Product Authorisation Holzschutz-Imprägnierung aq. 9005 containing Propiconazole and 3-Iodo-2-propynyl butyl carbamate (IPBC)

From Saicos Colour GmbH for use in product type 8

UK Competent Authority Product Assessment Report

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1. APPLICANT, ACTIVE INGREDIENT MANUFACTURER, PRODUCT FORMULATOR AND AUTHORISATION DETAILS

1.1. Applicant and Authorisation holder

[redacted]

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Germany

Tel: [redacted]

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1.2 Active Ingredient Manufacturer

Propiconazole

Syngenta Crop Protection AG

For manufacturing site address please see Member State confidential Annex

IPBC

Troy Chemical Company

For manufacturing site address please see Member State confidential Annex

1.2.1 Statement of Technical Equivalence

The manufacturer and manufacturing sites for the production of Propiconazole and IPBC are the same as that evaluated during Annex I (further details in the Annex I confidential Annexes). The Propiconazole active concentrate used is Wocosen WFC. The IPBC active concentrate used is Polyphase P100. Therefore, we believe that there are no issues raised regarding the technical equivalence of the active ingredient. (See Member State Confidential Annex for further details)

1.3. Manufacturer/formulator of product

Saicos Colour GmbH

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Germany

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1.4 Date of authorisation and authorisation number

Product authorisation granted on 29th May 2012

Product authorisation expires on 31st March 2020

Authorisation number : UK-2012-0442

2 GENERAL PRODUCT INFORMATION

2.1 Product details

Holzschutz-Imprägnierung aq. 9005 is a product containing 0.9% w/w Propiconazole, and 0.3% w/w IPBC, supported by the product [redacted] As such the UK CA's view is that the Product Assessment Report (PAR) that has been produced for the product [redacted] is suitable to support this product. [redacted] has given their permission for Saicos Colour GmbH to use the PAR for [redacted] to support the product authorisation of Holzschutz-Imprägnierung aq. 9005.

Key points to note:

- The assessment (sections 3-7 plus Annexes A-C) that follows is the one that has been generated for the [redacted] The applicant details (section 1), general product information (section 2), the decision (section 10) and the Summary of Product Characteristics (Annex C) are specific to the product Holzschutz-Imprägnierung aq. 9005.

- The technical specification of the product Holzschutz-Imprägnierung aq. 9005 (please see R4BP for the technical specification) is supported by the [redacted] Please see Member State confidential Annex for further details.

- The formulator of the product Holzschutz-Imprägnierung aq. 9005 is different to the formulator of the [redacted] product. The UK CA has determined that the non-active components of Holzschutz-Imprägnierung aq. 9005 are equivalent to those used for [redacted] and therefore supports the use of the [redacted] PAR for this authorisation. (Please see Member State confidential annex for further details.)

- No new data have been provided on the product Holzschutz-Imprägnierung aq. 9005.

2.2 Product Type

PT8

2.3 Procedure for evaluation

Product authorisation

2.4 Classification and Labelling of the active ingredients

a) Propiconazole

The proposed classification of the active ingredient propiconazole in accordance with Annex VI of Regulation (EC) No 1272/2008 is:-

Classification	In accordance with Annex I of Directive 67/548/EEC	
Class of danger	Xn -	Harmful
	N -	Dangerous for the environment
R phrases	R22	Harmful if swallowed.
	R43	May cause sensitization by skin contact.
	R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

b) IPBC

The proposed classification of the active ingredient IPBC following evaluation at Annex I is:-

Classification	In accordance with Directive 67/548/EEC	
Class of danger	T -	Toxic
	N -	Dangerous for the environment
R phrases	R22	Harmful if swallowed.
	R23	Toxic by inhalation
	R37	Irritating to the respiratory system
	R41	Risk of serious damage to eyes
	R43	May cause sensitisation by skin contact
	R50*	Very toxic to aquatic organisms.

*There is still an outstanding question about risk phrase R53. As no common agreement between Member States could be achieved this has been sent to the C+L group for clarification.

2.4.1 Overall classification and labelling proposed for Holzschutz-Imprägnierung aq. 9005

Classification	In accordance with Annex I of Directive 67/548/EEC
Class of danger	-
R phrases	R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S phrases	S2: Keep out of reach of children* S23 : Do not breathe vapour and spray** S61: Avoid release to the environment. Refer to special instructions/Safety data sheets.

* for professional and non-professional users only

** Relevant for spray applications only

Once the harmonised classification for the active ingredient IPBC has been concluded the UK CA will re-examine the classification and labelling of these IPBC / Propiconazole based products.

2.5 Packaging

Non-professionals: lined metal or HDPE container up to 5 litres capacity.

Professionals: lined metal or HDPE container, up to 25 litres capacity.

Industrial users: lined metal or HDPE container, up to 1000 litres capacity.

3 PHYSICAL AND CHEMICAL PROPERTIES OF THE BIOCIDAL PRODUCT

A summary of the physical and chemical properties of the bioicdal product is given in the table below.

Study	Method	Result	Reference
Physical state and nature, colour and odour	-	White, homogeneous liquid free from visible suspended matter and sediment, with a chemical odour.	de Ryckel, June 2010
Explosive properties	-	Experience in use and contents indicate that the product should not be considered a hazard with respect to explosive properties.	-
Oxidising properties	-	Experience in use and contents indicate that the product should not be considered a hazard with respect to oxidising properties.	-
Flammability (Flash Point)	CIPAC MT 12.2	>79 ºC	de Ryckel, June 2010
Auto-flammability	EEC Method A.15	> 600 ºC	Mak, May 2010
pH	CIPAC MT 75.3	6.8 (dilution10% v/v) at 22°C	de Ryckel, June 2010
Acidity/alkalinity	CIPAC MT 191	Not conducted since pH is >4 and < 10	-
Density	EEC Method A.3	1.0022 g/mL (20°C)	de Ryckel, June 2010
Relative density	Calculation	1.0022	-

Study	Method	Result	Reference
Storage stability (1)			
Storage stability (8 weeks at 40ºC)	CIPAC MT 46.3	**Active content** **IPBC** **Pre storage** 0.2832% **Post storage** 0.2590% **Propiconazole** **Pre storage** 0.8682% **Post storage** 0.8736%	de Ryckel, May 2010
Appearance	-	**Pre storage** Homogeneous, opaque white liquid, free from sediments **Post storage** Homogeneous, opaque brown liquid, free from sediments	
Reactivity towards container material	CIPAC MT 46.3	No change of packaging was observed during the storage period, and no weight loss of product. However, small modification of appearance difference in colour between the level of product and the top of the box.	
Storage stability (2)			
Storage stability (7 days at 5°C) Appearance	-	**Pre storage** White opaque liquid, free from sediments **Post storage:** The test item is visually stable at low temperature.	de Ryckel, May 2010
Storage stability (3)			

Study	Method	Result	Reference
Storage stability (18 months at 20ºC)	CIPAC MT 46.3	**Active content** **Propiconazole** **Pre storage:** 0.8682% **12 months 0.**8796% **18 months** 0.8606% **IPBC** **Pre storage:** 0.2832% **12 months** 0.2643% **18 months** 0.2571%	de Ryckel, 2011 (interim report upto 18 month data)
Appearance	-	**Pre storage**: White, opaque liquid, free from sediments, chemical odour **12 months** No modifications of appearance **18 months** No modifications of appearance	-
Reactivity towards container material	-	**Pre storage**: Metallic box 115mL, metallic cap. No leaking during shaking. **12 months** No modifications of appearance or significant weight change. **18 months** No modifications of appearance or significant weight change.	-
Surface tension	EEC Method A.5	35.8 mN/m at 25°C 32.7 mN/m at 40°C	de Ryckel, 2010
Viscosity	CIPAC MT 192	Dynamic Viscosity 8.1 mPa.s (20°C) 6.0 mPa.s (40°C)	de Ryckel, 2010
Viscosity	Calculation	Kinematic Viscosity 1.2798 cSt (20°C) 0.8247 cSt (40°C)	de Ryckel, 2010
Particle size distribution	-	Not applicable since liquid formulation	-

The applicant has successfully demonstrated that the product remains stable for a period of 18 months.

3.1 Analytical Methods for Detection and Identification

3.1.1 Formulation analysis

The company have submitted details of an analytical method capable of measuring Propiconazole and IPBC in product formulations. The determination of the active ingredient is performed by HPLC with a UV detector at 230nm. The samples are extracted with Ethyl Acetate and diluted in Methanol and then analysed using a Hyperclone ODS, 3µm column.

Sample	Test substance	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			LOD	Reference
						Range	Mean	Rel. St. dev.		
[redacted]	Propiconazole	HPLC-UV	50, 100 and 150% / 2 at each level	31 -183 µg/ml R^2 = >0.999	No interferants	99.2 – 101.8	99.9	1.00	0.4603%	De Ryckel, 2010
			6 repeat sample injections			Day 1 96.0 – 96.6 Day 2 96.2 – 96.9	Day 1 96.3 Day 2 96.6	Day 1 0.25 Day 2 0.28		
	IPBC		50, 100 and 150% / 2 at each level	40 -195 µg/ml R^2 = >0.999		95.2 – 97.5%	96.1%	0.94%	0.1549%	
			6 repeat sample injections			Day 1 93.3 – 94.2 Day 2 94.0 – 95.5	Day 1 93.8 Day 2 95.0	Day 1 0.32 Day 2 0.60		

The method is satisfactorily validated in accordance with SANCO/3030/99 rev. 4.

3.1.2 Residue analysis

Analytical methods for the determination of Propiconazole and IPBC residues in relevant environmental media (soil, air, water), in animal and human body fluids and tissues and also treated food or feeding stuff have not been submitted for the bioicdal product since these points are already covered by the data set for the active substances which can be found in the Annex I Documents IIA, Section 1.4. Access to an analytical method for body fluids and tissues submitted with the IPBC PT6 dossier has also been granted.

Analytical methods for the determination of the active substance residues in/on food or feedstuffs are required if the active substance or the material with it is to be used in a manner which may cause contact with food or feedstuffs. Since [redacted] is not recommended for the treatment of wood in contact with food and feedstuffs, and as exposure to food and feedstuffs can be excluded when applied according to the recommended use, the UK CA believes it is justified to not require an analytical method for the determination of the active ingredient residues in/on food and feed/stuffs.

3.2 Risk characterisation for the physico-chemical properties

Propiconazole does not exhibit any hazardous physico-chemical properties. The substance is thermally stable and not highly flammable. It does not show any explosive or oxidising properties.

IPBC does not exhibit any hazardous physico-chemical properties. The substance is thermally stable and not highly flammable. It does not show any explosive or oxidising properties.

The product is not highly flammable and is not expected to have any explosive or oxidising properties. The product is water based ready-for-use and the co-formulants are not expected to be hazardous according to the available product data and supporting MSDS's. Therefore there is no risk expected from the formulated product with regards to the physico-chemical properties.

