cm²	115,2	115,2	115,2
Hand area contaminated %	100%	100%	100%
Hand deposit mg a.s./day	6,98	6,98	1,75
Dermal absorption %	9%	30%	13%
Systemic exposure via dermal route mg a.s.	0,6283	2,0943	0,2269
Oral exposure			

Hand deposit mg a.s./day	6,98	6,98	1,75
Oral absorption %	86%	100%	57%
Transferable fraction of paint from hand to mouth	10%	10%	10%
Systemic exposure via oral route mg a.s.	0,6004	0,6981	0,0995
Systemic exposure			
Total systemic exposure a.s. mg	1,2287	2,7924	0,3264
Body weight kg	10	10	10
Systemic exposure mg kg^{-1} day^{-1}	**0,12287**	**0,27924**	**0,03264**
AEL mg kg^{-1} day^{-1}	**0,3**	**0,35**	**0,088**
% AEL	40,96%	79,78%	37,09%

Scenario 9: Acute secondary exposure, Infant chewing on a treated piece of wood

Mouthing of treated wood			
	Propiconazole	**IPBC**	**Cypermethrin**
Active substance % (w/w)	0,80%	0,80%	0,20%
Concentration in wood			
Application rate [product] g/m²	151,5	151,5	151,5
Application rate [a.s.] mg/cm²	0,121	0,121	0,030
Layer thickness cm	1,00	1,00	1,00
Retention of a.s. in wood	100%	100%	100%
Concentration in wood [a.s.] mg/cm³	0,121	0,121	0,030
Oral exposure			
Size of the wood chip cm³	16	16	16
Extraction of active substance when chewing	10%	10%	10%
Extraction from wood mg a.s./day	0,19	0,19	0,05
Oral absorption %	86%	100%	57%
Systemic exposure via oral route mg a.s.	0,167	0,194	0,028
Systemic exposure			
Body weight kg	8	8	8
Systemic exposure mg kg^{-1} day^{-1}	**0,0208**	**0,0242**	**0,0035**
AEL mg kg^{-1} day^{-1}	**0,3**	**0,35**	**0,088**
% AEL	6,95%	6,93%	3,93%

Scenario 10: Chronic secondary exposure, Child or toddler playing on playground structure treated with wood preservative

Toddler playing wooden structure (e.g. playground)			
	Propiconazole	**IPBC**	**Cypermethrin**
Concentration a.s. % (w/w)	0,80%	0,80%	0,20%
Concentration in wood			
Application rate [product] g/m²	151,5	151,5	151,5
Application rate [a.s.] mg/cm²	0,1212	0,1212	0,0303
Dermal exposure			
Hand size cm^2	115,4	115,4	115,4
Portion of hand in contact with the paint	20%	20%	20%
Transfer efficiency %	3%	3%	3%
Dermal absorption %	9%	30%	13%
Systemic exposure via dermal route mg a.s.	0,008	0,025	0,003
Oral exposure			
Transfer coefficient of dried paint from hands to mouth %	50%	50%	50%
Oral absorption %	86%	100%	57%
Systemic exposure via oral route mg a.s	0,0016	0,0018	0,0003
Total systemic exposure			
Body weight kg	10	10	10
Systemic exposure mg kg^{-1} day^{-1}	**0,0009**	**0,0027**	**0,0003**
AEL mg kg^{-1} day^{-1}	**0,04**	**0,2**	**0,022**
% AEL	2,28%	1,35%	1,36%

Scenario 11: Inhalation of residues, indoors

Scenario 12 - Inhalation of residues, indoors			
	Propiconazole	**IPBC**	**Cypermethrin**
Concentration a.s. % (w/w) in Induline SW-900IT	0,80%	0,80%	0,20%
Saturated vapour pressure			
Vapour pressure Pa	5,60E-05	4,50E-03	2,30E-07
Molecular weight g/mol	342,2	281,0	416,3
Gas constant	8,31	8,31	8,31
Temperature K	293	293	293
Saturated vapour concentration (SVC) mg/m^3	7,87E-03	5,19E-01	3,93E-05
1% af SVCmg/m3	7,87E-05	5,19E-03	3,93E-07
Adult exposure by inhalation			
Inhalation rate m^3/d	16	16	16
Body weight kg	60	60	60
Systemic exposure mg/kg bw/d	2,10E-05	1,38E-03	1,05E-07
AEL mg/kg bw/d	0,04	0,2	0,022
% AEL	0,1%	0,7%	0,0005%
Child exposure by inhalation			
Inhalation rate m^3/d	12	12	12
Body weight kg	23,9	23,9	23,9
Systemic exposure mg/kg bw/d	3,95E-05	2,61E-03	1,97E-07
AEL mg/kg bw/d	**0,04**	**0,2**	**0,022**
% AEL	0,10%	1,3%	0,00090%
Toddler exposure by inhalation			
Inhalation rate m^3/d	8	8	8
Body weight kg	10	10	10
Systemic exposure mg/kg bw/d	6,30E-05	4,15E-03	3,15E-07
AEL mg/kg bw/d	**0,04**	**0,2**	**0,022**
% AEL	0,16%	2,1%	0,0014%

3.3 New information on the active substance

Not applicable.

3.4 Residue behaviour

Not applicable.

3.5 Summaries of the efficacy studies

Please find the summaries of the efficacy studies in the table below. The efficacy assessments can be found in separate documents. The documents have been uploaded in IUCLID, section 6.7 (annotations for Plarre and Klutzny, 2009a) as well.

- Assessment report by FCBA n 401/15/248Z version 2 of 22/06/2016
- Assessment report by Danish Technological Institute, dated 30.05.2016

<table>
<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th><th>Assessed in report by</th></tr>
<tr>
<td>VP 21075, 0.20 % Cypermethrine, 0.80 % Propiconazole and 0.80 % IPBC</td>
<td><u>Insects:</u>
Reticulitermes flavipes (formerly R. santonensis) (workers, soldiers, nymphs)</td>
<td>Visual evaluation of test blocks after 2 weeks leaching period and 8 weeks exposure.
Test was performed according to NF EN 118 and NF EN 84
Brushing procedure
Solvent or diluent used: Distilled water
Theoretical amount tested: 100, 150, and 200 mL/m^2 (i.e. 101, 151, and 202 g/m^2)
Species of wood: Pinus sylvestris</td>
<td>Table: Determination of the preventive action against Reticulitermes flavipes (formerly R. santonensis)
<table>
<tr><th></th><th>Number of test specimens</th><th>Retention of preservative g/m^2</th><th>ml/m^2</th><th>Survival of workers %</th><th>Living Soldiers (S) and Nymphs (N)</th><th>Visual examination</th></tr>
<tr><td>Untreated Dry Sample</td><td>T$1</td><td>-</td><td>-</td><td>66</td><td>N – S</td><td>4</td></tr>
<tr><td></td><td>T$2</td><td>-</td><td>-</td><td>69</td><td>N – S</td><td>4</td></tr>
<tr><td></td><td>T$3</td><td>-</td><td>-</td><td>61</td><td>N – S</td><td>4</td></tr>
<tr><td rowspan="6">Treated Sample
100 g/m^2</td><td>E 1</td><td>101</td><td>100</td><td>0</td><td>-</td><td>0</td></tr>
<tr><td>E 2</td><td>103</td><td>102</td><td>0</td><td>-</td><td>2</td></tr>
<tr><td>E 3</td><td>101</td><td>100</td><td>0</td><td>-</td><td>0</td></tr>
<tr><td>E 4</td><td>100</td><td>99</td><td>0</td><td>-</td><td>1</td></tr>
<tr><td>E 5</td><td>101</td><td>100</td><td>0</td><td>-</td><td>0</td></tr>
<tr><td>E 6</td><td>101</td><td>100</td><td>0</td><td>-</td><td>0</td></tr>
<tr><td rowspan="6">Treated Sample
150 g/m^2</td><td>E 7</td><td>151</td><td>149</td><td>0</td><td>-</td><td>0</td></tr>
<tr><td>E 8</td><td>151</td><td>149</td><td>0</td><td>-</td><td>0</td></tr>
<tr><td>E 9</td><td>151</td><td>150</td><td>0</td><td>-</td><td>1</td></tr>
<tr><td>E10</td><td>151</td><td>150</td><td>0</td><td>-</td><td>1</td></tr>
<tr><td>E11</td><td>151</td><td>150</td><td>0</td><td>-</td><td>1</td></tr>
<tr><td>E12</td><td>151</td><td>149</td><td>0</td><td>-</td><td>1</td></tr>
<tr><td rowspan="6">Treated Sample
200 g/m^2</td><td>E13</td><td>202</td><td>200</td><td>0</td><td>-</td><td>0</td></tr>
<tr><td>E14</td><td>202</td><td>200</td><td>0</td><td>-</td><td>0</td></tr>
<tr><td>E15</td><td>200</td><td>198</td><td>0</td><td>-</td><td>0</td></tr>
<tr><td>E16</td><td>201</td><td>199</td><td>0</td><td>-</td><td>1</td></tr>
<tr><td>E17</td><td>200</td><td>199</td><td>0</td><td>-</td><td>1</td></tr>
<tr><td>E18</td><td>201</td><td>199</td><td>0</td><td>-</td><td>0</td></tr>
</table>
</td>
<td>Ansard and Paulmier (2009); 401/09/108F/1/a,b,c-e</td>
<td>DTI</td>
</tr>
</table>

<table>
<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
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<tr>
<td>Induline SW-900 IT
0.15 % Cypermethrine,
0.8 % Propiconazole and 0.80 % IPBC</td>
<td><u>Fungi:</u>
Coriolus versicolor,
CTB 863 A</td>
<td>Preservative treatment of Fagus sylvatica against wood destroying basidiomycetes after leaching procedure.
Test was performed according to EN 113 (1996) in combination with leaching procedure according to EN 84 (1997)
Application procedure: vacuum pressure treatment
Test conditions:
Wood species: European beech
Solvent used: Water
Product concentrations tested: 0.0, 2.3, 3.1, 4.2, 5.4, 7.0 (% m/m)
Sterilization procedure applied: ionizing radiation ^{60}Co (Synergy Health Radeberg GmbH, Radeberg)</td>
<td>Tabelle: Grenzen der Wirksamkeit gegenüber dem Prüfpilz
Toxic threshold values against the test fungus
Prüfprodukt: test product Induline SW-900 IT
Alterungsbeanspruchung: ageing tests carried out EN 84
<table>
<tr><th>Versuchspilz
test fungusi</th><th>Holzart
wood species</th><th colspan="3">Grenze der Wirksamkeit
toxic threshold values</th></tr>
<tr><th></th><th></th><th>Konzentration des Prüfproduktes
concentration of test product</th><th>Aufnahme Prüfprodukt
retention of test product</th><th>Mittlerer korrigierter Masseverlust für die höchste Konzentration ohne Schutzwirkung
mean corrected mass loss for the highest concentration without protective effect</th></tr>
<tr><td></td><td></td><td>% (m/m)</td><td>kg/m³</td><td>%</td></tr>
<tr><td>Coriolus versicolor</td><td>Fagus sylvatica</td><td>< 2,3</td><td>< 15,2</td><td>-</td></tr>
</table>
</td>
<td>Fennert, E-M. and Wessely, S. (2014a)</td>
<td>DTI</td>
</tr>
<tr>
<td>Induline SW-900 IT
0.15 % Cypermethrine,
0.8 % Propiconazole and 0.80 % IPBC</td>
<td><u>Fungi:</u>
Coriolus versicolor,
CTB 863 A</td>
<td>Preservative treatment of Fagus sylvatica against wood destroying basidiomycetes after ageing procedure.
Test was performed according to EN 113 (1996) in combination with evaporative ageing procedure according to EN 73 (1988)
Application procedure: vacuum pressure treatment
Test conditions:
Wood species: European beech
Solvent used: water
Product concentrations tested: 0.0, 2.3, 3.1, 4.2, 5.4, 7.0 (% m/m)
Sterilization procedure applied: ionizing radiation ^{60}Co (Synergy Health Radeberg</td>
<td>Tabelle: Grenzen der Wirksamkeit gegenüber dem Prüfpilz
Toxic threshold values against the test fungus
Prüfprodukt: test product Induline SW-900 IT
Alterungsbeanspruchung: ageing tests carried out EN 73
<table>
<tr><th>Versuchspilz
test fungusi</th><th>Holzart
wood species</th><th colspan="3">Grenze der Wirksamkeit
toxic threshold values</th></tr>
<tr><th></th><th></th><th>Konzentration des Prüfproduktes
concentration of test product</th><th>Aufnahme Prüfprodukt
retention of test product</th><th>Mittlerer korrigierter Masseverlust für die höchste Konzentration ohne Schutzwirkung
mean corrected mass loss for the highest concentration without protective effect</th></tr>
<tr><td></td><td></td><td>% (m/m)</td><td>kg/m³</td><td>%</td></tr>
<tr><td>Coriolus versicolor</td><td>Fagus sylvatica</td><td>3,1 – 4,2</td><td>20,4 – 27,8</td><td>3,3</td></tr>
</table>
</td>
<td>Fennert, E-M. and Wessely, S. (2014b)</td>
<td>DTI</td>
</tr>
</table>

Experimental data on the efficacy of the biocidal product against target organism(s)					
		GmbH, Radeberg)			

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	**Test organism(s)**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**	**Assessed in report by**
VP 21075, 0.15 % Cypermethrine, 0.8 % Propiconazole and 0.80 % IPBC	Fungi: *Coniophora puteana*, Ebw 15 *Gloeophyllum trabeum*, Ebw 109 *Poria placenta*, FPRL 280 *Coriolus versicolor*, CTB 863 A	Preservative treatment of *Pinus sylvestris* against wood destroying basidiomycetes after leaching procedure. Test was performed according to DIN EN 113: 1996 Application procedure: Vacuum impregnation Test conditions: Wood species: Scots pine sapwood Solvent used: water Product concentrations tested: 0.0, 2.00, 2.70, 3.35, 4.30 and 5.50 (% m/m) Sterilization procedure applied: ionizing radiation ^{60}Co (Gamma Produktbestrahlung GmbH	Tabelle 5 (table 5): Grenze der Wirksamkeit von „VP-21075" nach Alterungsbeanspruchung des behandelten Holzes – Auswaschbeanspruchung gemäß DIN EN 84:1997 Toxic values for „VP-21075"(accelerated ageing procedure of treated specimens according to DIN EN 84:1997) **Grenze der Wirksamkeit** toxic values Versuchspilz / test fungus; Stamm-Nr. / strain; Holzart / Wood species; Konzentration der Tränklösung (Masse-% / concentration of product tested % m/m); Aufnahme / preservative retention kg/m³ *Coniophora puteana*; BAM Ebw. 15; Kiefernsplint / scots pine; <15,3; <2,0 *Poria placenta**; FPRL 280; Kiefernsplint / scots pine; <15,3; <2,0 *Gloeophyllum trabeum*; BAM Ebw. 109; Kiefernsplint / scots pine; 25,7>...<32,9; 3,4>...<4,3 *Coriolus versicolor*; CTB 863A; Kiefernsplint / scots pine; <15,4; <2,0	Plarre and Klutzny (2009a); IV.1/8222 Ba A	FCBA

<table>
<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th><th>Assessed in report by</th></tr>
<tr>
<td>VP 21075, 0.15 % Cypermethrine, 0.8 % Propiconazole and 0.80 % IPBC</td>
<td><u>Fungi:</u>
Coniophora puteana, Ebw 15
Gloeophyllum trabeum, Ebw 109
Poria placenta, FPRL 280
Coriolus versicolor, CTB 863 A</td>
<td>Preservative treatment of Pinus sylvestris against wood destroying basidiomycetes after evaporative ageing procedure (DIN EN 73: 1990).
Test was performed according to DIN EN 113: 1996
Application procedure: Vacuum impregnation
Test conditions:
Wood species: Scots pine sapwood
Solvent used: water
Product concentrations tested: 0.0, 2.00, 2.70, 3.35, 4.30 and 5.50 (% m/m)
Sterilization procedure applied: ionizing radiation ^{60}Co (Gamma Produktbestrahlung GmbH</td>
<td>Tabelle 5 (table 5):
Grenze der Wirksamkeit von „VP-21075" nach Alterungsbeanspruchung des behandelten Holzes – Verdunstungsbeanspruchung gemäß DIN EN 73:1990
Toxic values for „VP-21075" (accelerated ageing procedure of treated specimens according to DIN EN 73:1990)
<table>
<tr><th rowspan="2">Versuchspilz
test fungus</th><th rowspan="2">Stamm-Nr.
Strain</th><th rowspan="2">Holzart
Wood species</th><th colspan="2">Grenze der Wirksamkeit
toxic values</th></tr>
<tr><th>Konzentration der Tränklösung (Masse-%)
concentration of product tested % m/m</th><th>Aufnahme
preservative retention kg/m³</th></tr>
<tr><td>Coniophora puteana</td><td>BAM Ebw. 15</td><td>Kiefernsplint
scots pine</td><td><15,2</td><td><2,0</td></tr>
<tr><td>Poria placenta*</td><td>FPRL 280</td><td>Kiefernsplint
scots pine</td><td><15,2</td><td><2,0</td></tr>
<tr><td>Gloeophyllum trabeum</td><td>BAM Ebw. 109</td><td>Kiefernsplint
scots pine</td><td><15,3</td><td><2,0</td></tr>
<tr><td>Coriolus versicolor</td><td>CTB 863A</td><td>Kiefernsplint
scots pine</td><td><15,3</td><td><2,0</td></tr>
</table>
</td>
<td>Plarre and Klutzny (2009b); IV.1/8222 Ba B</td>
<td>FCBA</td>
</tr>
</table>

<table>
<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th><th>Assessed in report by</th></tr>
<tr>
<td>VP 21075, 0.15 % Cypermethrine, 0.8 % Propiconazole and 0.80 % IPBC</td>
<td><u>Fungi:</u>
Aureobasidium pullulans, P 268
Sclerophoma pithyophila, S 231</td>
<td>Preservative treatment of Pinus sylvestris against blue stain fungi after 4 weeks artificial weathering.
Test was performed according to EN 152 part 1 (08/89)
Application procedure: Brushing
Test conditions:
Wood species: pine sapwood
Amount of product tested: 80 – 90 ml/m^2 and 120 – 140 ml/m^2
The top coat Induline LW 700 was applied by spraying
Standard top coat based alkyd resin according to EN 152/1 three coatings:
1. coat: alkyd resin diluted at mass fraction 15 % (m/m) white sp
2. coat: alkyd resin diluted at mass fraction 7,5 % (m/m) white sp
3. coat: alkyd resin diluted
0,37 – 0,41 g per test block and coating

Artificial weathering by QUV
Method of sterilization: ionising irradiation carried out by Fa. Gamma – Service Produktbestrahlung GmbH</td>
<td>Tabelle 1: Bewertung der Probehölzer nach Versuchende (Einzeldaten siehe Anlage 1)
Table 1: Evaluation of blocks after testing (single data see annex 1)
<table>
<tr><th>Test product</th><th>Test amount
mean</th><th>Number of coatings</th><th>Top coat / test amount
mean</th><th colspan="3">Zone width free of blue stain</th><th>Visual evaluation of test blocks on the surface*</th></tr>
<tr><th></th><th></th><th></th><th></th><th>minimum
mm</th><th>mean
mm</th><th>maximum
mm</th><th></th></tr>
<tr><td>VP-21075</td><td>87 ml/m²</td><td>1 - 2</td><td></td><td rowspan="2">1,5</td><td rowspan="2">2,6</td><td rowspan="2">4,5</td><td rowspan="2">6 x 0</td></tr>
<tr><td>Induline LW 700</td><td></td><td></td><td>269 g/m²</td></tr>
<tr><td>VP-21075</td><td>129 ml/m²</td><td>2</td><td></td><td rowspan="2">2,0</td><td rowspan="2">2,8</td><td rowspan="2">4,5</td><td rowspan="2">6 x 0</td></tr>
<tr><td>Induline LW 700</td><td></td><td></td><td>326 g/m²</td></tr>
<tr><td colspan="8">Reference - control</td></tr>
<tr><td>Preventol A 4-S
(= 0,459 % Dichlofluanid)</td><td>250 ml/m²</td><td>4</td><td>ca. 250 g/m²
Standard top coat acc. to EN 152</td><td>4,0</td><td>5,8</td><td>8,0</td><td>3 x 0
1 x 0**
2 x 1</td></tr>
<tr><td colspan="8">Virulence- control</td></tr>
<tr><td>Preventol A 4-S
(= 0,459 % Dichlofluanid)</td><td>125 ml/m²</td><td>1 - 2</td><td>ca. 250 g/m²
Standard top coat acc. to EN 152</td><td>3,0</td><td>4,7</td><td>6,0</td><td>1 x 0
3 x 1
2 x 2</td></tr>
<tr><td colspan="8">Top coat – control</td></tr>
<tr><td>Induline LW 700</td><td></td><td>1
by spraying</td><td>295 g/m²</td><td>0</td><td>0</td><td>0</td><td>3 x 3</td></tr>
</table>
*) Visuelle Bewertung der Probehölzer - Oberfläche gemäß EN 152/1
visual evaluation of test blocks on the surface according to EN 152/1
0 = nicht verblaut (no blue stain)
Auf der Oberfläche ist visuell keine Verblauung festzustellen. (Blue stain cannot be observed visually on the surface.
1 = unbedeutend verblaut (insignificantly blue-stained)
Die Oberfläche weist nur vereinzelt kleine verblaute Stellen auf (only occasional small specks of blue stain on the surface)
2 = verblaut (blue – stained)
Die Oberfläche ist höchstens zu einem Drittel durchgehend oder zur Hälfte stellenweise bzw. streifenförmig verblaut.
(a maximum of one third of the surface is completely blue - stained or half of the surface is partly blue – stained)
3 = stark verblaut (strongly blue – stained)
Die Oberfläche ist mehr als zu einem Drittel durchgehend oder mehr als zur Hälfte stellenweise verblaut. (more than a third of the surface is completely blue - stained or more than half of the surface is partly blue – stained)

**) Vom Querschnitt bis max. 4 mm eingedrungene Bläue (Länge angeschnittener Tracheiden) wurde in der Bewertung nicht berücksichtigt.
Blue stain penetrating from the cross cuts to a maxim depth of 4 mm (length of tracheids) was not considered.</td>
<td>Schumacher and Fennert (2009a); 32/08/9197/01-02</td>
<td>FCBA</td>
</tr>
</table>