4 EFFICACY

4.1 FIELD OF USE ENVISAGED

[redacted] is a ready-to-use wood preservative for preventive use against wood discolouring fungi such as blue stain, moulds and sapstain, and wood rotting fungi, and preventive and curative use against dry rot.

The product contains 0.9 % propiconazole and 0.3 %% w/w 3-iodo-2-propynyl-n-butyl carbamate (IPBC). The product is for use on wood in outdoor environments above-ground in use classes 2 and 3, including the insides of wooden window frames and exterior doors.

The label claim is that the product is used against blue stain, decay fungi, sapstain and moulds. In addition, it can be used to control dry rot.

The product is applied by penetrative treatment i.e. vacuum pressure impregnation to give required retentions of 38.3 kg product m^{-3}. This is equivalent to 0.345 kg propiconazole m^{-3} and 0.115 kg IPBC m^{-3}, and thus equivalent to 0.46 kg total active substance m^{-3}.

The product is also applied by superficial treatments i.e. brushing, manual spraying, automated spraying, roller, low pressure deluge, dipping, flow coat and injection/surface treatments (for dry rot).

A total of 1 – 2 coats will be applied (1 – 3 for dry rot treatment) to give application rates of 80.0 – 160.0 g product m^{-2} (0.72 – 1.44 g propiconazole m^{-2} and 0.24 – 0.48 g IPBC m^{-2}).

When used against blue stain, the product should be used in conjunction with a subsequently applied top coat.

4.2 SUPPORTING DATA

The supporting data are summarised below.

4.2.2 WOOD DISCOLOURING FUNGI

In a study conducted according to test standard EN 152-1, [redacted] was tested for efficacy against blue stain fungi.

The results showed that, following treatment at an application rate of 80.0 g product m^{-2} (0.72 g propiconazole m^{-2} and 0.24 g IPBC m^{-2}), 3 of the treated blocks were rated 0 and 3 were rated 1, the minimum depth of blue stain-free zone was 2.0 mm and the mean depth of blue stain-free zone was 3.0 mm.

As the ratings were all < 2, and the minimum and mean depths of blue stain-free zones were > 1.0 and > 1.5 mm, respectively, the product passed the test.

In a second study conducted according to test standard EN 152-1, [redacted] was tested for efficacy against blue stain fungi.
The results showed that, following treatment at application rates of 160.0 g product m^{-2} (1.44 g propiconazole m^{-2} and 0.48 g IPBC m^{-2}), all of the treated blocks were rated 0, the minimum depth of blue stain-free zone was 2.0 mm and the mean depth of blue stain-free zone was 3.2 mm.

As the ratings were all < 2, and the minimum and mean depths of blue stain-free zones were > 1.0 and > 1.5 mm, respectively, the product passed the test.

4.2.3 WOOD ROTTING FUNGI

In a study conducted according to test standard EN 113, [redacted] was tested for efficacy against wood rotting basidiomycetes fungi.

The wood blocks used in the test were artificially aged according to EN 84.

The results showed that the biological reference values (b.r.v) were 0.40 kg total active substance m^{-3} (*Coniophora puteana*), 0.14 kg total active substance m^{-3} (*Oligoporus placenta*) and 0.39 kg total active substance m^{-3} (*Gloeophyllum trabeum*).

In a second study conducted to test standard EN 113, [redacted] was tested for efficacy against wood rotting basidiomycetes fungi.

The wood blocks used in the test were artificially aged according to EN 73.

The results showed that the b.r.v were 0.39 kg total active substance m^{-3} (*C. puteana*), 0.14 kg total active substance m^{-3} (*O. placenta*) and 0.21 kg total active substance m^{-3} (*G. trabeum*)

4.2.4 DRY ROT

In a stick test, [redacted] was tested for efficacy against 2 different strains of *Serpula lacrymans* (dry rot).

In the test, the product was applied at 2 different application rates i.e. 80.0 g product m^{-2} (equivalent to 0.72 g propiconazole m^{-2} and 0.24 g IPBC m^{-2}) and 160.0 g product m^{-2} (equivalent to 1.44 g propiconazole m^{-2} and 0.48 g IPBC m^{-2}).

For 80.0 g product m^{-2}, the results showed that, 1 week after exposure of the treated wood blocks to the actively growing *S. lacrymans* colonies, inhibition of mycelium growth, relative to the untreated control blocks, was observed. After 3 weeks, no mycelium growth was present on the treated blocks, with inhibition zones around the blocks of 0.5 and 1.2 mm for the 2 *S. lacrymans* strains, respectively. After the same period, > 50.0 % of the untreated blocks were covered with mycelium growth.

For 160.0 g product m^{-2}, the results showed that, 1 week after exposure of the treated wood blocks to the actively growing *S. lacrymans* colonies, inhibition of mycelium growth, relative to the untreated control blocks, was observed. After 3 weeks, no mycelium growth was present on the treated blocks, with inhibition zones around the blocks of 5.5 and 7.5 mm for the 2 *S. lacrymans* strains, respectively. After the same period, > 50.0 % of the untreated blocks were covered with mycelium growth.

4.3 DISCUSSION

4.3.2 WOOD DISCOLOURING FUNGI

The EN 152-1 results demonstrated the efficacy of [redacted] as a preventive wood preservative against blue stain at a minimum application rate of 80.0 g product m^{-2} (equivalent to 0.72 g propiconazole m^{-2} and 0.24 g IPBC m^{-2}).

The Applicant has indicated that the minimum application rate for the product is 80.0 g product m^{-2} (0.72 g propiconazole m^{-2} and 0.24 g IPBC m^{-2}). The results therefore support the application rates for the product.

The brush application method used in the test is a superficial treatment. Manual and automated spraying, surface injection, roller, low pressure deluge, dipping and flow coat, are

also superficial methods. In the UK CA's view, the results support all of the requested application methods.

The Applicant has indicated to the UK CA that the product is for use on Use Class 2 & 3 wood. On the basis of the TNsG on Product Authorisation, Appendices to Chapter 7, Product Type 8, Section 2.2.1, the submitted data meet the required criteria for Use Classes 2 & 3.

For the above reasons, the UK CA considers the data to be acceptable in support of [redacted]

4.3.3 WOOD ROTTING FUNGI

From European standard EN 599-1, the critical value (c.v.) is the highest b.r.v from all of the biological tests carried out. On this basis, the c.v. derived from the 2 tests conducted on [redacted] is 0.40 kg total active substance m^{-3} (400 g total active substance m^{-3}).

The Applicant has indicated that the retention required for the use of the product against wood rotting fungi by vacuum pressure impregnation is 0.46 kg total active substance m^{-3} i.e. 460.0 g total active substance m^{-3}. The results therefore support the required retention for the product.

The Applicant has indicated that [redacted] will also be applied as a superficial treatment against wood rotting fungi.

The minimum application rates for application by manual and automated spraying, surface injection, roller, low pressure deluge, dipping and flow coat, are 0.72 g propiconazole m^{-2} and 0.24 g IPBC m^{-2}. This gives an application rate of 0.96 g total active substance m^{-2} i.e. 960 mg total active substance m^{-2}.

Test standard EN 599-1 states (section 5.2.15) that, for superficial treatments, the b.r.v. in grams per square metre shall be deemed to be equivalent to twice the b.r.v. established in kilograms per cubic metre.

On this basis, the c.v. of 0.40 kg total active substance m^{-3} is equivalent to an application rate of 0.80 g total active substance m^{-2} i.e. 800 mg total active substance m^{-2}.

Therefore, as this value is below the minimum required application rate of 960 mg total active substance m^{-2}, the data supports the application rates for superficial treatment with [redacted]

The Applicant has indicated to the UK CA that the product is for use on Use Class 2 & 3 wood. On the basis of the TNsG on Product Authorisation, Appendices to Chapter 7, Product Type 8, Section 2.2.1, the submitted data meet the required criteria for Use Classes 2 & 3.

For the above reasons, the UK CA considers the data to be acceptable in support of [redacted]

The EN 113 standard stipulates that, for hardwood, the reference wood species is beech (*Fagus sylvatica*). As the tests were not conducted using *F. sylvatica*, the results do not support the use of the product as a penetrative and superficial treatment on hardwood against wood rotting fungi. This represents a gap in the data set in support of the efficacy of [redacted]

In the absence of supporting efficacy data on hardwood, suitable data demonstrating the efficacy of [redacted] against wood rotting fungi on hardwood, will need to be provided in support of the authorisation.

4.3.4 DRY ROT

The stick test results demonstrated the efficacy of [redacted] against dry rot at a minimum application rate of 80.0 g product m^{-2} (0.72 g propiconazole m^{-2} and 0.24 g IPBC m^{-2}).

The Applicant has indicated that the minimum application rate for the product is 80.0 g product m^{-2} (0.72 g propiconazole m^{-2} and 0.24 g IPBC m^{-2}). The results therefore support the application rates for the product.

The application method used in the test i.e. pipette, is a superficial treatment. In the UK CA's view, the application method requested for the product against dry rot i.e. surface injection/treatment, is also a superficial method. The results therefore support the requested application method.

The TNsG on Product Authorisation, Appendices to Chapter 7, Product Type 8, does not include efficacy requirements for wood preservatives against *S. lacrymans* (dry rot).

In the UK CA's view, as laboratory-based data are acceptable in support of the product authorisation of wood preservatives against wood rotting and staining fungi, so laboratory based data are acceptable in support of authorisation against dry rot. Therefore, as the UK CA considers the test methodology to be acceptable, the results are considered acceptable in support of the efficacy of [redacted] as a wood preservative against dry rot.

4.4 RECOMMENDATIONS

As the efficacy of [redacted] has been demonstrated, and the label claims supported, authorisation of the product should be granted.

However, in the absence of supporting efficacy data on hardwood, suitable information demonstrating the efficacy of [redacted] as a superficial treatment against wood rotting fungi on hardwood, will need to be provided post authorisation.

5 HUMAN EXPOSURE ASSESSMENT

5.1 INTENDED USES

[redacted] is a water based ready to use formulation for use as a wood preservative in industrial application techniques. The product contains 0.3% w/w IPBC and 0.9% w/w propiconazole. Industrial application is conducted via dipping (automated and manual), automated spraying, flow coating (deluge) and vacuum pressure. Professional users may apply the product both indoors and outdoors via brush/roller, spraying, manual dipping and surface injection. Non-professionals may apply the product both indoors and outdoors via brush/roller and spraying. The Applicant informs that the use rate of application is 80 - 160 ml/m^2, depending on application type and retention capacity of the wood. This equates to a maximum rate of 0.48 g IPBC/ m^2 and 1.44 g propiconazole/m^2 assuming a density of 1 g/ml. The proposed packaging can be found in section 2.3.2

Use of the 'risk envelope' approach can be applied by reference to the related product [redacted] is a water based ready to use formulation for use as a wood preservative in industrial application techniques and also by professionals and non professionals. The product contains 0.60% w/w IPBC and 1.2% w/w propiconazole. Industrial application is conducted via automated spraying, flow coating (deluge)/flow tunnel/vacuumat and via manual dipping in small scale operations. Professionals and non professionals may apply the product both indoors and outdoors via brushing and spraying and professionals via injection technique (indoors). The maximum application rate of [redacted] is equivalent to 140 g/$m^{2,}$ which equates to a maximum rate of 0.84 g IPBC/ m^2 and 1.68 g propiconazole/m^2.
[redacted] has recently been assessed under BPD ([redacted] and, as it represents a worse case with regard to the rate of application of IPBC and propiconazole, it is possible to extrapolate most of the exposure scenarios to [redacted] a comparison of which is shown in Table 5.1 (a copy of the human health risk assessment conducted for [redacted] can be found in Annex B of this document). Based on this comparison it is only necessary to consider for [redacted] the additional scenarios relating to vacuum pressure and automated dipping processes. In addition, the exposure arising from use of [redacted] via indoor brush application was not considered acceptable as predicted exposure to IPBC exceeded the AEL. This scenario will be reconsidered at the reduced dose arising from the use of [redacted]

Table 5.1 : Comparison of primary exposure scenarios relevant to [redacted] and [redacted]

User	**Exposure scenario**	[redacted]	[redacted]
Industrial	Flow coating (deluge)	Yes	Yes
	Automated spraying	Yes	Yes
	Vacuum pressure	No	Yes
	Automated dipping	No	Yes
	Manual dipping	Yes	Yes
	Handling treated wet wood	Yes	Yes
	Cleaning out dipping tank	Yes	Yes
Professional	Brush application (indoors and outdoors)	Yes	Yes
	Cleaning brush	Yes	Yes
	Handling treated wet wood	Yes	Yes
	Spraying (indoors and outdoors)	Yes	Yes
	Injection	Yes	Yes
	Manual dipping (covered by industrial manual dipping assessment)	No	Yes
Non professional	Brush application (indoors and outdoors)	Yes	Yes
	Spraying (indoors and outdoors)	Yes	Yes

5.1.1 Primary exposures

Assumptions used in the estimations of exposure:

- Adult body weight: 60 kg;
- clothing penetration: 10% for coated coveralls and 5% for impermeable coveralls (Manual Of Technical Agreements 4.2.9.9)
- inhalation rate: 1.25 m^3/h, inhaled uptake 100% (User Guidance, p.45)
- density of formulation taken as 1.0 mg/ml for water based formulations.
- dermal penetration for propiconazole 2.0%
- dermal penetration for IPBC 30.0%
- given that this product includes industrial/professional use, PPE has been included where appropriate

5.1.1.1 Primary exposures – Industrial

5.1.1.1.1 Industrial – vacuum pressure

Mixing and loading: Exposure is not normally expected. Reference : User Guidance p. 41 Handling during industrial wood preservation, Model 1, water based process – TNsG 2002, Part 2, p. 160 as revised by the User Guidance p. 26, 40 and 41 for which three cycles per day and three hours per cycle is stated. Indicative exposure values take into account the patterns of use and exposure data when multiple cycles of the same work are carried out on the same day. Given the indicative exposure values are expressed as mg/cycle it is considered appropriate to calculate exposure using the per cycle per method rather than duration of exposure as used by the Applicant. In addition, the Applicant has estimated exposure based on a working day of 360 minutes, but it is not stated how this value has been derived given the default value in BEAT is 540 minutes (i.e. 3 cycles x 180 minutes per cycle)

Indicative (75^{th} percentile) exposure values are as follows:

Hands: 1080 mg/cycle
Body: 8570 mg/cycle
Inhalation : 1.9 mg/m^3

Using these values, total systemic exposures were predicted to be as follows, with the detailed calculations presented in Appendices A1.1 to 1.2

Coated coveralls and gloves **IPBC - 0.0882 mg/kg bw/day**
propiconazole – 0.0206 mg/kg bw/d

The Applicant has also considered exposure arising from cleaning the system, however, the levels of exposure arising from this activity are considered to be within those considered for [redacted] (cleaning of dipping tanks) for which levels of exposure were considered acceptable.

5.1.1.1.2 Industrial – automated dipping

In TM III 2009 HEEG agreed that for automated dipping processes using a fork-lift it is appropriate to use Handling Model 1 (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.

Indicative (75^{th} percentile) exposure values are as follows:

Hands: 1080 mg/cycle
Body: 8570 mg/cycle
Inhalation : 1.9 mg/m^3

Using these values, total systemic exposures were predicted to be as follows, with the detailed calculations presented in Appendices A1.3 to 1.4

Coated coveralls and gloves **IPBC - 0.1162 mg/kg bw/day**
propiconazole – 0.0232 mg/kg bw/d

5.1.1.1 Primary exposures – Professional

These are within the risk envelope of [redacted] and no further consideration is necessary.

5.1.1.2 Primary Exposures – Non Professional

With the exception of indoor brush application for which the estimated exposure to IPBC was in excess of the AEL, all other uses are within the risk envelope of [redacted] and no further consideration is necessary.

5.1.1.3.1 Non professional brush and roller application (indoors)

The product can be applied indoors on joists and floorboards in potentially cramped and poorly ventilated areas. The Consumer product painting, Model 1: TNsG 2002, Part 2, p. 200 and User Guide p. 28 is considered a suitable surrogate for indoor application. This model includes exposure arising from decanting the product from the tin and as this is a ready to use product no other consideration of mixing and loading is required. User Guidance p. 47; indicates that non professionals would undertake sessions of up to 150 minutes painting once or twice a year. A Tier 2 assessment has been undertaken for which 50% protection is assumed from individuals wearing shirt, trousers and shoes during application (MOTA 4.2.9.9).

Indicative (75th percentile) exposure values are as follows:

Hands/forearms: 150 mg/min
Legs/feet/face: 35.7 mg/min
Inhalation : 3.1 mg/m^3

Using these values, total systemic exposures were predicted to be as follows, with the detailed calculations presented in Appendices A1.3 to 1.4

Shirt, trousers and shoes IPBC - 0.3781 mg/kg bw/day

5.1.1.1 Summary of primary exposures

The calculations in Annex A A1.1 to A1.4 give the potential exposures from application of [redacted] These are summarised in Table 5.2

Table 5.2 summary of primary exposure

Exposure Scenario	Total Systemic dose (mg kg/bw/d)		PPE
	IPBC 0.3% w/w	Propiconazole 0.9% w/w	
Industrial vacuum pressure	0.0882	0.0206	Coated coveralls (10% penetration), gloves and boots
Industrial automated dipping	0.1162	0.0232	Coated coveralls (10% penetration), gloves and boots
Non professional	0.3781	-	Shirt, trousers and shoes (50%

brush application (indoors)			penetration)

5.1.2 Secondary (indirect) exposures

Secondary exposures occur as a result of treated timber being used in areas accessible to professionals and non-professionals (including children). The table below details possible routes of exposure and identifies those arising from the proposed use of [redacted] in comparison with the reference product [redacted] for which the rate of application and concentration of actives in the formulation are the same or greater and for which acceptable levels of secondary exposure have been established.

Table 5.3 Summary of secondary exposure scenarios

Secondary exposure scenario		[redacted]	[redacted]
Acute	Adult non professional sanding treated wood	Yes	Yes
	Infant chewing wood	Yes	Yes
Chronic	Adult professional sanding treated wood	Yes	Yes
	Adult cleaning work clothes at home	Yes	Yes
	Adult, child and infant inhalation of volatilised residues indoors.	Yes	Yes
	Children playing on weathered playground structure and mouthing	Yes	Yes

6 HUMAN HEALTH EFECTS ASSESSMENT

No specific studies have been generated to support [redacted] with regard to acute toxicity, irritation and sensitisation. However, in the interests of animal welfare the UK CA agree that the toxicological properties and classification can be deduced using the known properties of the active substance (appropriate Letters of Access are available), and the non-active components of the product and so accept the applicant's position.

6.1 PERCUTANEOUS ABSORPTION

No studies on the dermal absorption of [redacted] were performed. The required data has been derived from the Annex I evaluation as follows:

Propiconazole

The applicant has proposed the use of a dermal absorption value of 2% for exposure to treating (ready-to-use) formulations (please refer to Annex I Doc IIIB 6.4.). The UK CA agrees with this proposed value.

IPBC

The applicant has proposed the use of a value of 30 % dermal penetration for IPBC to support the [redacted] product representing a reasonable worst case assumption for a water based formulation (please refer to Annex I Doc IIIB 6.4). The UK CA agrees with this proposed value.

6.2 ACUTE TOXICTY

The acute toxicity of the product [redacted] has not been investigated experimentally. A complete data package on the toxicity of both active ingredients are available from the Annex I evaluations. The toxicological relevance of the exposure can therefore be extrapolated from the information on the active substances, together with data available on the co-formulants (e.g. from MSDSs).

According to EC Directive 1999/45 on the classification, labelling and packaging of dangerous preparations, no classification and labelling of the biocidal products with regard to its acute oral, dermal or inhalation toxicity is required.

6.3 IRRITATION AND CORROSIVITY

The acute irritating/corrosive effects to the skin or eyes of the product [redacted] have not been investigated experimentally.

Based on the results of the skin and eye irritation studies with the active substances, information on the hazards of the key co-formulants and their compositions, [redacted] frame is not predicted to be a skin or eye irritant.

According to EC Directive 1999/45 on the classification, labelling and packaging of dangerous preparations, no classification and labelling of the biocidal products with regard to irritating/corrosive effects to skin or eyes is required.

6.4 SENSITISATION

The potential to induce delayed hypersensitivity on dermal contact of the product [redacted] has not been investigated experimentally.

Data has been extrapolated from the information on the active substances, together with data available on the co-formulants (e.g. from MSDSs).

According to EC Directive 1999/45 on the classification, labelling and packaging of dangerous preparations, no classification and labelling of the biocidal product with regard to sensitizing effects to skin is required.

However, based on the results of the sensitisation studies with the active substances, the following text will be added to the [redacted] label.

"Contains Propiconazole and IPBC. May cause an allergic reaction."

7 RISK CHARACTERISATION FOR HUMAN HEALTH

7.1 TOXICOLOGICAL ENDPOINTS

7.1.1 Active ingredients

a) Propiconazole

Propiconazole is moderately toxic with an oral acute LD_{50} of 1500 mg/kg bw/day. Propiconazole is a skin sensitizer.