<table>
<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th><th>Assessed in report by</th></tr>
<tr>
<td>VP 21075, 0.20 % Cypermethrine, 0.80 % Propiconazole and 0.80 % IPBC</td>
<td><u>Insects:</u>
Hylotrupes bajulus
(larvae)</td>
<td>Visual evaluation of test blocks after 2 weeks leaching period and 4 weeks exposure of larvae.
Test was performed according to EN 46 - 1(06/05) and EN 84 (05/97)
Brushing procedure
Solution retention: 100 mL/m^2
Density of the product: 1.009 g/cm^3
Concentration tested: 100 %
Number of coatings: 1
Conditioning period after impregnation: at least 28 days
Species of wood: Pinus sylvestris
Retention of active ingredient (Cypermethrin): 0.20 g/m2</td>
<td>Table: Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus
<table>
<tr><th rowspan="3">Untersuchte Konzentrationen
concentration of product tested</th><th rowspan="3">Prüfkörper
test block</th><th rowspan="3">Lösungsaufnahme
solution retention</th><th colspan="3">Anzahl der Larven
number of larvae</th><th rowspan="3">Anzahl der nicht wiedergefundenen Larven
number of larvae not recovered</th></tr>
<tr><th colspan="2">tot
dead</th><th rowspan="2">lebend
alive</th></tr>
<tr><th>nicht genagt
not gnawed</th><th>genagt
gnawed</th></tr>
<tr><td>[Masse %]</td><td>[Nr.]</td><td>[ml/m^2]</td><td>[Stück]</td><td>[Stück]</td><td>[Stück]</td><td>[Stück]</td></tr>
<tr><td rowspan="7">100</td><td>1663</td><td>101,5</td><td>10</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>1664</td><td>100,7</td><td>10</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>1665</td><td>102,3</td><td>10</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>1666</td><td>102,3</td><td>10</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>1667</td><td>103,1</td><td>10</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>1668</td><td>101,5</td><td>10</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>mean</td><td>101,9</td><td colspan="4"></td></tr>
<tr><td colspan="7">Kontrolle control - after EN 84</td></tr>
<tr><td rowspan="3">-</td><td>1669</td><td>-</td><td>0</td><td>0</td><td>10</td><td>0</td></tr>
<tr><td>1670</td><td>-</td><td>1</td><td>0</td><td>9</td><td>0</td></tr>
<tr><td>1671</td><td>-</td><td>1</td><td>0</td><td>9</td><td>0</td></tr>
</table>
</td>
<td>Schumacher and Fennert (2009b); 32/08/9197/03</td>
<td>FCBA</td>
</tr>
<tr>
<td>VP 21075, 0.20 % Cypermethrine, 0.80 % Propiconazole and 0.80 % IPBC</td>
<td><u>Insects:</u>
Hylotrupes bajulus
(larvae)</td>
<td>Visual evaluation of test blocks after 12 weeks evaporative ageing period and 4 weeks exposure of larvae.
Test was performed according to EN 46 - 1(06/05) and EN 73 (04/90)
Brushing procedure
Solution retention: 100 mL/m^2
Density of the product: 1.009 g/cm^3
Concentration tested: 100 %
Number of coatings: 1
Conditioning period after impregnation: at least 28 days
Species of wood: Pinus sylvestris
Retention of active ingredient (Cypermethrin): 0.20 g/m2</td>
<td>Table: Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus</td>
<td>Schumacher and Fennert (2009c); 32/08/9197/04</td>
<td>FCBA</td>
</tr>
</table>

Experimental data on the efficacy of the biocidal product against target organism(s)

Untersuchte Konzentrationen *concentration of product tested*	Prüfkörper *test block*	Lösungsaufnahme *solution retention*	Anzahl der Larven *number of larvae*			Anzahl der nicht wiedergefundenen Larven *number of larvae not recovered*
			tot *dead*		lebend *alive*	
			nicht genagt *not gnawed*	genagt *gnawed*		
[Masse %]	[Nr.]	[ml/m²]	[Stück]	[Stück]	[Stück]	[Stück]
100	1672	99,9	10	0	0	0
	1673	100,7	10	0	0	0
	1674	103,1	10	0	0	0
	1675	102,3	10	0	0	0
	1676	101,5	10	0	0	0
	1677	102,3	10	0	0	0
	mean	**101,6**				
Kontrolle *control - after EN 73*						
-	1678	-	1	0	9	0
	1679	-	0	1	9	0
	1680	-	0	0	10	0

<table>
<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th><th>Assessed in report by</th></tr>
<tr>
<td>VP 21075, 0.20 % Cypermethrine, 0.80 % Propiconazole and 0.80 % IPBC</td>
<td><u>Insects:</u>
Hylotrupes bajulus
(larvae)</td>
<td>Visual evaluation of test blocks after 2 weeks leaching period and 4 weeks exposure of larvae.
Test was performed according to EN 47 (06/2005) and EN 84 (05/97)
Vacuum impregnation
Solvent or diluent used: Water quality 3 according to ISO 3696 (06/1991)
Concentrations tested: 0, 0.28, 0.35, 0.42, 0.69, 1.39 % (m/m)
Mean preservative retention: 0, 2.0, 2.5, 3.0, 5.0, 10 kg/m^3
Density of the product: 1.009 g/cm^3
Conditioning period after impregnation: at least 28 days
Species of wood: Pinus sylvestris
Retention of active ingredient (Cypermethrin): 0, 4.1, 5.1, 6.1, 9.8, 20.1 g/m3</td>
<td>Table: Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus
<table>
<tr><td rowspan="4">Untersuchte Konzentrationen
concentration of product tested</td><td colspan="2">Aufnahme
retention</td><td colspan="4">Anzahl der Larven
number of larvae</td></tr>
<tr><td>Prüfprodukt
test product</td><td>Cypermethrin</td><td colspan="2">tot
dead</td><td>lebend
alive</td><td>nicht wiedergefunden
not discovered</td></tr>
<tr><td>Mittelwert
mean</td><td>Mittelwert
mean</td><td>nicht genagt
not gnawed</td><td>genagt
gnawed</td><td></td><td></td></tr>
<tr><td>[% m/m]</td><td>[kg/m³]</td><td>[g/m³]</td><td>[exemplar]</td><td>[exemplar]</td><td>[exemplar]</td><td>[exemplar]</td></tr>
<tr><td colspan="7">Examination after 4 weeks</td></tr>
<tr><td>1,39</td><td>10,1</td><td>20,1</td><td>30</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>0,69</td><td>4,9</td><td>9,8</td><td>30</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>0,42</td><td>3,1</td><td>6,1</td><td>30</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>0,35</td><td>2,6</td><td>5,1</td><td>28</td><td>2</td><td>0</td><td>0</td></tr>
<tr><td>0,28</td><td>2,0</td><td>4,1</td><td>24</td><td>6</td><td>0</td><td>0</td></tr>
<tr><td>0 (water)</td><td>0,0</td><td>0,0</td><td>1</td><td>0</td><td>29</td><td>0</td></tr>
<tr><td>control</td><td>-</td><td>-</td><td>0</td><td>0</td><td>30</td><td>0</td></tr>
</table>
</td>
<td>Schumacher and Fennert (2009d); 32/08/9 197/05</td>
<td>FCBA</td>
</tr>
</table>

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<tr>
<td>VP 21075, 0.20 % Cypermethrine, 0.80 % Propiconazole and 0.80 % IPBC</td>
<td><u>Insects:</u>
Hylotrupes bajulus
(larvae)</td>
<td>Visual evaluation of test blocks after 12 weeks evaporative ageing period and 4 weeks exposure of larvae.
Test was performed according to EN 47 (06/2005) and EN 73 (04/90)
Vacuum impregnation
Solvent or diluent used: Water quality 3 according to ISO 3696 (06/1991)
Concentrations tested: 0, 0.28, 0.35, 0.42, 0.69, 1.39 % (m/m)
Mean preservative retention: 0, 2.0, 2.6, 3.1, 5.0, 10.1 kg/m^3
Density of the product: 1.009 g/cm^3
Conditioning period after impregnation: at least 28 days
Species of wood: Pinus sylvestris
Retention of active ingredient (Cypermethrin): 0, 4.1, 5.1, 6.1, 9.9, 20.2 g/m^3
Toxic values: < 2.0 kg/m^3, respectively < 0.28%</td>
<td>Table: Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus
<table>
<tr><th rowspan="3">Untersuchte Konzentrationen
concentration of product tested
[% m/m]</th><th colspan="2">Aufnahme
retention</th><th colspan="4">Anzahl der Larven
number of larvae</th></tr>
<tr><th>Prüfprodukt
test product
Mittelwert
mean
[kg/m³]</th><th>Cypermethrin
Mittelwert
mean
[g/m³]</th><th colspan="2">tot
dead</th><th>lebend
alive</th><th>nicht wiedergefunden
not discovered</th></tr>
<tr><th>nicht genagt
not gnawed
[exemplar]</th><th>genagt
gnawed
[exemplar]</th><th>[exemplar]</th><th>[exemplar]</th></tr>
<tr><td colspan="7">Examination after 4 weeks</td></tr>
<tr><td>1,39</td><td>10,1</td><td>20,2</td><td>30</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>0,69</td><td>5,0</td><td>9,9</td><td>30</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>0,42</td><td>3,1</td><td>6,1</td><td>30</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>0,35</td><td>2,6</td><td>5,1</td><td>30</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>0,28</td><td>2,0</td><td>4,0</td><td>22</td><td>8</td><td>0</td><td>0</td></tr>
<tr><td>0 (water)</td><td>0,0</td><td>0,0</td><td>0</td><td>0</td><td>30</td><td>0</td></tr>
<tr><td>control</td><td>-</td><td>-</td><td>1</td><td>0</td><td>29</td><td>0</td></tr>
</table>
</td>
<td>Schumacher and Fennert (2009e); 32/08/9197/06</td>
<td>FCBA</td>
</tr>
</table>