Liver toxicity is the most critical effect of Propiconazole. Increased liver weights and slight histopathological changes in the liver were seen in short term studies. Mice were more sensitive than rats to the liver toxicity elicited by Propiconazole; male mice were particularly susceptible to hepatotoxicity. In long-term feeding studies neoplastic changes of the liver including mainly adenomas but not carcinomas were observed in male mice. Mechanistic

studies indicate that Propiconazole is a phenobarbital-like hepatotoxic substance. Propiconazole is a strong inducer of xenobiotic metabolism and a tumour promoter in rodents, which probably explains the induction of tumours in mice. It may be presumed that rodents are more susceptible than humans to the hepatotoxicity of Propiconazole. The lowest relevant NOAEL was 3.6 mg/kg bw/day from a 2-year study in rat.

A slight increase in the incidence of cleft palate was observed in rat teratogenicity studies. The low incidences of this rare malformation were not clearly treatment-related and occurred at dose levels causing marked maternal toxicity. It was therefore concluded that the effect seen in rats is probably occasional. The lowest relevant NOAEL for developmental effects was 30 mg/kg bw/day in rats, based on a slight increase in cleft palate and increased visceral and skeletal variations in a teratology study in rat.

Results of a two-generation study in rats included, in addition to hepatotoxicity in parental animals at low dose levels, slight reproductive effects at a high dose (reduced litter sizes and pup weights, reductions in testes/epididymides weights). The lowest relevant NOAEL for effects on fertility was 8 mg/kg bw/day from a 2-generation study, based on reduced litter size, pup weight and viability.

b) IPBC

The potential human health effects of IPBC have been well investigated, almost exclusively in experimental animals. IPBC is of moderate acute toxicity by the oral route (R22) and of low acute toxicity by the dermal routes of exposure but has high acute toxicity by the inhalation route. The data support classification of IPBC for acute toxicity by the inhalation route (T, R23). IPBC is not a skin irritant, but does exhibit the potential to produce severe eye irritation. In animal studies, IPBC met the criteria for classification as a severe eye irritant. There is evidence that IPBC can cause some respiratory tract irritation; however, the strength of evidence does not meet the EU criteria for classification for this endpoint.

Positive findings from guinea pig sensitisation studies (GPMTs) indicate that IPBC has skin sensitisation potential (R43).

Following repeated oral administration of IPBC post-dose salivation was observed immediately after dosing by gavage with 30 mg/kg bw/day, but not when IPBC was administered via the diet. Food consumption was reduced from 80 mg/kg bw/day (dietary, gavage) and body weights and/or body weight gains from 40 mg/kg bw/day (dietary) or 80 mg/kg bw/day (gavage). Brain and RBC cholinesterase activities were not reduced up to and including the highest dose level administered. Local erosions, ulceration, and/or inflammation of the stomach (forestomach and/or glandular stomach) were observed from about 20 to 30 mg/kg bw/day (dietary, gavage). Increased liver weights, sometimes accompanied by

hepatocellular changes, and increased kidney weight (females only) were observed from 30 to 40 mg/kg bw/day. Increased incidence in foamy macrophages aggregates was noted in the lungs of male rats from 40 mg/kg bw/day in the 2-year study. In the 78-week mice study, an increased incidence in enlarged thyroids accompanied by foci of small vacuolated cells most likely of follicular origin and general follicular enlargement was noted at 150 mg/kg bw/day; the toxicological significance of these findings in thyroids remains unclear.

Following repeated dermal administration to rats dermal irritation persisting throughout the treatment period, and hyperkeratosis and ulceration was observed at 500 mg/kg bw/day; at 200 mg/kg bw/day, mild hyperkeratosis. No adverse systemic effects were observed.

Following repeated inhalation to rats decreased RBC cholinesterase activity observed in females at 6.7 mg/m^3 and decreased brain cholinesterase activities in females from 1.16 mg/m^3 and in males at 6.7 mg/m^3. Histopathological findings were epithelial hyperplasia in the central region of the larynx, hyperplasia or squamous metaplasia in the ventrolateral region of the larynx, and necrosis of the underlying cartilage of the larynx from 1 mg/m^3.

IPBC was not neurotoxic when administered via the oral route.

The weight of evidence from the available well-conducted *in vitro* and *in vivo* genotoxicity studies indicates that IPBC is not genotoxic substance.

IPBC was not carcinogenic in rats and mice up to and including the highest dose levels tested (80 and 150 mg/kg bw/day for rats and mice, respectively).

In experimental animal studies IPBC did not affect fertility and did not cause developmental toxicity. The evidence suggests that this substance does not possess significant potential with respect to toxicity to reproduction.

7.1.2 Toxicological reference doses

Two reference doses for the systemic toxicity of Propiconazole and IPBC should be defined, with relevance to the assessment of risks associated with exposure to a wood preservative. The risks are related to the length of exposure and take into account the most relevant adverse health effects expected on the basis of animal studies. The reference values are applicable to both direct exposure in professional and non-professional use, as well as indirect exposure to the treated products.

Correction for bioavailability was not considered necessary at Annex I

The reference values are based on systemic NOAELs from oral studies in experimental animals as follows:

Propiconazole:

With regard to long-term (chronic) exposure an **AEL $_{\text{long-term}}$ = 0.08 mg/kg bw/d** based on the NOAEL of the 2-generation rat study (8 mg/kg bw/d) with a safety factor of 100.

With regard to short-term (acute) exposure an **AEL $_{\text{short-term}}$ = 0.30 mg/kg bw/d** based on the NOAEL of the developmental toxicity study in rats (30 mg/kg bw/d) with a safety factor of 100.

IPBC:

With regard to long-term (chronic) exposure an **AEL $_{\text{long-term}}$ = 0.20 mg/kg bw/d** based on the NOAEL of the 2-year chronic toxicity/carcinogenicity study in rats (20 mg/kg bw/d) with a safety factor of 100.

With regard to short-term (acute) exposure an **AEL $_{\text{short-term}}$ = 0.35 mg/kg bw/d** based on the NOAEL of the 90-day subchronic oral toxicity study in rats (35 mg/kg bw/d) with a safety factor of 100.

7.1.3 Combination toxicity

There is currently no agreed methodology for performing a combined risk assessment of multi-active biocidal products. A proposal from the French CA is due to be discussed and agreed at TM level. Once a methodology is agreed by all Member States and included in the manual for Product Authorisation, a harmonised approach on how to implement this requirement for multi-active products already authorised should be considered.

7.1.4 Product formulations

Based on the information available on the active substances and of co-formulants, the product [redacted] will not require acute toxicity classification. The product does not meet the EU criteria for classification as harmful if swallowed, by inhalation or dermal contact, nor does it require classification as a skin irritant, eye irritant or a skin sensitizer, and as such these endpoints are not considered further in the risk assessment.

However, based on the results of the sensitisation studies with the active substances, the following text will be added to the [redacted] label.

"Contains, Propiconazole and IPBC. May cause an allergic reaction."

For potential substances of concern to human health contained in [redacted] see Confidential Annex.

7.2 RISK CHARACTERISATION FOR THE PRODUCT

7.2.1 primary exposure

A summary of the results of the risk characterisation for primary exposure of [redacted] for those uses outside the risk envelope (i.e. those uses not covered by the [redacted] assessment in Annex B of this document) is presented in Table 7.2.1.

Table 7.2.1 Summary of results of risk characterisation for primary exposure

Scenario	PPE	AEL (mg/kg bw/day)	Systemic dose (mg/kg bw/day)	% AEL
IPBC				
Industrial vacuum pressure	Coated coveralls (10% penetration), gloves and boots	0.2	0.0882	44
Industrial automated dipping	Coated coveralls (10% penetration), gloves and boots	0.2	0.1162	58
Non professional brush application (indoors)	Shirt, trousers and shoes (50% penetration).	0.35	0.3781	108
Propiconazole				
Industrial vacuum pressure	Coated coveralls (10% penetration), gloves and boots	0.08	0.0206	26
Industrial automated dipping	Coated coveralls (10% penetration), gloves and boots	0.08	0.0232	29

The proposed use of [redacted] via brush application by non professionals in indoor situations exceeds the short term AEL for IPBC. It is noted, however, that the short term AEL was derived from a 90 day rat study in which critical effects of decreased bodyweight and increased organ weight occurred over the duration of the study and not after one or two exposure events as anticipated for this application scenario. In the absence of an acute AEL, exposure arising from [redacted] s considered to be sufficiently close to the short term AEL to be considered acceptable. All other uses do not exceed the relevant AELs for propiconazole and IPBC when recommended PPE are worn and product authorisation is therefore recommended.

7.2.2 Secondary exposure

All secondary exposure scenarios have been assessed for the product [redacted] please see Annex B of this document). The AELs for both propiconazole and IPBC are not reached. This product is therefore recommended for product authorisation

8. ENVIRONMENTAL RISK ASSESSMENT

8.1 ENVIRONMENTAL EXPOSURE ASSESSMENT

The following risk assessment for the environment has been submitted by the applicant and reviewed by the UK CA. Any comments made by the UK CA, together with our assessment of any new data submitted with the product application, have been added to each section in the green boxes.

8.1.1 Fate and distribution in the environment

From the Competent Authority Report for **Propiconazole** (December 2007, Rapporteur : Finland), the following environmental half-lives are derived for the purposes of risk assessment :

Water – disspipation half-life of 6.4 days

Sediment - degradation half-life of 1206 days

Soil - dissipation half-life of 129 days

Log K_{ow} of propiconazole was 3.7 at 25 °C and pH 6.6. BCF of propiconazole was 180. The BCF for soil dwelling species was estimated to be 64.

From the Competent Authority Report for **IPBC** (February 2008, Rapporteur : Denmark), the following environmental half-lives are derived for the purposes of risk assessment :

Water – degradation half-life of 3.1 hours

Sediment - degradation half-life of 3.3 hours

Soil - dissipation half-life of 4.7 hours

Log K_{ow} of IPBC was 2.81 at 25°C. BCF of propiconazole was 180.

8.1.2 EMISSION TO Environmental Compartments

8.1.2.1 Emission scenarios

UK CA : Product application - water based formulation

- Contains 0.3 % of IPBC plus 0.9 % of propiconazole
- Product relative density of 1.0022 (reported at 20 °C)

Product application rate stated by applicant as 80 - 160 g m^{-2} to achieve required effectiveness and this equates to maximum application rates of 480 mg m^{-2} for IPBC and 1440 mg m^{-2} for propiconazole.

Product applied by industrial operators using vacuum-pressure impregnation, dip, flowcoat (deluge / vacumat) and automated spraying ;
Product applied by professional operators using brush / roller, spray (coarse low pressure), dip and surface injection ;
Product applied by non-professionals using brush / roller and spray (coarse low pressure).

Mention of application to exterior timbers (generally with vertical orientation) where exposed to weathering but not in ground contact – it is anticipated that treated wood will then be finished with a decorative varnish, lacquer or paint. The risk assessment has been undertaken by the UK CA on the basis of the above listed information.

Issue with AR for propiconazole such that UC 3 is unacceptable due to risks to soil, sediment and surface waters so leaching data required to refine PEC/PNECs demonstrated in EU review document.

It should be noted that leaching study data have only been provided to address leaching of propiconazole from superficially treated wood and therefore use of the product by penetrative means (vacuum-pressure impregnation) would be considered unacceptable.