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<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th><th>Assessed in report by</th></tr>
<tr>
<td>VP 21075, 0.20 % Cypermethrine, 0.80 % Propiconazole and 0.80 % IPBC</td>
<td><u>Insects:</u>
Reticulitermes santonensis (workers, soldiers, nymphs)</td>
<td>Visual evaluation of test blocks after 2 weeks leaching period and 8 weeks exposure.
Test was performed according to EN 117 (06/2005) and EN 84 (05/97)
Vacuum impregnation
Solvent or diluent used: Water quality 3 according to ISO 3696 (06/1991)
Concentrations tested: 0, 1.39, 2.08, 2.88, 3.47, 5.55 % (m/m)
Mean preservative retention: 0, 10.1, 15.1, 20.7, 25.2, 40.2 kg/m^3
Conditioning period after impregnation: at least 28 days
Species of wood: Pinus sylvestris
Retention of active ingredient (Cypermethrin): 0, 20.2, 30.1, 41.4, 50.3, 80.4 g/m^3
Toxic values: < 10.1 kg/m^3, respectively < 1.39%</td>
<td>Table: Determination of toxic values against Reticulitermes santonensis
<table>
<tr><th rowspan="2">Untersuchte Konzentration
concentration of product tested
% (m/m)</th><th rowspan="2">Prüfkörper Nr.
test block No</th><th colspan="3">Aufnahme
Retention</th><th colspan="4">überlebende Termiten
surviving termites</th><th rowspan="2">Visuelle Bewertung der Probehölzer*
visual evaluation of test blocks*</th></tr>
<tr><th>Tränklösung
treating solution
kg/m³</th><th>Prüfprodukt
test product
kg/m³</th><th>Cypermethrin
Cypermethrin
g/m³</th><th>Arbeiter workers
%</th><th colspan="2">Soldaten soldiers / Nymphen nymphs
Anzahl number</th><th></th></tr>
<tr><td rowspan="4">water</td><td>1621</td><td>710,7</td><td>0,0</td><td>0,0</td><td>66</td><td>2</td><td>3</td><td>4</td></tr>
<tr><td>1622</td><td>726,7</td><td>0,0</td><td>0,0</td><td>76</td><td>1</td><td>2</td><td>4</td></tr>
<tr><td>1623</td><td>714,0</td><td>0,0</td><td>0,0</td><td>63</td><td>1</td><td>4</td><td>4</td></tr>
<tr><td>mean</td><td>717,1</td><td>0,0</td><td>0,0</td><td colspan="4"></td></tr>
<tr><td rowspan="4">1,39</td><td>1624</td><td>726,5</td><td>10,1</td><td>20,2</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1625</td><td>726,8</td><td>10,1</td><td>20,2</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1626</td><td>728,2</td><td>10,1</td><td>20,2</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>mean</td><td>727,1</td><td>10,1</td><td>20,2</td><td colspan="4"></td></tr>
<tr><td rowspan="4">2,08</td><td>1627</td><td>710,0</td><td>14,8</td><td>29,5</td><td>1</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1628</td><td>736,8</td><td>15,3</td><td>30,7</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1629</td><td>724,6</td><td>15,1</td><td>30,1</td><td>1</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>mean</td><td>723,8</td><td>15,1</td><td>30,1</td><td colspan="4"></td></tr>
<tr><td rowspan="4">2,88</td><td>1630</td><td>718,1</td><td>20,7</td><td>41,4</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1631</td><td>709,8</td><td>20,4</td><td>40,9</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1632</td><td>728,6</td><td>21,0</td><td>42,0</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>mean</td><td>718,9</td><td>20,7</td><td>41,4</td><td colspan="4"></td></tr>
<tr><td rowspan="4">3,47</td><td>1633</td><td>723,6</td><td>25,1</td><td>50,2</td><td>1</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1634</td><td>739,8</td><td>25,7</td><td>51,3</td><td>1</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1635</td><td>712,7</td><td>24,7</td><td>49,5</td><td>1</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>mean</td><td>725,4</td><td>25,2</td><td>50,3</td><td colspan="4"></td></tr>
<tr><td rowspan="4">5,55</td><td>1636</td><td>722,0</td><td>40,1</td><td>80,1</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1637</td><td>723,4</td><td>40,1</td><td>80,3</td><td>1</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1638</td><td>726,4</td><td>40,3</td><td>80,6</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>mean</td><td>723,9</td><td>40,2</td><td>80,4</td><td colspan="4"></td></tr>
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(controls)</td><td>1639</td><td>-</td><td>-</td><td>-</td><td>63</td><td>2</td><td>3</td><td>4</td></tr>
<tr><td>1640</td><td>-</td><td>-</td><td>-</td><td>67</td><td>2</td><td>3</td><td>4</td></tr>
<tr><td>1641</td><td>-</td><td>-</td><td>-</td><td>66</td><td>2</td><td>4</td><td>4</td></tr>
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</td>
<td>Schumacher and Fennert (2009f); 32/08/9197/07</td>
<td>FCBA</td>
</tr>
</table>

<table>
<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th><th>Assessed in report by</th></tr>
<tr>
<td>VP 21075, 0.20 % Cypermethrine, 0.80 % Propiconazole and 0.80 % IPBC</td>
<td><u>Insects:</u>
Reticulitermes santonensis
(workers, soldiers, nymphs)</td>
<td>Visual evaluation of test blocks after 12 weeks evaporative ageing period and 8 weeks exposure.
Test was performed according to EN 117 (06/2005) and EN 73 (04/1990)
Vacuum impregnation
Solvent or diluent used: Water quality 3 according to ISO 3696 (06/1991)
Concentrations tested: 0, 1.39, 2.08, 2.88, 3.47, 5.55 % (m/m)
Mean preservative retention: 0, 10.1, 15.2, 21.2, 25.4, 40.1 kg/m^3
Conditioning period after impregnation: at least 28 days
Species of wood: Pinus sylvestris
Retention of active ingredient (Cypermethrin): 0, 20.1, 30.4, 42.4, 50.7, 80.3 g/m^3
Toxic values: < 10.1 – 15.2 kg/m^3, respectively < 1.39 – 2.08%</td>
<td>Table: Determination of toxic values against Reticulitermes santonensis
<table>
<tr><th rowspan="3">Untersuchte Konzentration
concentration of product tested
% (m/m)</th><th rowspan="3">Prüfkörper Nr.
test block No</th><th colspan="3">Aufnahme
Retention</th><th colspan="4">überlebende Termiten
surviving termites</th><th rowspan="3">Visuelle Bewertung der Probehölzer*
visual evaluation of test blocks*</th></tr>
<tr><th>Tränklösung
treating solution</th><th>Prüfprodukt
test product</th><th>Cypermethrin
Cypermethrin</th><th>Arbeiter
workers</th><th colspan="3">Soldaten | Nymphen
soldiers | nymphs
Anzahl
number</th></tr>
<tr><th>kg/m³</th><th>kg/m³</th><th>g/m³</th><th>%</th><th colspan="3"></th></tr>
<tr><td rowspan="4">water</td><td>1642</td><td>712,6</td><td>0,00</td><td>0</td><td>57</td><td>3</td><td>3</td><td>4</td></tr>
<tr><td>1643</td><td>710,5</td><td>0,00</td><td>0</td><td>63</td><td>3</td><td>4</td><td>4</td></tr>
<tr><td>1644</td><td>715,2</td><td>0,00</td><td>0</td><td>61</td><td>3</td><td>4</td><td>4</td></tr>
<tr><td>mean</td><td>712,8</td><td>0</td><td>0</td><td colspan="4"></td></tr>
<tr><td rowspan="4">1,39</td><td>1645</td><td>720,0</td><td>10,01</td><td>20,0</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1646</td><td>729,1</td><td>10,13</td><td>20,3</td><td>1</td><td>0</td><td>1</td><td>2</td></tr>
<tr><td>1647</td><td>724,4</td><td>10,07</td><td>20,1</td><td>1</td><td>0</td><td>2</td><td>1</td></tr>
<tr><td>mean</td><td>724,5</td><td>10,07</td><td>20,1</td><td colspan="4"></td></tr>
<tr><td rowspan="4">2,08</td><td>1648</td><td>724,2</td><td>15,06</td><td>30,1</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1649</td><td>731,8</td><td>15,22</td><td>30,4</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1650</td><td>734,5</td><td>15,28</td><td>30,6</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>mean</td><td>730,2</td><td>15,19</td><td>30,4</td><td colspan="4"></td></tr>
<tr><td rowspan="4">2,88</td><td>1651</td><td>733,2</td><td>21,12</td><td>42,2</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
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<tr><td>mean</td><td>736,0</td><td>21,20</td><td>42,4</td><td colspan="4"></td></tr>
<tr><td rowspan="4">3,47</td><td>1654</td><td>734,8</td><td>25,50</td><td>51,0</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1655</td><td>732,4</td><td>25,41</td><td>50,8</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1656</td><td>726,5</td><td>25,21</td><td>50,4</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>mean</td><td>731,2</td><td>25,37</td><td>50,7</td><td colspan="4"></td></tr>
<tr><td rowspan="4">5,55</td><td>1657</td><td>720,1</td><td>39,96</td><td>79,9</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>1658</td><td>721,0</td><td>40,01</td><td>80,0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>1659</td><td>729,2</td><td>40,47</td><td>80,9</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>mean</td><td>723,4</td><td>40,15</td><td>80,3</td><td colspan="4"></td></tr>
<tr><td rowspan="3">Kontrollen
(controls)</td><td>1660</td><td>-</td><td>-</td><td>-</td><td>60</td><td>2</td><td>4</td><td>4</td></tr>
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<td>Schumacher and Fennert (2009g); 32/08/9197/08</td>
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</table>

<table>
<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th><th>Assessed in report by</th></tr>
<tr>
<td>VP 21075, 0.20 % Cypermethrine, 0.80 % Propiconazole and 0.80 % IPBC</td>
<td><u>Insects:</u>
Reticulitermes santonensis (workers, soldiers, nymphs)</td>
<td>Visual evaluation of test blocks after 16 weeks leaching period and 8 weeks exposure.
Test was performed according to EN 118 (06/2005) and EN 84 (05/97)
Brushing procedure
Solvent or diluent used: Water quality 3 according to ISO 3696 (06/1991)
Amount of product tested: 150 mL/m2
Coatings: 1
Concentration tested: 100 % (m/m)
Conditioning period after impregnation: at least 28 days
Species of wood: Pinus sylvestris
Retention of active ingredient (Cypermethrin): 0, 30 g/m^2</td>
<td>Table: Determination of the preventive action against Reticulitermes santonensis
<table>
<tr><th rowspan="2">Prüfkörper - Nr.
test block no</th><th rowspan="2">Prüfmenge
amount of product tested
ml/m²</th><th colspan="3">Anzahl der überlebenden Termiten
number of surviving termites</th><th rowspan="2">Visuelle Bewertung der Prüfkörper
visual evaluation of test blocks
0 = kein Angriff / no attack
1 = Nagespuren / traces of gnawing
2 = leichter Angriff / slight attack
3 = mittlerer Angriff / medium attack
4 = starker Angriff / heavy attack</th></tr>
<tr><th>Arbeiter
workers
%</th><th>Soldaten
Soldiers</th><th>Nymphen
nymphs
Anzahl
numbers</th></tr>
<tr><td>805</td><td>153,4</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>806</td><td>152,6</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>807</td><td>151,4</td><td>0</td><td>0</td><td>0</td><td>4</td></tr>
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<tr><td>810</td><td>152,2</td><td>1</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>mean</td><td>152,4</td><td colspan="4"></td></tr>
<tr><td colspan="6">Kontrolle (control)</td></tr>
<tr><td>703</td><td>-</td><td>63</td><td>0</td><td>1</td><td>4</td></tr>
<tr><td>704</td><td>-</td><td>57</td><td>1</td><td>1</td><td>4</td></tr>
<tr><td>705</td><td>-</td><td>67</td><td>1</td><td>1</td><td>4</td></tr>
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</td>
<td>Schumacher and Fennert (2009h); 32/08/9197/09</td>
<td>FCBA</td>
</tr>
<tr>
<td>VP 21075, 0.20 % Cypermethrine, 0.80 % Propiconazole and 0.80 % IPBC</td>
<td><u>Insects:</u>
Reticulitermes santonensis (workers, soldiers, nymphs)</td>
<td>Visual evaluation of test blocks after 12 weeks evaporative ageing period and 8 weeks exposure.
Test was performed according to EN 118 (06/2005) and EN 73 (04/90)
Brushing procedure
Solvent or diluent used: Water quality 3 according to ISO 3696 (06/1991)
Amount of product tested: 150 mL/m2
Coatings: 1
Concentration tested: 100 % (m/m)
Conditioning period after impregnation: at least 28 days
Species of wood: Pinus sylvestris
Retention of active ingredient (Cypermethrin): 0, 30 g/m^2</td>
<td>Table: Determination of the preventive action against Reticulitermes santonensis
<table>
<tr><th rowspan="2">Prüfkörper - Nr.
test block no</th><th rowspan="2">Prüfmenge
amount of product tested
ml/m²</th><th colspan="3">Anzahl der überlebenden Termiten
number of surviving termites</th><th rowspan="2">Visuelle Bewertung der Prüfkörper
visual evaluation of test blocks
0 = kein Angriff / no attack
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3 = mittlerer Angriff / medium attack
4 = starker Angriff / heavy attack</th></tr>
<tr><th>Arbeiter
workers
%</th><th>Soldaten
Soldiers</th><th>Nymphen
nymphs
Anzahl
numbers</th></tr>
<tr><td>814</td><td>153,72</td><td>1</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>815</td><td>153,33</td><td>2</td><td>0</td><td>1</td><td>0</td></tr>
<tr><td>816</td><td>152,14</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
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<tr><td>818</td><td>150,94</td><td>1</td><td>0</td><td>0</td><td>1</td></tr>
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<tr><td>mean</td><td>152,27</td><td colspan="4"></td></tr>
<tr><td colspan="6">VP-21075 Blank – biocide free formulation</td></tr>
<tr><td>820</td><td>152,93</td><td>59</td><td>3</td><td>5</td><td>4</td></tr>
<tr><td>821</td><td>151,34</td><td>62</td><td>2</td><td>5</td><td>4</td></tr>
<tr><td>822</td><td>153,33</td><td>61</td><td>3</td><td>6</td><td>4</td></tr>
<tr><td>mean</td><td>152,53</td><td colspan="4"></td></tr>
<tr><td colspan="6">Kontrolle (control)</td></tr>
<tr><td>823</td><td>-</td><td>63</td><td>3</td><td>5</td><td>4</td></tr>
<tr><td>824</td><td>-</td><td>55</td><td>3</td><td>6</td><td>4</td></tr>
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</td>
<td>Schumacher and Fennert (2009i); 32/08/9197/10</td>
<td>FCBA</td>
</tr>
</table>

3.6 Environmental Risk Assessment - Annexes

3.6.1 Leaching calculations

Leaching behaviour

The leaching of propiconazole, IPBC/PBC and cypermethrin, a.i. of Induline SW-900 IT, from treated timber was investigated in a semi-field study (point 10.3: Wegner, R., 2011a, Wegner, R., 2011b; Wegner, R. 2013; Wegner, R., 2015a and Wegner R., 2015b) at Wald Campus of FH Eberswalde, Germany. Application was superficial treatment (brushing). The test design is in accordance with NT Build 509, developed by the Nordic Innovation Centre (approved 2005-03). The data available comprises of nearly 5 years of leaching.

Pine sapwood was treated with SW 900 (nominal 0.8% w/w propiconazole, 0.8% w/w IPBC, and 0.2% w/w cypermethrin) by brushing once, resulting in a final product retention of mean **146 g/m²**, corresponding to nominal 1.168 g a.i./m² wood for propiconazole and IPBC, respectively and 0.292 g cypermethrin/m². Since the product used for the semi-field test is comparable to Induline SW-900 IT (0.8% propiconazole and 0.8% IPBC, 0.2% cypermethrin) in terms of a.i. and further ingredient contents, the results of the semi-field test are applicable for characterising the leaching properties of the active ingredients within Induline SW-900 IT. The SW 900 application was followed by spraying the topcoat LW 700/40 (2 x 125 ml/m²) twice. The timber received an end sealant by brushing three times with a transparent silicon system.

The total leaching for propiconazole and IPBC/PBC amounts to 37.14 mg a.i./m² (3.18 %) and 30.22 mg a.i./m² (2.59 %) treated timber, respectively. Cypermethrin could not be detected in any leachate above the limit of detection, which was between 0.3 µg/L and 0.1 µg/L. To ensure that this was not due to stability or analytical problems, a stability study of cypermethrin in leachate was assessed (at different temperatures and +/- sunlight); reasonable recoveries were found. In addtion the validation of the determination of cypermethrin in leachate water samples was presented, showing good recoveries (100.6% +/- 2.6 %). These studies did not give any reason to question the finding of no cypermethrin in the leachate

Leaching rates used for the risk assessment

For determination of the leaching rates used for the risk assessment, the experimental leaching rates were normalised to a yearly precipitation of 700 mm. For cypermethrin, the semi-field leaching test did not yield concentrations in the leachate above the limits of detection of 0.3 (before 22 Nov.2013) and 0.1 µg/L (after 22 Nov.2013). As a worst case assumption, concentrations of 0.3 µg/L (until 22 Nov. 2013) and 0.1 (from 22 Nov. 2013 on), representing the limits of detection, were assumed for each sampling point. Taking the wooden surface and the volume of collected leachates, concentrations in mg/m² wood have been calculated.

FLUX values (mg/m²/d) for propiconazole, IPBC/PBC and cypermethrin normalised to a precipitation of 700 mm / year					
Cum. sampling time (d)	**Cum. precipitation (mm)**	**Cum. normalised sampling time (d)**	**Normalised FLUX**		
			Propiconazole (mg/m²/d)	**IPBC/ PBC (mg/m²/d)**	**Cypermethrin (mg/m²/d)**
30	62	32	6.08E-02	1.62E-01	3.34E-05
78	120	62	2.31E-02	7.14E-02	3.02E-05
165	239	124	6.38E-02	1.67E-01	4.32E-05
277	494	258	3.31E-02	4.76E-02	2.84E-05
365	724	378	2.91E-02	1.26E-02	1.64E-05
546	969	505	2.11E-02	1.03E-02	1.66E-05
606	1204	628	2.21E-02	4.16E-03	1.88E-05
730	1447	755	2.65E-02	2.84E-03	1.81E-05
847	1675	873	3.76E-02	6.39E-03	3.96E-05
963	1920	1001	5.01E-03	6.26E-04	1.19E-05
1099	2164	1128	7.31E-03	6.29E-04	1.06E-05
1249	2390	1246	1.33E-02	1.70E-03	2.50E-05
1394	2672	1393	1.01E-02	2.11E-03	1.20E-05
1460	2785	1452	7.13E-03	1.19E-03	1.60E-05
1694	3142	1638	1.48E-02	3.60E-03	9.02E-06
1828	3310	1726	8.90E-03	1.71E-03	4.76E-06
1904	3462	1805	1.03E-02	1.51E-03	1.73E-05

Cum. = cumulative

The data available comprises of nearly 5 years of leaching, corresponding to the service life period of wood treated by brushing.

IPBC and propiconazole:

Time 1
For TIME 1 the leaching rate for the emission calculations are based on the first measure. This measure is corrected for the application amount (1168 mg a.i./m²) in the study compared to 1212 mg/m² for Induline Sw-900 IT:

IPBC/PBC (30 d): **0.168 mg/m²/d** (0.163 mg/m²/d * (1212/1168))
Propiconazole (30 d): **0.0630 mg/m²/d** (0.061 mg/m²/d * (1212/1168))

Time 2 (5 years):
For TIME 2 the leaching rate for the emission calculations are based on the last measure subtracted the leached amount at TIME 1. This result is corrected for the application amount. No assessment factor has been applied as the data from the leaching study comprised nearly 5 years of leaching.

IPBC/PBC (5 y): **0.0146 mg/m²/d**
((30.22 mg/m² -5.21 mg/m²) / (1805 d-32 d)* (1212/1168))

Propiconazole (5 y): **0.0205 mg/m²/d**
((37.14 mg/m² -1.95 mg/m²)/(1805 d-32 d) * (1212/1168))

Time 2 (15 years)
For Time 2 (15 years) the applicant has suggested a similar approach as for Time 2 (5 years). In line with the second leaching workshop (ECHA, 2014) an assessment factor of 5 was applied to the leaching rate. This is a conservative approach and is accepted by eCA.

IPBC/PBC: **0.0730 mg/m²/d**
((30.22 mg/m² – 5.21 mg/m²) / (1805 d-32 d)* (1212/1168)*5)

Propiconazole: **0.103 mg/m²/d**
((37.14 mg/m² – 1.95 mg/m²)/(1805 d-32 d) * (1212/1168)* 5)

The calculated leaching based on these flux rates does not exceed the amount of propiconazole and IPBC applied on the wood.

Cypermethrin:
Due to the 'artificial' nature of the FLUX values for cypermethrin, a correction for the application amount has not been done. Likewise, the assignment of an assessment factor to the leaching rates is not considered to be an appropriate means since real leaching rates could not be derived from the test. **Therefore, for TIME 1 as well as TIME 2 (5 and 15 years), a FLUX of 4.32E-05 mg/m²/d is applied,** representing the highest FLUX value calculated.

3.6.2 Non-compartment-specific exposure relevant to the food chain (secondary poisoning), Cypermethrin

According to Guidance on BPR Vol. IV Environment (ECHA, 2015) 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. Cypemethrin cis:trans/40:60 is characterized by log K_{ow} values ranged from 5.3-5.6. Further it is stated in the assessment report for cypermethrin that a risk for secondary poisoning will have to be performed at product authorisation based on the formulation and the envisaged used.

Assessment of secondary poisoning via the aquatic food chain

According to the Guidance on BPR (2015) the BCF_{fish} of a chemical with a log K_{ow} between 2 and 6 can be calculated by using equation 74:

$$\log BCF_{fish} = 0.85 \cdot \log Kow - 0.70$$

For a conservative estimate, the maximum value for log Kow (5.6) for cypermethrin has been used in the calculation of log BCF_{fish}. This results in a BCF of 11482 $L/kg_{wetfish}$.

The predicted environmental concentration in food (fish) of fish eating predators ($PEC_{oral, predator}$) is calculated from the PEC for surface water, the measured or estimated BCF for fish and the biomagnification factor (BMF) (equation 76)

$$PEC_{oral,predator} = PEC_{water} \cdot BCF_{fish} \cdot BMF$$

Based on the log K_{OW}, a BMF of 10 is used for the calculation (Table 24). The PEC_{water} value from the scenario "Industrial application, spraying (big plant)" has been used (1.49E-03 µg/L), as this was the second highest (the highest concentration from the scenario "In situ treatment, bridge over pond" is not used, as this scenario is not a part of the final authorisation). This results in a maximal **$PEC_{oral,predator}$ for fish eating birds and mammals of 1.71E-01 mg/kg wet fish**.

In the following, all data included in these calculations are listed:

Parameters for calculating secondary poisoning, water, cypermethrin			
Symbol	**Value**	**Unit**	
PECwater	1.49E-03	$\mu g*L^{-1}$	I
Log Kow	5.6	-	I
BMF	10	-	I
BCFfish	11482	$L/kg_{wetfish}$	I
PECoral, predator(water)	1.71E-01	mg/kg $_{wet\ fish}$	O

Assessment of secondary poisoning via the terrestrial food chain

Biomagnification may also occur via the terrestrial food chain. According to the Guidance on BPR (2015) section 3.8.3.7 a similar approach as for the aquatic route can be used here. The food-chain soil → earthworm → worm-eating birds or mammals is used. The $PNEC_{oral}$ is derived in the same way as for the aquatic route. Since birds and mammals consume worms with their gut contents and the gut of earthworms can contain substantial

amounts of soil, the exposure of the predators may be affected by the amount of substance that is in this soil.

The PECoral, predator for worm-eating birds and mammals is calculated as (equation 80):

$$PEC_{oral,\ predator} = C_{earthworm}$$

Using equation 82c, the concentration in a full worm can be written as:

$$C_{earthworm} = \frac{BCF_{earthworm} \cdot C_{porewater} + C_{soil} \cdot F_{gut} \cdot CONV_{soil}}{1 + F_{gut} \cdot CONV_{soil}}$$

Where $BCF_{earthworm}$ has been estimated using equation 82d, since no measured data on bioconcentration in worms is available:

$$BCF_{earthworm} = \left(0.84 + 0.012K_{ow}\right) / RHO_{earthworm}$$

And by the use of equation 82b and an un-numbered equation page 53:

$$CONV_{soil} = \frac{RHO_{soil}}{F_{solid} \cdot RHO_{solid}} \quad \text{and} \quad K_{comp\text{-}water} = \frac{Ctotal_{comp}}{Cporew_{comp}}$$

In the following, all data included in these calculations are listed. The Csoil value from the scenario "Industrial storage, big plant, 15 years" has been used as this was the second largest (the highest concentration from the scenario "In situ treatment, house" is not used, this scenario is not a part of the final authorisation).