The environmental exposure assessment of [redacted] has been determined with the Emission Scenario Document (ESD) developed for product type 8 (wood preservatives) by OECD: OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Emission Scenario Document for Wood Preservatives. The emission scenarios estimate the emission of wood preservatives from the following stages of their life cycle :

1. - application and storage of treated wood prior to shipment
2. - in situ treatment of wood
3. - treated wood in service

Several relevant emission scenarios have been identified based on intended uses.

1. - In the case of application and storage of treated wood prior to shipment, the Annex 1 inclusion directives for both propiconazole (Commission Directive 2008/78/EC) and IPBC (Commission Directive 2008/79/EC) include the following specific provision.

"In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal."

Furthermore, in the Competent Authority Report for Propiconazole (December 2007, Rapporteur : Finland), it is confirmed that
"*application solutions must be collected and reused or disposed of as hazardous waste and they must not be released to soil, surface water or any kind of sewer."*
The Competent Authority Report also notes that
"These requirements may be determined in detail in the environmental permits of the application plants on the basis of the Council Directive 96/61/EC on Integrated Pollution Prevention and Control (IPPC) but should be listed in the instructions for use of a biocidal product."

Similarly, in the Assessment Report for IPBC (December 2008, Rapporteur : Denmark), it is confirmed that
"*According to the EU waste legislation waste from wood preservative products and application solutions are considered hazardous waste. Therefore, application solutions must be collected and reused or disposed of as hazardous waste and they must not be released to soil, surface water or any kind of sewer."*
The Assessment Report also notes that
"These requirements may actually be determined in detail in the environmental permits of the application plants on the basis of the Council Directive 96/61/EC on Integrated Pollution Prevention and Control (IPPC) but should be listed in the instructions for use of a biocidal product.".

On the basis of the above provisions, no further assessment of emissions from industrial treatment processes using [redacted] and subsequent storage of treated wood, has

been undertaken. The appropriate instructions are included in the safety data sheet for [redacted]

2. - In the case of professional and amateur <u>in situ treatments</u> – Brushing and spraying outdoors – the following scenarios have been run for [redacted] n hazard class 3 :

Brushing outdoors – House, fence (PT8)
Spraying outdoors – treatment of a façade (adapted from PT10)

3. - In the case of <u>treated wood in service</u>, the following emission scenarios have been run for [redacted] for hazard class 3:

- House
- Fence
- Noise barrier
- Bridge over pond

Detailed calculations of PEC values, based on the Emission Scenario Documents are in Appendices 2 and 3 to this document . All PEC calculations are based on the maximum recommended application rates of 1.44 g/m^2 Propiconazole and 0.48 g/m^2 IPBC(superficial application) and 345 g/m^3 Propiconazole and 115 g/m^3 IPBC (impregnation). Where lower application rates are employed (e,g, to fulfil a lesser claim), it may be assumed that PEC values will be proportionately lower.

[redacted] is not used as such for the treatment of wood in contact with ground (hazard class 4a) fresh water (hazard class 4b) and wood permanently exposed to salt water (hazard class 5).
The exposed environmental compartments that may potentially be impacted by the normal use of [redacted] are :

	Air (outdoors)	Sewage treatment plant	Surface water and sediment	Soil	Ground Water[1]

Treated wood in service	No	✓[2]	✓[2]	✓	✓
In-situ treatment	No	✓[2]	✓[2]	✓	✓

[1] Indirect exposure via leaching of the substance in soil

[2] Noise barrier scenario

Environmental emission from application by brushing, spraying or injection of [redacted] indoors is considered not to occur. According to OECD ESD potential emissions from hazard class 2 wood in service to the outer environment are considered negligible and therefore no PECs are calculated for HC 2 wood in service.

OECD Emission Scenarios provide estimation of the local concentration based on the use of a wood preservative. Concerning production and formulation, the manufacture of [redacted] is only carried out in industrial premises which are controlled by various higher tier EU regulations which ensure that no unacceptable effect upon the environment may occur. In this document therefore, the evaluation of the manufacture of the biocidal product is not evaluated.

It is most unlikely that [redacted] wastes containing propiconazole and IPBC will result in an environmental risk during incineration under controlled conditions required in the waste legislation, and this view is confirmed in the respective Assessment Reports for the two active substances. The active substance emissions from a landfill site due to disposal of treated wood are evaluated to be less significant than that described for the house scenario for wood in service during the period from up to 20 years because the amount of treated wood per m^2 soil is assumed to be less. Therefore, it is unlikely that treated timber wastes will result in an environmental risk from a normal landfill site. If treated wood is collected and disposed in special areas of a landfill it is assumed that special precaution has been taken for this part of the landfill.

8.1.2.2 LEACHING FROM TREATED WOOD

8.1.2.2.1 Leaching study and related extrapolations

The leaching profile of propiconazole in [redacted] was studied in a laboratory trial, according to CEN TS 15119-1, in which treated blocks were subjected to repeated immersion in water.
The treated blocks were protected with a surface coating.

The blocks were treated with [redacted] in the laboratory, by brush treatment, at an application level to achieve 1.44 g/m^2 propiconazole, and were then dried/conditioned at room temperature for one week before the top coat was applied. The blocks were then further conditioned at room temperature for approximately two weeks before the leaching test was commenced.

The blocks were immersed in water according to the schedule :

3 x 1 minute immersions per immersion day

9 immersion days over a period of 19 days

On each immersion day, the three water samples were pooled for analysis. After analysis, the concentration of propiconazole in ng/ml was converted to mg/m^2 of wood.

A graph of cumulative leaching (mg/m^2) vs. time was plotted for each application, and a trend line was fitted using the functionality within Microsoft Excel in the form Qc = a + b * ln (T), where

Qc = cumulative quantity leached (mg/m^2)

T = time (days).

Using the derived terms a and b, the trend line was extrapolated to cover the maximum service life proposed (20 years, for vacuum-pressure/double-vacuum treated timber items). From the cumulative quantity leached at the appropriate time point, the average daily emission from treated wood, in mg propiconazole/m^2, was calculated for :

30 days - Time 1

1825 days - default service life for brush treated wood

5475 days - default service life for automated spray/dip treated wood

7300 days - default service life for vacuum-pressure/double-vacuum treated wood

In each case, the average daily emission was adjusted by an assessment factor of 10, in line with the recommendations of the Arona Leaching Conference of 2005.

The following short term (30 day) daily leaching value was determined :

Brush application (1.44 g/m^2):	4.33E-07 g/m^2/day
Dip application (1.44 g/m^2):	4.33E-07g/m^2/day(*)
Vac-pressure application (345 g/m^3):	2.99E-07 g/m^2/day(*)

(*) It is assumed that the daily leaching values for dipping and impregnating applications (vacuum-pressure treatment), at an equivalent application rate (conversion factor from EN 599-1) will be no higher than the value for brush treatment.
The following long term daily leaching values were determined :

1825 days
Brush application (1.44 g/m^2): 1.57E-08 g/m^2/day

5475 days
Dip application (1.44 g/m^2): 6.00E-09 g/m^2/day

7300 days
VP/DV application (345 g/m^3): 3.21E-09 g/m^2/day

With regard to IPBC, for the purposes of risk assessment it is assumed as a worst-case that all of the applied IPBC will leach from the treated wood during the service life of the wooden article.

Thus, at an application level to achieve 0.48 g/m^2 IPBC, the following daily leaching values can be determined:

30 days
All application methods 1.60E-02 g/m^2/day

1825 days
Brush application (0.48 g/m^2): 2.63E-04 g/m^2/day

5475 days
Dip application (0.48 g/m^2): 8.77E-05 g/m^2/day

7300 days
VP/DV application (240 g/m^3): 6.58E-05 g/m^2/day

UK CA : Initially, the Applicant submitted a laboratory 3 x 1 minute leaching test (CEN TS 15119-1) which for reasons outlined below was found to be unacceptable for use in risk assessment. However, the Applicant has additionally submitted an interim report for a semi-field leaching test based on NT 509, which the UK CA considers will provide more realistic data for risk assessment purposes.

Test material in semi-field NT 509 leaching study is [redacted] formulation which is reported as containing IPBC (0.3%) and propiconazole (0.9%) - water based formulation (no correction to test results required for composition). Any correction of test results should

be due to application rate discrepancies compared to that proposed for the marketed product: maximum of 160 g m^{-2}.

Application method for semi-field leaching interim studies (report No. 11047 and 11050): brush, which is likely to be worst case and over-predict for other methods. Therefore, it can be used to cover all proposed superficial application methods. However, as set out in the Arona leaching workshop 2005, superficial tests cannot be used to read across to penetrative tests and *vice versa*. This means that there is insufficient data for any risk assessment to be carried out regarding treatments using vacuum-pressure impregnation.

Vertical planks: mean retention rate (3 samples) of 160 ml m^{-2} of product was reported so 160 g m^{-2}: equates to 0.48 g m^{-2} of IPBC and 1.44 g m^{-2} of propiconazole.
(*Sets 1, 2 and 3 all gave values of 160 ml m^{-2}*)

2 studies have been conducted : one using [redacted] (report no. 11047) on its own and one using [redacted] followed by overcoating with a commercially available topcoat, Delta Futura Venti Satin (acrylic dispersion, 50% solids content) – applied as 3 brushed coats for optimal finish (report no. 11050).

Studies are reported to have been ongoing for 490 (no. 11047) and 259 (no. 11050) consecutive days at the time reports were written, with specific planned sampling points based on rainfall volume resulting in total collection of 1145 and 682.9 mm of rainfall respectively. Assuming normalised annual EU rainfall of 700 mm, this is equivalent to leaching over a period of 597.0 and 356.1 days (based on the calculation of {rainfall mm / 700 mm} x 365 d).

8.1.2.3 EFFECT OF RE-APPLICATION

Re-application of [redacted] during service-life would have the effect of increasing PEC values. The effect of re-application is discussed further in section 8.2 risk characterisation

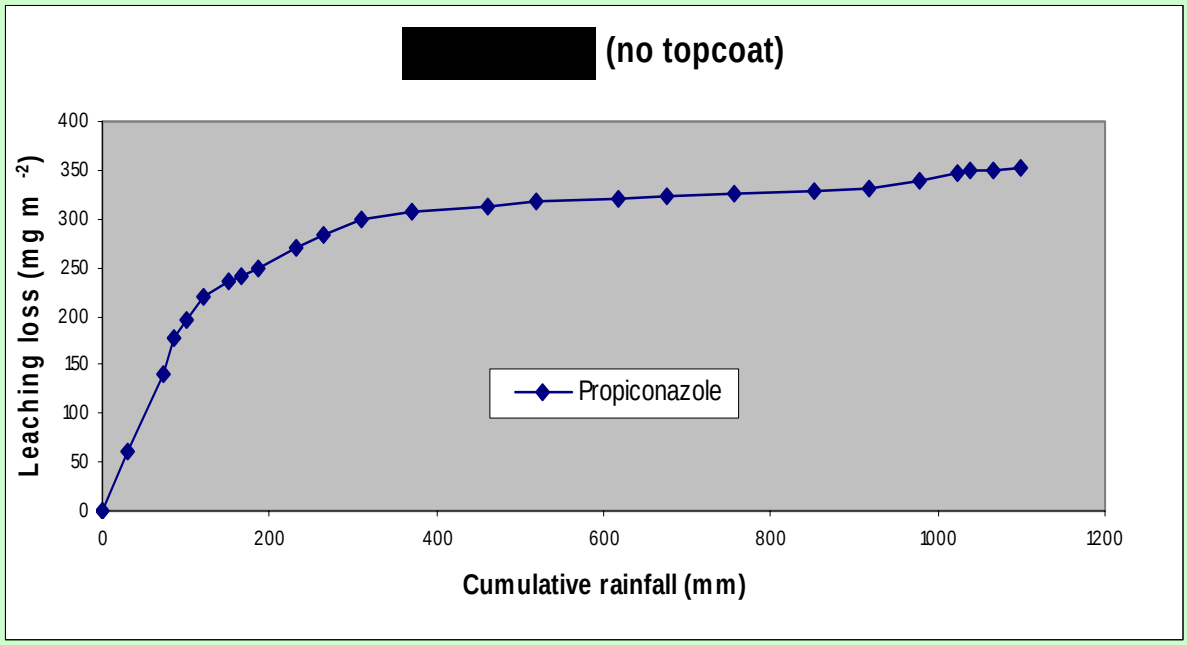
UK CA : Additional semi-field studies provided by the Applicant are summarised as follows :-

1) Propiconazole leaching from vertical surfaces : non topcoated timber (Test no. 11047)

Date	Rainfall (mm)	Mean propiconazole (mg m^{-2})	Total mean propiconazole (mg m^{-2})
04.11.09 - 10.11.09	29	60.37	60.37

11.11.09 - 23.11.09	72.1	80.56	140.93
24.11.09 - 24.11.09	86.1	35.83	176.76
25.11.09 - 27.11.09	101.1	18.65	195.41
28.11.09 - 30.11.09	122.1	23.93	219.34
01.12.09 - 07.12.09	150.2	15.32	234.66
08.12.09 - 14.12.09	166.2	5.84	240.5
15.12.09 - 04.01.10	187.2	9.28	249.78
05.01.10 - 02.02.10	231.2	20.1	269.88
03.02.10 - 23.02.10	265.2	13.85	283.73
24.02.10 - 01.03.10	310.2	15.58	299.31
02.03.10 - 01.04.10	370.2	9.18	308.49
02.04.10 - 21.06.10	462.2	3.8	312.29
22.06.10 - 15.07.10	518.2	5.99	318.28
16.07.10 – 17.08.10	616.7	1.62	319.9
18.08.10 – 27.08.10	675.2	2.45	322.35
28.08.10 – 16.09.10	755.2	2.42	324.77
17.09.10 – 22.10.10	851.7	2.51	327.28
23.10.10 – 10.11.10	917.7	4.7	331.98
11.11.10 – 14.11.10	977.7	6.96	338.94
15.11.10 – 03.01.11	1023.1	0*	338.94
04.01.11 – 12.01.11	1053.3	6.89	345.83
13.01.11 – 20.01.11	1083.7	2.72	348.55
21.01.11 – 14.02.11	1112.1	2.1	350.65
15.02.11 – 08.03.11	1145.1	0.98	351.63

* Sample lost



Therefore, on day 490, the total accumulated rainfall was measured as 1145.1 mm and the average (n=3) accumulated amount of leached propiconazole in that period was determined as 351.63 mg m^{-2} from vertical surfaces. However, at 1023.1 mm rain, the sample was lost so, in the interests of accuracy, the amount of rainfall between 14.11.10 - 03.01.11 has been discounted to reduce the total cumulative volume of rainfall down to 1099.7 mm.

On the basis that mean total leaching loss is based on 1099.7 mm of rainfall (equivalent to 573.4 d if 700 mm rainfall is considered to be equivalent to 1 normalised year), annual leaching loss of 223.83 mg m^{-2} (propiconazole) from [redacted] can be predicted from vertical surfaces.

Whilst losses from vertical surfaces are not as severe as those expected from horizontal surfaces, they do best represent the types of external timber surface (fence panels, sheds, summerhouses, cladding etc) that will be treated with this type of [redacted] product.

TIME 1 (30 d) values could be derived by proportionally scaling down values based on annual loss from vertical surfaces (223.83 x 30/365 = 18.40 mg m^{-2}) for propiconazole but the graph plots clearly show much higher initial leaching losses. Readings from graph plots for leaching loss from vertical surfaces would suggest 30 d (TIME 1) losses to be approximately 115 mg m^{-2} of propiconazole so use of these values would be more realistic (and more precautionary) than back-extrapolation. Therefore, using the higher 30 d values predicted from graph plots, average daily flux rate would be :-

Propiconazole (vertical planks) : 115 / 30 = 3.83 mg m^{-2} d^{-1}

It is quite clear from the graph plot (covering loss of actives substance from treated timber

after exposure to 1099.7 mm of rainfall) that, after an initial period of high leaching (150 – 300 mm of rainfall), losses of the active substance will reduce to a significantly lower rate. Annual leaching loss (which includes the initial "high loss" phase) has been determined as 223.83 mg m^{-2} this is equivalent to percentage losses per year of 15.54 % for propiconazole (based on application rate of 1440 mg m^{-2} for propiconazole). This is in line with the proposed maximum application rates set out by the Applicant and thus no need for any further correction value.

Assuming 15.54 % leaching per year for propiconazole, then losses at 5 years (service life for brush) can be predicted as being < 80 % (more specifically, 77.7 %).

As all propiconazole can be predicted to have leached from treated timber in < 7 yr, long-term flux rate to cover other superficial methods can only be based on a calculation using total application rate and extended service life (15 yr).

Propiconazole (no topcoat) flux rate values for Time 1 and Time 2 :-

[30 d] would be (115 / 30) = 3.83E+0 mg m^{-2} d^{-1}
[5 yr]* would be (223.83 x 5 / 5 x 365) = 6.13E-1 mg m^{-2} d^{-1}
[15 yr]** would be (1440 / 15 x 365) = 2.63E-1 mg m^{-2} d^{-1}

* service life for brush application

** service life for dip, automated spray and flowcoat application etc

Tier 2 assessment : TIME 2 flux rate for non-topcoated timber treated with [redacted] (refinement using long-term data)

The Applicant has provided leaching loss data covering almost 19 months exposure to weathering (based on EU normalised rainfall of 700 mm per year). Graph plots of leaching loss demonstrate an initial phase of very high leaching loss so significant loss in Year 1 (0 – 700 mm) but much lower loss during notional first 7 months of Year 2 (701 – 1099.7 mm).

It is quite clear than during the first year (0 – 700 mm), cumulative leaching loss from the graph plot can be predicted as approximately 323.10 mg m^{-2} whilst leaching loss for the next 7 months (701 – 1099.7 mm) can be determined as (351.63 – 323.10 =) 28.53 mg m^{-2}. Correcting up to a full year (700 mm of rain), the predicted cumulative loss for Year 2 would increase to (28.53 x 700 / 399.7 =) 49.96 mg m^{-2} of propiconazole.

Based upon re-interpretation of Applicant's leaching data, leaching loss would be :-

Year 1 : 323.10 mg m^{-2} of propiconazole
Year 2 : 49.96 mg m^{-2} of propiconazole

Application rate of propiconazole in the semi-field study is reported as being 1440 mg m^{-2} so leaching loss in Year 1 represents 22.44% of applied dose whilst, in Year 2, it reduces to 3.47% of applied dose.

As Year 2 demonstrates leaching loss approaching steady state after the initial surge in Year 1, it can be argued that cumulative loss in Year 2 also represents a more realistic representation for leaching loss in Years 3 – 5 and Years 3 – 15 (depending on service life).

Predicted total losses after 5 yr service life would be [(1 x 22.44%) + (4 x 3.47%) =] 36.32% whilst, after 15 yr service life, predicted total losses would be [(1 x 22.44%) + (14 x 3.47%) =] 71.02%.

As retention rate in the semi-field study uses a retention rate of 160 ml m^{-2} (or 160 g m^{-2} based on formulation density) which is identical to the rate proposed for the marketed product, no correction factor will be required. On the basis of these assumptions, it is proposed to calculate cumulative loss on an annual basis and determine mean daily flux rate from the cumulative 5-year and 15-year leaching loss.

<u>Mean flux rate for brush (5 year service life) of propiconazole – TIER 2</u>

Cumulative loss of propiconazole over 5 yr would be :-
(1 x 323.10) + (4 x 49.96) = 522.94 mg m^{-2} of propiconazole
: daily flux rate would be (522.94 / 365 x 5) = 2.865E-1 mg m^{-2} d^{-1}

<u>Mean flux rate for spray / flowcoat etc (15 year service life) of propiconazole – TIER 2</u>

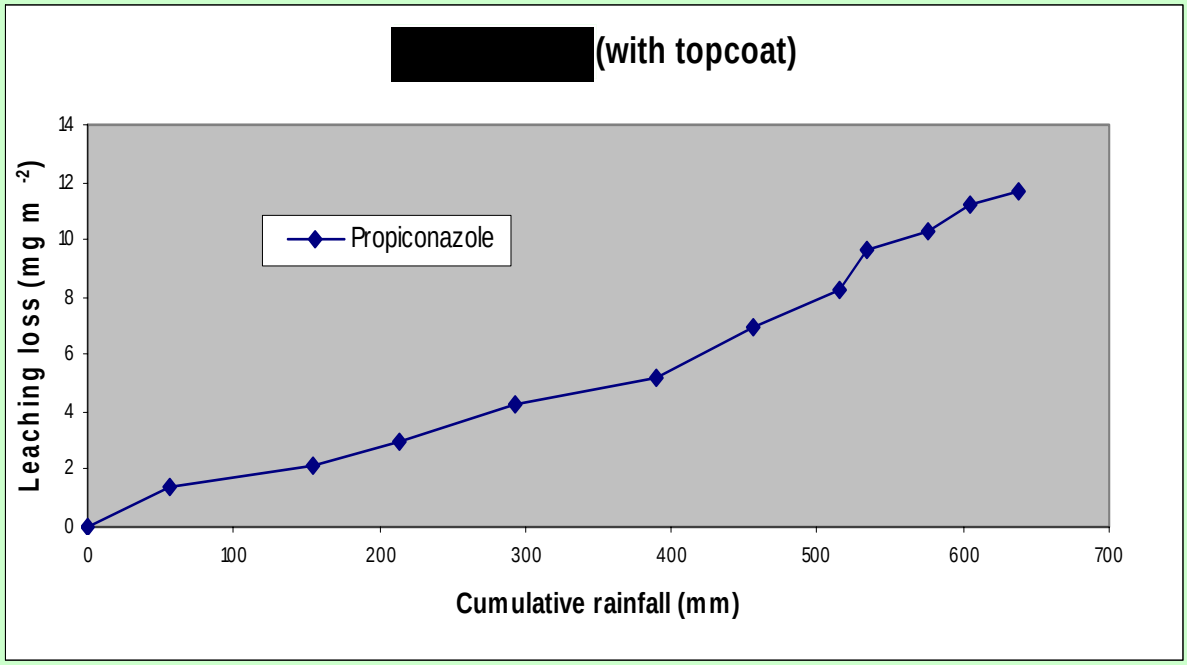
Cumulative loss of propiconazole over 15 yr would be :-
(1 x 323.10) + (14 x 49.96) = 1022.54 mg m^{-2} of propiconazole
: daily flux rate would be (1022.54 / 365 x 15) = 1.868E-1 mg m^{-2} d^{-1}