Parameters for calculating secondary poisoning, soil, cypermethrin			
Symbol	**Value**	**Unit**	
C_{soil} (industrial storage, big plant, 15 years)	6.90E-05	$mg*kg_{wwt}^{-1}$	I
$C_{porewater}$ (calculated from C_{soil})	6.00E-09	$mg*L^{-1}$	I
$W_{earthworms}$	1	kg_{wwt} tissue	D
Fgut	0.1	$kg_{dwt}*kg_{wwt}^{-1}$	D
Fsolid	0.6	m^3*m^{-3}	D
$RHO_{earthworm}$	1.0	kgwwt.L-1	D
RHOsoil (wet)	1700	kg/m^3	D
RHOsolid	2500	$kg*m^{-3}$	D
Kow	398107	-	I
$BCF_{earthworm}$	4778	$L*kg_{wet\ earthworm}^{-1}$	O
$C_{earthworm}$ / $PEC_{oral\ preadator}$	**3.28E-05**	**$mg*kg_{wet\ earthworm}^{-1}$**	**O**

Based on the parameter above, the maximum **$PEC_{oral,predator}$ for worm- eating birds and mammals results in a concentration of 3.28E-05 mg/kg wet earthworm.**

Cypermethrin Secondary Poisoning			
Model Scenario	**Time 3 (day 1825)**		
	PEC [mg/kg_{wwt}]	**PNEC [mg/kg_{food}]**	$\frac{PEC}{PNEC}$
Scenario related to brushing (UC 3)			
Aquatic food chain			
Birds	1.71E-01	33	5.2E-03
Mammals		3.3	5.2E-02
Terrestrial food chain			
Birds	3.28E-05	33	9.9E-07
Mammals		3.3	9.9E-06

According to the calculated risk quotients above, the risk of Cypermethrin for birds and mammals via secondary poisoning is acceptable.

3.6.3 Environmental risk assessment for iodine (transformation product from IPBC)

Degradation of IPBC yields the primary degradate propargyl butyl carbamate (PBC) as well as Iodine. In the assessment report of IPBC (PT8) the risk assessment of iodine was left out, as iodine was evaluated by SE as an active substance for disinfectant. On the TM II, 2012 it was agreed to include iodine in the future evaluations and to base the calculations on the CAR of iodine.

In comparison to the other transformation product from IPBC, iodine is not a xenobiotic substance but an essential dietary trace element and is ubiquitously present in the environment. Because of iodine's natural presence in the environment, background values have to be taken into account in the environmental risk assessment.

Background values

Iodine and iodine compounds are ubiquitously distributed and there is a natural cycle of iodine species in the environment. Iodine can be present in different forms in the environment; the form of iodine is largely dependent on redox potential and pH. Iodide and iodate are the dominant iodine species in soil and surface water. The background values (as iodine) are presented below (CAR, iodine 2013).

Background concentration of iodine in the environment	
Compartment	Background level (as iodine)
Soil	Typically 0.5 - 20 mg/kg dw but with extremes up to 98 mg/kg Global mean value of 5 mg/kg
Groundwater	Mean concentration: 1 µg/l Range: < 1-70 µg/l with extremes up to 400 µg/l
Freshwater (river and lake)	0.5 - 20 µg/l
Marine water	45 - 60 µg/L
Rainwater	0.1-15 µg/l
Freshwater sediment	Typically: 6 mg/kg
Marine sediment	Typically: 3-400 mg/kg
Air	Atmosphere: 10-20 ng/m3 Atmospheric concentration: over land 2-14 ng/m3; over ocean 17-52 ng/m3 Marine air contains: 100 µg/l (may refer to local inhalable air)

PEC calculations

The PEC calculations follow the available guidance documents (Revised Emission Scenario Document for Wood Preservatives (OECD, 2013); Vol IV, Part B). For the iodine risk assessment only the worst case scenarios (highest IPBC output values) for each relevant compartment has been taken into consideration.

In the evaluation of iodine released from IPBC, it is chosen to consider 100% formation of both iodide and iodate. This proposed assessment is however worst case as it is expected that much less than 100% of the different iodine species will be present. However, for calculation of soil concentrations it is assumed that the total iodine concentration in soil is

transformed into 14% iodide and 100% iodate (CAR for IPBC, PT6 (2013) and agreed to use for PT 8 products at TM II, 2012).

If 100 % transformation of IPBC is assumed, the molar fraction of PBC produced is 0.552 and for iodine (I_2) it is 0.451 (2 moles of IPBC to form one mole of I_2). Further it is assumed that all iodine is transformed either to iodide or iodate. As one mole of iodine (I_2) forms two moles of iodide (I^-) the molar fraction between iodine and iodide is 1, whereas for iodate (IO_3^-) the molar fraction is 1.38.

PEC for sewage treatment plant
In the CAR 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 and iodine species. Hence, the STP risk assessment is based on IPBC influent concentration with no removal/degradation or translocation processes.

A risk assessment for soils being target for iodine species emission via sewage sludge is not considered to be necessary as the house scenario is considered worst case with respect to the soil compartment.

The PEC_{STP}-value for iodine is calculated based on the PEC_{STP} values for IPBC. For iodine only 80% of the emission is discharged to the surface water, since 20% of the influent concentration is adsorbed to the sewage sludge (CAR for iodine, 2013). Therefore, the PEC_{STP}-value for iodine is calculated according the following formulas:

$PEC_{STP,iodine}$ = PEC_{STP} for IPBC * 0.451 * 80%

For the worst case ($PEC_{STP,IPBC}$ 364 µg/L) ”industrial application – spraying (big plant)” this results in a $PEC_{STP,iodine}$ of 131 µg/L.

PEC for surface water
For the iodine risk assessment the bridge over pond scenario has been chosen as a worst case since it represents an intake into a static water body. Iodine as an inorganic compound is not biodegradable so it was assumed, that the whole IPBC emissions might accumulate during the service life. For IPBC this results in a concentration of 3.98 µg/L after 15 years. Mol weight transformation results in 1.79 µg/L iodine.

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

PEC for soil
With reference to the iodine risk assessment for soil, the same procedure as for surface water has been followed, taking the house scenario and a service life of 15 years. IPBC emissions are assumed to accumulate over 15 years, and this yields an IPBC concentration of 2.3 mg/kg wet weight soil (2.6 mg IPBC /kg dwt). Mol weight corrected this result in 1.03 mg/kg (wwt) iodine.

PEC for air
Exposure to air is not considered as it is assumed that iodine speciate into non-volatile iodide and iodate in the different compartments.

PEC for groundwater
The environmental fate and behaviour of IPBC and PBC 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. However, iodine might reach groundwater. It is not appropriate to take over the approach as for soil and static surface water since groundwater is a 'flowing' system, moving through soil and bedrock and being diluted.

In the Assessment Report for IBPC used as in-can preservative (Product Type 6, 2013), FOCUS-PEARL-3.3.3 groundwater modelling was carried out using a worst-case scenario of 35 simultaneously treated wooden houses per hectare. The calculations were undertaken for a IPBC release of 52.3 mg/m^2 treated wood over a period of 5 years. The maximum calculated concentrations of iodide/iodate in the leachate at one metre soil depth were found for the Hamburg scenario (2.59 µg iodide/L and 3.77 µg iodate/L) (80th percentile). The concentration in one metre soil depths is considered to represent predicted environmental concentrations in groundwater. The calculated concentrations of iodide and iodate in the leachate are within the background concentration and in the assessment report it was concluded that the direct release of IPBC to soil can considered being safe with respect to leaching to groundwater and contamination of drinking water. Thus for the intended use of Induline SW-900 IT lower groundwater concentrations can be expected since the estimated maximum total IPBC release after 5 years (30.5 mg/m^2 leached after 1805 normalised days) is less than that investigated in the Assessment Report. In conclusion, the risk to the groundwater from the use of the product Induline SW-900 IT is considered to be acceptable.

Environmental risk characterisation
The PNEC values are taken from the Assessment Report of Iodine:

PNEC values used for risk characterisation (all PNEC's refer to mg iodine)			
	Iodine (I_2)	**Iodate (IO_3^-)**	**Iodide (I^-)**
$PNEC_{STP}$ (µg iodine/L)	2900	-	-
$PNEC_{surface\ water}$ (µg iodine/L)	0.59	58.5	0.83
$PNEC_{sediment}$ (mg iodine/kg wwt)	Covered by surface water		
$PNEC_{soil}$ (mg iodine /kg wwt)	0.0118	0.304	0.0043

STP

An acceptable risk is found for the STP when considering the worst case scenario. For the sewage treatment plant only PEC/PNEC values for iodine has been calculated as no PNEC values are available for iodide and iodate.

PEC/PNEC	Worst case scenario	Iodine (I_2)	Iodate (IO_3^-)	Iodide (I^-)
STP	industrial application – spraying (big plant)	0.05	-	-

Surface water

The PEC/PNEC ratios for iodine and iodide in surface water are above 1 for the bridge scenario, which is indicative of unacceptable risk. The initial risk assessment covered formation of 100% iodine, 100% iodide and 100% iodate. In water however, the prevalent iodine forms are iodide (I^-) and iodate (IO_3^-), which would mean that the PEC should be compared to the PNEC for iodide and iodate. Additionally removal by adsorption onto suspended matter and into sediment will take place and could be taken into consideration for refinement.

PEC/PNEC	Worst case scenario	Iodine (I_2)	Iodate (IO_3^-)	Iodide (I^-)
Surface water	Bridge (15 years)	3.04	0.031	2.16

However, the calculated iodine concentration was 1.79 µg/L which is well within the reported background level for iodine in freshwater (0.5-20 µg/L). In addition, it should be noted that the background levels for iodine (iodine and iodide) in freshwater exceeds the derived PNEC's, which is also noted in the CAR of iodine. Hence, the derived PNEC values are very conservative estimates.

Taking into account the reported background level for iodine,the risk to the aquatic environment from the use of the product Induline SW-900 IT is considered to be acceptable.

Soil

PEC/PNEC	Worst case scenario	Iodine (I_2)	Iodate (IO_3^-)	Iodide (I^-)
Soil	House (15 years)	87.1	4.66	33.5

As in water iodine may undergo different hydrolytical, photolytical and microbial transformation processes (i.e. speciation) in the soil compartment. The presence of different forms of iodine is largely dependent on redox potential and pH. In soil, the prevalent iodine forms are iodide (I^-) and iodate (IO_3^-). As a worst case it is assumed that all iodine will be transformed to iodate, while the total iodine concentration in soil is transformed into 14% iodide (according to the CAR for iodine and agreed at TMII 2012). The risk assessment therefore covers formation of 100% iodine, 14% iodide and 100% iodate.

The PEC/PNEC ratios for iodine, iodide and iodate in soil are above 1 for the house scenario, which is indicative of unacceptable risk. However, the calculated iodine concentration was 2.3 mg/kg wwt (2.6 mg/kg dwt) which is well within the reported background level for iodine in soil (0.5-20 mg/kg dwt).

Taking into account the reported background level for iodine, the risk to soil from the use of the product Induline SW-900 IT is considered to be acceptable.

3.7 Confidential annex (separate document)

3.7.1 Product composition and formulation

3.7.1.1 Qualitative and quantitative information on the composition of the biocidal product.

3.7.1.2 Detailed information on the composition of the premixs WorleeSol 37, Grotan TK 5, and Polyphase AF3

3.7.2 Information on the substance(s) of concern

4 ANNEXES (CONFIDENTIAL TO THE APPLICANT) (SEPARATE DOCUMENT)

4.1 Manufacturers of the active substances

4.2 Product composition and formulation

4.2.1.1 Detailed information on the composition of the premix Polyphase AF3

4.3 Justification for read-across to dermal absorptions values for IPBC, propiconazole and cypermethrin

5 Amendments

5.1 Amendment 15.05.2018

Additional tradename has been added to the PAR:

Aqua IG-15-Imprägniergrund IT

For the following countries: Poland, Germany, Denmark, Austria and France.