2) Propiconazole leaching from vertical surfaces : topcoated timber (Test no. 11050)

Date	Total Rainfall (mm)	Mean propiconazole (mg m^{-2})	Total mean propiconazole (mg m^{-2})
22.06.10 - 15.07.10	56	1.35	1.35
16.07.10 – 17.08.10	154.5	0.74	2.09

18.08.10 – 27.08.10	213	0.92	3.01
28.08.10 – 16.09.10	293	1.25	4.26
17.09.10 – 22.10.10	389.5	0.97	5.23
23.10.10 – 10.11.10	455.5	1.75	6.98
11.11.10 – 14.11.10	515.5	1.26	8.24
15.11.10 – 03.01.11	560.9	0*	8.24
04.01.11 – 12.01.11	579.1	1.39	9.63
13.01.11 – 20.01.11	621.5	0.68	10.31
21.01.11 – 14.02.11	649.9	0.92	11.23
15.02.11 – 08.03.11	682.9	0.43	11.66

* Sample lost



Therefore, after running the study for 259 consecutive days, the total accumulated rainfall was measured as 682.9 mm and the average (n=3) accumulated amount of leached propiconazole in that period was determined as 11.66 mg m^{-2} from vertical surfaces. However, at 560.9 mm rain, the samples were lost so, in the interest of accuracy, the amount of rainfall between 14.11.10 and 03.01.11 has been discounted thus bringing the new total volume of rainfall to 637.5 mm.

On the basis that mean total leaching loss is based on 637.5 mm of rainfall (equivalent to 332.4 d if 700 mm rainfall is considered to be equivalent to 1 normalised year), annual leaching loss of 12.80 mg m^{-2} (propiconazole) from [redacted] can be predicted from vertical surfaces when topcoated with Delta Futura Venti Satin finish.

Whilst losses from vertical surfaces are not as severe as those expected from horizontal surfaces, they do best represent the types of external timber surface (fence panels, sheds, summerhouses, cladding etc) that will be treated with this type of [redacted] product.

TIME 1 (30 d) values could be derived by proportionally scaling down values based on annual loss from vertical surfaces (12.80 x 30/365 = 1.05 mg m^{-2}) for propiconazole but the graph plots clearly show much higher initial leaching losses.

Readings from graph plots for leaching loss from vertical surfaces would suggest 30 d (TIME 1) losses to be approximately 1.40 mg m^{-2} of propiconazole so use of these values would be more realistic (and more precautionary) than back-extrapolation. Therefore, using the higher 30 d values predicted from graph plots, average daily flux rate would be :-

Propiconazole (vertical planks) : 1.4 / 30 = 4.67E-2 mg m^{-2} d^{-1}

Although not as clear as the non-topcoated study, it is expected that the graph plot (covering leaching loss of propiconazole from treated timber after exposure to 637.5 mm of rainfall) would demonstrate an initial period of high leaching. Over time, losses of the active substance would then reduce to a significantly lower (and steady) rate. Yearly leaching loss has been determined as 12.80 mg m^{-2} and this is equivalent to an annual percentage loss of 8.89E-1 % for propiconazole (based on application rate of 1440 mg m^{-2} for propiconazole). This application rate is in line with the proposed maximum application rates set out by the Applicant and thus no need for any further correction value.

Assuming 8.89E-1 % leaching per year for propiconazole, then losses at 5 years (service life for brush) can be predicted as being < 5 % (more specifically, 4.45 %). After 15 years (service life for dip / flowcoat /automated spray), losses would be < 15 % (i.e. 13.34 %) for propiconazole.

Propiconazole (with topcoat) flux rate values for Time 1 and Time 2 would be :-

[30 d] would be (1.4 / 30) = 4.67E-2 mg m^{-2} d^{-1}
[5 yr]* would be (12.80 x 5 / 5 x 365) = 3.51E-2 mg m^{-2} d^{-1}
[15 yr]** would be (12.80 x 15 / 15 x 365) = 3.51E-2 mg m^{-2} d^{-1}

* service life for brush application

** service life for dip, automated spray and flowcoat application

8.1.3 PEC IN SEWAGE TREATMENT PLANT (STP)

Noise barrier in service

The OECD scenario “noise barrier” assumes that 70% of the emissions from wood will reach the wastewater treatment plant. The dimensions of the wastewater treatment plant (2000 m^3 per day) was taken from the Technical Guidance Document (TGD, Part II, 2003). PECs in STP are listed in Table 8.1.3.1.

Table 8.1.3.1. Propiconazole PECs in STP
(*input: 345 g a.i/ m^3 for vacuum-pressure, 1.44 g a.i./m^2 for professional brushing/spraying, dipping/automated spraying/flow-coat, and amateur brushing/spraying*).

Scenario **Wood in service**	**Application rate 1.44 g/m^2 and 345 g/m^3 propiconazole**	
	TIME 1 (30 days)	**TIME 2 (default service life)**
	PEC in STP effluent (µg a.i./l)	
Noise barrier - treatment professional brushing	0.36	0.0130
Noise barrier - treatment dipping / automated spraying	0.36	0.0050
Noise barrier - treatment vacuum-pressure/double-vacuum	0.25	0.0027

* PEC_{STP} = Emission / 2000 m^3 (STP)

Table 8.1.3.2. IPBC PECs in STP (*input: 115 g a.i/ m^3 for vacuum-pressure, 0.48 g a.i./m^2 for professional brushing/spraying ,dipping/automated spraying/flow-coat, and amateur brushing/spraying*).

Scenario Wood in service	Application rate 0.48 g/m^2 and 115 g/m^3 IPBC	
	TIME 1 (30 days)	TIME 2 (default service life)
	PEC in STP effluent (µg a.i./l)	
Noise barrier - treatment professional brushing	9.58	0.157
Noise barrier - treatment dipping / automated spraying	9.58	0.052
Noise barrier - treatment vacuum-pressure/double-vacuum	4.59	0.019

* PEC_{STP} = Emission / 2000 m^3 (STP)

8.1.4 PEC IN SURFACE WATER

In-situ treatment (brushing or spraying)

[redacted] s not intended for in-situ application in the vicinity of water courses where emissions to the surface water can not be prevented. Indeed, in the Competent Authority Report for Propiconazole (December 2007, Rapporteur : Finland), it is confirmed that *„In-situ application by brush or spray in the vicinity of water courses must not be conducted where direct losses to the aquatic compartment cannot be prevented.“*

On the basis of the above, no further assessment of emissions to water from in-situ treatment processes using [redacted] has been undertaken. The appropriate instructions are included in the safety data sheet for [redacted]

Service-life of treated wood

The OECD scenario “bridge over a small pond” calculates concentrations in pond water after 30 days and a longer relevant time period based on the leaching. In the calculations the dissipation half-lives of propiconazole and IPBC in water are taken into account. PECs in surface water for wood in service at Time 1 (30 days after the application) and Time 2 (default service life) are summarized in Table 8.1.4.1. and 8.1.4.2. The OECD scenario “noise barrier” assumes that 70% of the emissions from wood will reach the sewage and (via STP) the

surface water. The dimensions of the waste water treatment plant (2000 m³ per day) and the dilution factor (10) to the surface water were taken from the Technical Guidance Document (TGD, Part II, 2003). Resulting PECs in surface water are reported in Table 8.1.4.1. and 8.1.4.2.

Table 8.1.4.1 : Propiconazole PECs for the aquatic environment (*input: 345 g a.i/ m^3 for dipping and vacuum-pressure, 1.44 g a.i./ for spraying and brushing*).

Scenario **Wood in service**	**Application rate 1.44 g/m^2 and 345 g/m^3 propiconazole**	
	TIME 1 (30 days)	**TIME 2 (default service life)**
	PEC for the aquatic environment (ug a.i./l)	
Noise barrier - treatment professional brushing	0.036	0.0013
Noise barrier - treatment dipping / automated spraying	0.036	0.0005
Noise barrier - treatment vacuum-pressure	0.025	0.0003
Bridge over pond - treatment brushing	0.07	0.004
Bridge over pond - treatment dipping / automated spraying	0.07	0.001
Bridge over pond - treatment vacuum-pressure	0.05	0.001

Table 8.1.4.2 : IPBC PECs for the aquatic environment
(*input: 115 g a.i/ m^3 for vacuum-pressure, 0.48 g a.i./m^2 for professional brushing/spraying ,dipping/automated spraying/flow-coat, and amateur brushing/spraying*).

Scenario **Wood in service**	**Application rate 0.48 g/m^2 and 115 g/m^3 IPBC**	
	TIME 1 (30 days)	**TIME 2 (default service life)**
	PEC for the aquatic environment (ug a.i./l)	
Noise barrier - treatment professional brushing	0.958	0.016
Noise barrier - treatment dipping / automated spraying	0.958	0.005
Noise barrier - treatment vacuum-pressure	0.459	0.002
Bridge over pond - treatment brushing	1.48	0.02
Bridge over pond - treatment dipping / automated spraying	1.48	0.008
Bridge over pond - treatment vacuum-pressure	0.71	0.003

8.1.5 PEC IN SEDIMENT

The transferred concentration in suspended sediment was calculated from mg a.i./l (water) to mg a.i./kg suspended sediment using formula 50 with the aid of formulas 22, 23 and 24 from the TGD (2003), part II. The concentration in freshly deposited sediment was taken as the PEC for sediment, and therefore, the properties of suspended matter were used. The degradation half-lives of propiconazole and IPBC in the whole water-sediment system were used in order to provide PECs in surface water for the calculation of PECs in suspended sediment. The PECs in sediment for the in-service scenarios described under PEC in surface water are listed in Tables 8.1.5.1. and 8.1.5.2.

Table 8.1.5.1 : Propiconazole PECs for the sediment (*input: 345 g a.i/ m^3 for dipping and vacuum-pressure, 1.44 g a.i./m^2 for spraying and brushing*).