5.2 Amendment 23.12.2019

See the following addendum

ADDENDUM TO PAR

Major change of the product approval
R4BP case no: BC-CH045693-44
Authorisation no: BPR-reg no. 692-8
Date: 23rd of December 2019

1. Background

In the present application, the applicant applies for a major change of the authorisation of the product Induline SW-900 IT.
The changes applied for are:

1) Change of the amount of product needed for efficacy against termites from 150 g/m2 to 100 g/m2
2) Efficacy claimed for additional target organism: *Anobium punctuatum* (wood destroying beetle)

This amendment applies to the following countries: Poland, Austria, France, Germany and Denmark

2. Physical/chemical properties and storage stability

The change applied for by the applicant does not affect the physical/chemical properties and storage stability of the product

3. Classification and labelling

The change applied for by the applicant does not affect the classification and labelling of the product

4. Efficacy

New studies have been presented concerning the efficacy against termites (*Reticultermes flavipes*) and wood destroying beetles (*Anobium punctuatum*) along with an expert statement from Bundesanstalt für Materialforschung und -prüfung. The new material has been assessed.
The summaries of the new efficacy studies are shown in the table below.

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	**Test organism(s)**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**	**Assessed in report By**
Induline SW-900-IT, 0.20 % Cypermethrine, 0.80 % Propiconazole and 0.80 % IPBC	Insects: *Anobium punctuatum* (larvae)	Test was performed according to EN 49 (06/2005) with aging tests EN 73 (12/2014) and EN 84 (05/1997) Brush application, 50 mL/m^2 using European oak sapwood. Visual evaluation of test blocks after 4 or 12 weeks ageing period and 6 months exposure.	Please refer to data set 1 100% mortality at the end of the test.	Brunet and Paulmier (2017); FCBA 401/14/264F/1/a, b-e	DTI
Induline SW-900-IT (VP21075), 0.20 % Cypermethrine, 0.80 % Propiconazole and 0.80 % IPBC	Insects: *Reticulitermes flavipes* (workers, soldiers, nymphs)	Test was performed according to EN 118 (01/2014) and EN 73 (12/2014) Brushing procedure, 100 g/m^2 using Scots pine sapwood. Visual evaluation of test blocks after 12 weeks aging in wind tunnel and 8 weeks exposure.	Please refer to data set 2 No damage higher than rating 2 is recorded.	Ansard and Paulmier (2017); EN 118 + EN 73: FCBA 401/16/073F-e	DTI
Induline SW-900-IT (VP21075), 0.20 % Cypermethrine, 0.80 % Propiconazole and 0.80 % IPBC	Insects: *Reticulitermes flavipes* (workers, soldiers, nymphs)	Test was performed according to EN 118 (01/2014) and EN 73 (12/2014) Brushing procedure, 100 g/m^2 using Scots pine sapwood. Visual evaluation of test blocks after 12 weeks aging in wind tunnel and 8 weeks exposure.	Please refer to data set 3 No damage higher than rating 2 is recorded.	Ansard and Paulmier (2017); EN 118 + EN 73: FCBA 401/16/074F-e	DTI

Data set 1: Results from determination of the preventive action against egg-laying and larval surviving of *Anobium punctuatum*

Samples	Reference	Mass of product (g)	Amount of product (g/m²)	Number of laid eggs	Number of hatched eggs	Number of living larvae retrieved
Treated specimens After NF EN 84	E2	0.064	50.8	4	0	0
	E3	0.062	49.6	10	0	0
	E4	0.062	49.3	5	0	0
	E5	0.063	50.4	2	0	0
	E6	0.062	49.2	1	0	0
Untreated control specimens after NF EN 84	*T1*	-	-	*81*	*81*	*50*
	T2	-	-	*59*	*59*	*48*
	T3	-	-	*52*	*52*	*45*
	T4	-	-	*65*	*65*	*50*
	T5	-	-	*43*	*43*	*38*
					Total	*231*
Treated specimens After NF EN 73	E8	0.062	49.3	7	0	0
	E11	0.064	50.5	4	0	0
	E12	0.063	50.0	1	0	0
	E13	0.063	49.6	4	0	0
	E14	0.063	50.3	2	0	0
Untreated control specimens after NF EN 73	*T1*	-	-	*85*	*85*	*50*
	T2	-	-	*31*	*31*	*28*
	T3	-	-	*40*	*40*	*35*
	T4	-	-	*33*	*33*	*30*
	T6	-	-	*37*	*37*	*29*
					Total	*172*

Data set 2: Results from determination of the preventive action against *Reticulitermes flavipes.*

Samples	Reference number of test specimens	Test loading g/m²	Test loading ml/m²	Results of examinations		
				Survival of workers (%)	Living soldiers (S) and/or nymphs (N)	Level of attack of the specimen
Untreated control test specimens	T$1	-	-	76	N – S	4
	T$2	-	-	57	N – S	4
	T$3	-	-	52	N – S	4
Samples treated with INDULINE SW-900 IT	E1	99.7	99.7	0	-	1
	E2	100.6	100.6	0	-	1
	E3	102.0	102.0	0	-	1
	E4	100.5	100.5	0	-	0
	E5	100.5	100.5	0	-	1
	E6	101.2	101.2	0	-	1

Data set 3: Results from determination of the preventive action against *Reticulitermes flavipes*

Samples	Reference number of test specimens	Test loading g/m²	Test loading ml/m²	Results of examinations		
				Survival of workers (%)	Living soldiers (S) and/or nymphs (N)	Level of attack of the specimen
Untreated control test specimens	T$1	-	-	72	N – S	4
	T$2	-	-	66	N – S	4
	T$3	-	-	52	N – S	4
Samples treated with INDULINE SW900 IT	E1	101.5	101.5	0	-	1
	E2	100.4	100.4	0	-	1
	E3	100.5	100.5	0	-	2
	E4	99.9	99.9	0	-	1
	E5	100.9	100.9	0	-	1
	E6	100.8	100.8	0	-	1

The product, Induline SW-900 IT may be approved for preventive use on softwood and hardwood against blue stain fungi, wood destroying fungi (brown and white rot), wood destroying beetles (*Hylotrupes banjulus* and *Anobium punctatum*) and subterranean termites (*Reticulitermes* sp.) with 100 g/m² for superficial treatments in use classes 2 and 3. A top coat is required. This evaluation is in agreement with expert statement made by Bundesanstalt für Materialforschung und -prüfung, Germany.

5. Impact of change on human health

The application rate of 100 mL/m² is applied in the risk assessment for human health. After the major change, this must be considered as the worst case, not 150 ml/m².
Concerning the risk assessment for human health the new application rate affects the exposure scenarios

- 5: Acute: sanding of treated wood, amateur
- 6: Chronic: sanding of treated wood, professional
- 7: Handling treated wood
- 8: Infant touching wet treated wood
- 9: Infant chewing wood-chip
- 10: Child or toddler playing on playground structure

Please find the calculations in the attached excel document.
No use-specific risk mitigation measures have been changed according to the risk assessment.

6. Impact of change on the environmental risk assessment

The change in the efficacy claim affects the environmental assessment as the worst case scenario, the environmental assessment was based on, is no longer 150 ml/m², but 100 ml/m². This change affects the leaching and PEC results and therefore the PEC/PNEC, which could result in removal of risk mitigation measures. These results are therefore calculated and presented. As the calculations on secondary poisoning for cypermethrin for an application rate of 150 ml/m2 of the product showed acceptable exposure to birds and mammals, it is not relevant to recalculate the exposure with the lowered application rate.
As no new leaching study has been submitted, the leaching data are based on a study, where the application rate was 150 ml/m2. An application rate of 100

ml/m^2 was used in the calculations of the leaching of the specific product. The new calculated leaching values can be seen in the following table.

Leaching rates for Induline SW-900 IT with assessment factors (mg/m^2/day)			
	TIME1 (30 days)	TIME 2 (5 years)	TIME2 (15 years)
IPBC/PBC	0.1121	0.0097 (AF=1)*	0.0487 (AF=5)*
Propiconazole	0.0420	0.0137 (AF=1)*	0.0685 (AF=5)*
Cypermethrin	4.32E-05**	4.32E-05**	4.32E-05**

*Assessment factors were chosen in accordance with the conclusions taken at the follow-up leaching workshop in Varese (held 12th June 2013). AF=1 (5 years) was chosen, because the current study comprised nearly 5 years of leaching.
** No assessment factors were assigned, since real leaching rates could not be derived from the test. See the section "Leaching rates used for the risk assessment", page 145-147 of the PAR.

In the following, the tables with values affected by the change in application rate are presented with new values.

Input parameters for calculating the local emission		
Input	**Value**	**Unit**
Scenario 1B: Automated spraying of wooden articles **Scenario 2B:** Automated spraying of wooden articles **Scenario 3:** Bridge over pond, Timber cladded house **Scenario 4:** Bridge over pond, Timber cladded house, Noise barrier		
Application rate of biocidal product		
	100*	mL/m^2
Concentration of active substance in the product		
Propiconazole	808	mg/m²
IPBC	808	mg/m²
Cypermethrin	202	mg/m²
Scenario 1A: Automated dipping of wooden articles **Scenario 2A:** Automated dipping of wooden articles		
Application rate of biocidal product		
	4040	g/m^3
Concentration of active substance in the product		
Propiconazole	32.32	g/m^3
IPBC	32.32	g/m^3
Cypermethrin	8.08	g/m^3

* corresponding to 101 g/m^2 at maximum considering a product density of 1.01 g/mL at 20°C

Cypermethrin	PEC_{STP} (µg/L)	$PEC_{surface\ water}$ (µg/L)	$PEC_{sediment}$ (mg/kg wwt)	PEC_{soil} (mg/kg wwt)
Industrial application				
Spraying (small plant)	1.85E-03	9.92E-05	1.24E-03	-
Spraying (big plant)	1.85E-02	9.92E-04	1.24E-02	-
Dipping	3.70E-03	1.98E-04	2.48E-03	-
Industrial storage				
Spraying (30 days – small plant)	-	3.58E-07	4.47E-06	2.91E-06
Spraying (20 years – small plant)	-	3.58E-07	4.47E-06	6.90E-06
Spraying (30 days – big plant)	-	3.58E-06	4.47E-05	2.91E-05
Spraying (20 years – big plant)	-	3.58E-06	4.47E-05	6.90E-05
Dipping (30 days)	-	3.17E-06	3.96E-05	2.91E-06
Dipping (20 years)	-	3.17E-06	3.96E-05	6.90E-06
In-situ treatments				
House (prof. - day 0) brush	-	-	-	3.43E-02
Bridge over pond (prof. - day 0) brush	-	6.06E-02	-	-
In-service				
Noise Barrier (30 days)	4.15E-06	2.23E-07	2.79E-06	9.53E-07
Noise Barrier (15 years)	4.15E-06	2.23E-07	2.79E-06	2.26E-06
House (30 days)	-	-	-	2.55E-06
House (5 years)	-	-	-	6.01E-06
House (15 years)	-	-	-	6.05E-06
Bridge over pond (30 days)	-	5.64E-07	5.76E-05	-
Bridge over pond (5 years)	-	5.90E-07	1.42E-04	-
Bridge over pond (15 years)	-	5.91E-07	4.31E-04	-
Blue colored cells: Cells including degradation ($PEC_{sediment}$ is without degradation, but calculated based on $PEC_{surfacewater}$ with degradation included)				

IPBC/PBC	PEC_{STP} (µg/L)	$PEC_{surface\ water}$ (µg/L)	PEC_{soil} (mg/kg wwt)
Industrial application			
Spraying (small plant)	24.2	1.3 (*)	-
Spraying (big plant)	2.42E+02	12.9 (*)	-
Dipping	48.5	2.6 (*)	-
Industrial storage			
Spraying (30 days – small plant)	-	2.85E-04	2.03E-04
Spraying (20 years – small plant)	-	2.85E-04	2.05E-04
Spraying (30 days – big plant)	-	2.85E-03	2.03E-03
Spraying (20 years– big plant)	-	2.85E-03	2.05E-03
Dipping (30 days)	-	2.53E-03	2.03E-04
Dipping (20 years)	-	2.53E-03	2.05E-04
In-situ treatments			
House (prof. - day 0) brush	-	-	0.14
Bridge over pond (prof. - day 0) brush	-	0.24	-

In-service			
Noise Barrier (30 days)	0.12	6.28E-03 (*)	6.65E-05
Noise Barrier (15 years)	5.11E-02	2.73E-03 (*)	2.91E-05
House (30 days)	-	-	1.78E-04
House (5 years)	-	-	1.56E-05
House (15 years)	-	-	7.78E-05
Bridge over pond (30 days)	-	2.08E-04	-
Bridge over pond (5 years)	-	2.36E-03 (*)	-
Bridge over pond (15 years)	-	1.20E-02 (*)	-
Blue colored cells: Cells including degradation ($PEC_{sediment}$ is without degradation, but calculated based on $PEC_{surfacewater}$ with degradation included)			
(*) PBC			

Propiconazole	**PEC_{STP} (µg/L)**	**$PEC_{surface\ water}$ (µg/L)**	**$PEC_{sediment}$ (mg/kg wwt)**	**PEC_{soil} (mg/kg wwt)**
Industrial application				
Spraying (small plant)	10.8	1.1	2.31E-02	-
Spraying (big plant)	108.5	10.8	0.23	-
Dipping	21.7	2.2	4.62E-02	-
Industrial storage				
Spraying (30 days – small plant)	-	3.52E-04	7.49E-06	3.75E-03
Spraying (20 years – small plant)	-	3.52E-04	7.49E-06	3.14E-02
Spraying (30 days – big plant)	-	3.52E-03	7.49E-05	3.75E-02
Spraying (20 years – big plant)	-	3.52E-03	7.49E-05	0.31
Dipping (30 days)	-	3.12E-03	6.64E-05	3.75E-03
Dipping (20 years)	-	3.12E-03	6.64E-05	3.14E-02
In-situ treatments				
House (prof. - day 0) brush	-	-	-	0.14
Bridge over pond (prof. - day 0) brush	-	0.24	-	-
In-service				
Noise Barrier (30 days)	3.94E-02	3.94E-03	8.39E-05	1.23E-03
Noise Barrier (15 years)	6.44E-02	6.43E-03	1.37E-04	1.68E-02
House (30 days)	-	-	-	3.28E-03
House (5 years)	-	-	-	8.78E-03
House (15 years)	-	-	-	4.49E-02
Bridge over pond (30 days)	-	2.73E-03	1.33E-04	-
Bridge over pond (5 years)	-	1.26E-03	1.91E-03	-
Bridge over pond (15 years)	-	6.31E-03	1.76E-02	-
Blue colored cells: Cells including degradation ($PEC_{sediment}$ is without degradation, but calculated based on $PEC_{surfacewater}$ with degradation included)				

1,2,4-triazole (soil)				
	Tier 1 (100% transformation)		Tier 2 (43.2% transformation)	
PEC_{soil}	**PEC (mg/kg ww)**	**PEC/PNEC**	**PEC (mg/kg ww)**	**PEC/PNEC**
Application	2.74E-2	**2.74**	1.18E-2	**1.18**
In service, house	-	-	-	-
30 days	6.71E-4	6.71E-2	2.90E-4	2.90E-2
5 year	2.40E-3	0.24	1.04E-3	0.10
15 years	1.25E-2	1.25	5.42E-3	0.54

Cypermethrin	**PEC/ $PNEC_{STP}$**	**PEC/ $PNEC_{surface\ water}$**	**PEC/ $PNEC_{sediment}$**	**PEC/ $PNEC_{soil}$**
Industrial application				
Spraying (small plant)	1.13E-03	2.48E-02	9.92E-02	-
Spraying (big plant)	1.13E-02	2.48E-01	0.99	-
Dipping	2.27E-03	4.96E-02	0.20	-
Industrial storage				
Spraying (30 days – small plant)	-	8.94E-05	3.58E-04	3.16E-05
Spraying (20 years– small plant)	-	8.94E-05	3.58E-04	7.51E-05
Spraying (30 days – big plant)	-	8.94E-04	3.58E-03	3.16E-04
Spraying (20 years – big plant)	-	8.94E-04	3.58E-03	7.51E-04
Dipping (30 days)	-	7.92E-04	3.17E-03	3.16E-05
Dipping (20 years)	-	7.92E-04	3.17E-03	7.51E-05
In-situ treatments				
House (prof. - day 0) brush	-	-	-	0.37
Bridge over pond (prof. - day 0) brush	-	**15.15**	-	-
In-service				
Noise Barrier (30 days)	2.55E-06	5.57E-05	2.23E-04	1.04E-05
Noise Barrier (15 years)	2.55E-06	5.57E-05	2.23E-04	2.46E-05
House (30 days)	-	-	-	2.77E-05
House (5 years)	-	-	-	6.54E-05
House (15 years)	-	-	-	6.57E-05
Bridge over pond (30 days)	-	1.41E-04	4.61E-03	-
Bridge over pond (5 years)	-	1.48E-04	1.14E-02	-
Bridge over pond (15 years)	-	1.48E-04	3.45E-02	-
Blue colored cells: Cells including degradation ($PEC_{sediment}$ is without degradation. but calculated based on $PEC_{surfacewater}$ with degradation included)				

IPBC/PBC	PEC/ $PNEC_{STP}$	PEC/ $PNEC_{surface\ water}$	PEC/ $PNEC_{soil}$
Industrial application			
Spraying (small plant)	5.51E-02	3.13E-02 (*)	-
Spraying (big plant)	0.55	0.31 (*)	-
Dipping	0.11	6.26E-02 (*)	-
Industrial storage			
Spraying (30 days – small plant)	-	5.71E-04	4.68E-02
Spraying (20 years – small plant)	-	5.71E-04	4.72E-02
Spraying (30 days – big plant)	-	5.71E-03	0.47
Spraying (20 years – big plant)	-	5.71E-03	0.47
Dipping (30 days)	-	5.06E-03	4.68E-02
Dipping (20 years)	-	5.06E-03	4.72E-02
In-situ treatments			
House (prof. - 0 day) brush	-	-	**31.6**
Bridge over pond (prof. - 0 day) brush	-	0.48	-
In-service			
Noise Barrier (30 days)	2.68E-04	1.52E-04 (*)	1.53E-02
Noise Barrier (15 years)	1.16E-04	6.60E-05 (*)	6.71E-03
House (30 days)	-	-	4.09E-02
House (5 years)	-	-	3.59E-03
House (15 years)	-	-	1.79E-02
Bridge over pond (30 days)	-	4.15E-04	-
Bridge over pond (5 years)	-	5.71E-05 (*)	-
Bridge over pond (15 years)	-	2.90E-04 (*)	-

Blue colored cells: Cells including degradation ($PEC_{sediment}$ is without degradation. but calculated based on $PEC_{surfacewater}$ with degradation included)
(*) PBC

Propiconazole	PEC/ $PNEC_{STP}$	PEC/ $PNEC_{surface\ water}$	PEC/ $PNEC_{sediment}$	PEC/ $PNEC_{soil}$
Industrial application				
Spraying (small plant)	1.08E-04	0.16	0.43	-
Spraying (big plant)	1.08E-03	**1.59**	**4.27**	-
Dipping	2.17E-04	0.32	0.85	-
Industrial storage				
Spraying (30 days – small plant)	-	5.17E-05	1.39E-04	3.75E-02
Spraying (20 years – small plant)	-	5.17E-05	1.39E-04	0.31
Spraying (30 days – big plant)	-	5.17E-04	1.39E-03	0.38
Spraying (20 years – big plant)	-	5.17E-04	1.39E-03	**3.14**
Dipping (30 days)	-	4.58E-04	1.23E-03	3.75E-02
Dipping (20 years)	-	4.58E-04	1.23E-03	0.31
In-situ treatments				
House (prof. - day 0) brush	-	-	-	**1.37**

Bridge over pond (prof. - day 0) brush	-	3.56E-02	-	-
In-service				
Noise Barrier (30 days)	3.94E-07	5.79E-04	1.55E-03	1.23E-02
Noise Barrier (15 years)	6.44E-07	9.45E-04	2.54E-03	0.17
House (30 days)	-	-	-	3.28E-02
House (5 years)	-	-	-	8.78E-02
House (15 years)	-	-	-	0.45
Bridge over pond (30 days)	-	4.01E-04	2.47E-03	-
Bridge over pond (5 years)	-	1.85E-04	3.54E-02	-
Bridge over pond (15 years)	-	9.28E-04	0.33	-
Blue colored cells: Cells including degradation ($PEC_{sediment}$ is without degradation. but calculated based on $PEC_{surfacewater}$ with degradation included)				

Induline SW-900 IT, Σ PEC/PNEC	**PEC/ $PNEC_{STP}$**	**PEC/ $PNEC_{surface\ water}$**	**PEC/ $PNEC_{sediment}$**	**PEC/ $PNEC_{soil}$**
Industrial application				
Spraying (small plant)	5.63E-02	0.22 (*)	0.53	-
Spraying (big plant)	0.56	**2.15 (*)**	**5.27**	-
Dipping	0.11	0.43 (*)	1.05	-
Industrial storage				
Spraying (30 days – small plant)	-	7.12E-04	4.96E-04	8.43E-02
Spraying (20 years – small plant)	-	7.12E-04	4.96E-04	0.36
Spraying (30 days – big plant)	-	7.12E-03	4.96E-03	0.84
Spraying (20 years – big plant)	-	7.12E-03	4.96E-03	**3.62**
Dipping (30 days)	-	6.31E-03	4.40E-03	8.43E-02
Dipping (20 years)	-	6.31E-03	4.40E-03	0.36
In-situ treatments				
House (prof. - day 0) brush	-	-	-	**33.33 (33.15)**
Bridge over pond (prof. - day 0) brush	-	**15.67**	-	-
In-service				
Noise Barrier (30 days)	2.71E-04	7.87E-04 (*)	1.78E-03	2.76E-02
Noise Barrier (15 years)	1.19E-04	1.07E-03 (*)	2.76E-03	0.17
House (30 days)	-	-	-	7.37E-02 (6.99E-02)
House (5 years)	-	-	-	9.14E-02 (0.11)
House (15 years)	-	-	-	0.47 (0.56)
Bridge over pond (30 days)	-	9.58E-04	7.08E-03	-
Bridge over pond (5 years)	-	3.90E-04	4.67E-02	-
Bridge over pond (15 years)	-	1.37E-03	0.36	-
Blue colored cells: Cells including degradation ($PEC_{sediment}$ is without degradation, but calculated based on $PEC_{surfacewater}$ with degradation included)				

The results are the PEC/PNEC for the product. The PEC/PNEC for IPBC, propiconazole and cypermethrin are summarised.

(*) PBC values included instead of IPBC

Results in brackets: 1,2,4-triazole values included instead of propiconazole

The environmental risk assessment carried out with new values in this major change, does not result in change in the risk mitigation measures.

7. Change of label instructions

The change applied for by the applicant does not affect the label instructions of the product.

8. Overall conclusion

New studies have proven efficacy against *Anobium punctuatum* (wood destroying beetle) and a lower efficient application rate against termites (*Reticulitermes* sp.) than previously tested.
The major change lowers the application rate and hereby reduces or maintains the exposure for humans and the environment. The risk assessment does not result in change in instructions for use and risk mitigation measures.