Scenario **Wood in service**	**Application rate 1.44 g/m^2 and 345 g/m^3 propiconazole**	
	TIME 1 (30 days)	**TIME 2 (default service life)**
	PEC for the sediment (mg/kg)	
Noise barrier - treatment professional brushing	0.00077	0.00003
Noise barrier - treatment dipping / automated spraying	0.00077	0.00001
Noise barrier - treatment vacuum-pressure	0.00053	0.000006
Bridge over pond - treatment brushing	0.137	0.189
Bridge over pond - treatment dipping / automated spraying	0.137	0.106
Bridge over pond - treatment vacuum-pressure	0.095	0.059

Table 8.1.5.2 : IPBC PECs for the sediment
(*input: 115 g a.i/ m^3 for vacuum-pressure, 0.48 g a.i./m^2 for professional brushing/spraying ,dipping/automated spraying/flow-coat, and amateur brushing/spraying*).

Scenario **Wood in service**	**Application rate 0.48 g/m^2 and 115 g/m^3 IPBC**	
	TIME 1 (30 days)	**TIME 2 (default service life)**
	PEC for the sediment (mg/kg)	
Noise barrier - treatment professional brushing	0.0035	0.00006
Noise barrier - treatment dipping / automated spraying	0.0035	0.00002
Noise barrier - treatment vacuum-pressure	0.0016	0.000007
Bridge over pond - treatment brushing	0.112	0.0018
Bridge over pond - treatment dipping / automated spraying	0.112	0.0006
Bridge over pond - treatment vacuum-pressure	0.054	0.0002

8.1.6 PEC in marine water AND SEDIMENT

Marine assessment is not considered necessary based on the intended uses in wood preservatives and related Emission Scenario Documents.

8.1.7 PEC IN AIR

Propiconazole and IPBC both have a very low vapour pressure and therefore emission to air is not considered relevant.

8.1.8 PEC IN SOIL

The OECD ESD for wood in service assumes 10 cm horizontal and vertical distance in soil. However, it was decided by the 23rd Competent Authority Meeting to consider soil volumes representing 50 cm horizontal and vertical distances in the risk assessment, and it was confirmed by the 24th Competent Authority Meeting that the 50 cm horizontal and vertical distances should apply at product authorisation stage as well as the Annex 1 entry. All PEC calculations for in-situ and in-service scenarios listed in Table 3.3.8.1 were carried out based

on 50 cm horizontal and vertical distance. In the scenario 'house' the horizontal distance is 50 cm symmetrically to all four directions around the house (see ESD page 75 figure 5-3).

In-situ treatment (brushing or spraying)

During outdoor in-situ brush treatment , an initial PEC can be calculated according to OECD scenarios of fence and timber house. Assuming that 3% (professionals) and 5% (amateurs) of the applied product is lost due to spills and drips to soil, initial PECs for [redacted] are calculated.

For the in-situ spray-treatment of a house façade by a professional, an initial PEC can be calculated by adapting the Emission Scenario document for biocides used as masonry preservatives, PT10 (INERIS, 2002). In this document, the house has the same dimensions as in the PT08 Emission Scenario Document (OECD), but two distinct volumes of soil are considered as environmental compartments – soil adjacent to the house is considered to receive runoff and dripping from the spraying process (20% of applied product), soil distant to the house is considered to receive spray drift (10% of applied product). The ESD gives a volume of 0.5 m^3 for the adjacent soil, based on compartment dimensions of 10 cm x 10 cm, and a volume of 27.3 m^3 for the distant soil, based on a soil depth of 10 cm. In the calculations presented here, however, these dimensions have been amended in line with the decision of the 23rd Competent Authority Meeting so that a compartment size of 50 cm x 50 cm is considered for the adjacent soil, and a soil depth of 50 cm is considered for the distant soil. This gives soil volumes of 13 m^3 for the adjacent soil and 121.7 m^3 for the distant soil.

Service-life of treated wood

The OECD scenarios 1) fence, 2) timber house and 3) noise barrier are applied to calculate soil emissions from HC3 wood. The OECD scenario “noise barrier” assumes that 30% of the emissions from wood will seep into the adjacent soil.

Soil concentrations were calculated for 30 days (TIME 1) and a relevant longer period (TIME 2) after application taking into account the soil dissipation half-life of propiconazole and IPBC. PECs in soil for wood in service at Time 1 (30 days after the application) and Time 2 (default service life) are summarized in Table 3.3.8.1.

In-situ treatment (brushing) combined with service-life of treated wood

PECs in soil after Time 1 (30 days) and Time 2 (default service life) after brushing application can be calculated with the OECD scenarios 1) fence and 2) timber house. Initial PEC in soil after the in-situ application is combined with the PEC in soil after Time 1(30 days). The same

approach can be applied to the longer assessment period Time 2 (default service life). Combined PECs are reported in Table 3.3.8.1

In-situ treatment (spraying) combined with service-life of treated wood

PECs in soil after Time 1 (30 days) and Time 2 (default service life) after spray application can be calculated by combining the adapted PT10 scenario for treatment of a façade with the OECD scenario timber house.

Initial PEC in soil after the in-situ application is combined with the PEC in soil after Time 1(30 days). The same approach can be applied to the longer assessment period Time 2 (default service life). Combined PECs are reported in Table 3.3.8.1

Table 8.1.8.1 : Wood in-situ and in-service: Summary of calculated PECs (*input: 345 g propiconazole./m^3 and 115 g IPBC./m^3 for vacuum-pressure, 1.44 g propiconazole/m^2 and 0.48 g IPBC/m^2 for dipping/automated spraying/flow-coat ,/ spraying/brushing*).

Scenario	Application rate 1.44 g/m^2 and 345 g/m^3 propiconazole			Application rate 0.48 g/m^2 and 115 g/m^3 IPBC		
	Day of application	Time 1 (30 days)	Time 2 (default service life)	Day of application	Time 1 (30 days)	Time 2 (default service life)
Scenarios related to professional brushing treatment – in-situ + in-service combined						
	PEC for soil					
Fence	0.20	0.22	0.033	0.068	0.022	0.0004
House	0.24	0.26	0.040	0.081	0.026	0.0004
Scenarios related to professional brushing treatment –in-service only						
	PEC for soil					
Fence	n/a	0.029	0.012	n/a	0.021	0.0004
House	n/a	0.035	0.015	n/a	0.025	0.0004
Noise Barrier	n/a	0.013	0.0005	n/a	0.0095	0.0002
Scenarios related to amateur brushing treatment – in-situ + in-service combined						
	PEC for soil					
Fence	0.34	0.34	0.047	0.113	0.022	0.0004
House	0.41	0.41	0.056	0.136	0.027	0.0004
Scenarios related to amateur brushing treatment –in-service only						
	PEC for soil					
Fence	n/a	0.029	0.012	n/a	0.021	0.0004
House	n/a	0.035	0.015	n/a	0.025	0.0004
Noise Barrier	n/a	0.013	0.0005	n/a	0.0095	0.0002
Scenarios related to spraying treatment – in-situ + in-service combined						
	PEC for soil					
Façade / House – adjacent soil	1.63	1.54	0.062	0.543	0.031	0.0002
Façade / House – distant soil	0.087	0.080	0.003	0.029	0.0003	0.000002
Scenarios related to dipping / spraying /flow-coat – in-service only						
	PEC for soil					
Fence	n/a	0.029	0.005	n/a	0.021	0.0001
House	n/a	0.035	0.006	n/a	0.025	0.0001
Noise Barrier	n/a	0.013	0.0002	n/a	0.0095	0.00005
Scenarios related to vacuum pressure – in-service only						
	PEC for soil					
Fence	n/a	0.020	0.003	n/a	0.010	0.00004
House	n/a	0.024	0.003	n/a	0.012	0.00005
Noise Barrier	n/a	0.009	0.0001	n/a	0.0046	0.00002

Application of STP sludge to agricultural soil and grassland

Local PECs in agricultural soil and grassland as a result of the application of STP sludge was calculated, where the STP sludge may become contaminated due to the emission to drain in the Noise Barrier scenario. The highest emission rate from the Noise Barrier scenario was used as the input value (0.00091 kg a.i./day Propiconazole, 0.0336 kg a.i./day IPBC, Time 1 calculations). The resulting PEC s are reported in Table 3.3.8.2.

Table 8.1.8.2. STP sludge to agricultural soil and grassland: Summary of calculated PECs in soil
(*input: 345 g propiconazole./m^3 and 240 g IPBC./m^3 for vacuum-pressure, 1.44 g propiconazole/m^2 and 0.48 g IPBC/m^2 for dipping/automated spraying/flow-coat ,/ spraying/brushing*).

	Local PEC in agricultural soil averaged over 30 days (mg a.i./kg ww)		**Local PEC in agricultural soil averaged over 180 days (mg a.i./kg ww)**		**Local PEC in grassland averaged over 30 days (mg a.i./kg ww)**		**Local PEC in grassland averaged over 180 days (mg a.i./kg ww)**	
	Propi	**IPBC**	**Propi**	**IPBC**	**Propi**	**IPBC**	**Propi**	**IPBC**
Wood in service: noise barrier – based on highest emission to facility drain	0.00037	0.00014	0.00025	0.000023	0.00015	0.00005	0.00010	0.000009

8.1.9 PEC IN GROUNDWATER

<u>Propiconazole</u>

TGD does not contain a detailed approach to calculate PEC in groundwater but only the equation 67 to calculate concentration in pore water. Because this is a worst-case

assumption, neglecting transformation and dilution in deeper soil layers, FOCUS-PEARL 3.3.3 modelling was carried out.

In the PEARL modelling the following assumptions were made for all nine FOCUS scenarios:

1) Wood is treated with propiconazole at a rate of 1 g a.i./m^{-2}. It is assumed that the total amount applied will be emitted during service-life and thus is a conservative approach.
2) The housing density is 35 houses per hectare with each house having a treated area of 125 m^2 which results in a total area of 4375 m^2 yielding an emission of 4375 g a.i./ha.
3) An annual loss is 20% because the shortest assumed service-life of treated wood is 5 years,
   i.e. 0.2*4375 g a.i./ha = 875 g a.i./ha.
4) All the compound enters the soil compartment 10 equally spaced events per year,
   i.e. 875/10 = 87.5 g a.i./ha.
5) Given the way in which propiconazole is likely to enter the soil by being washed off the timber surface and running down to the soil as a result of precipitation, limited interception by the grass cover is considered to occur, and therefore, the whole amount of 87.5 g a.i./ha/year was loaded directly to the soil surface.

The modelling was made for the parent compound and the main degradation product in soil 1,2,4-triazole. In one soil study another degradation product (CGA 118 245) has been identified and quantified >10% of the initial radioactivity. However, CGA 118 245 degrading more rapidly and being slightly less mobile than 1,2,4-triazole the modelling results of the latter are considered sufficient.

The input parameters for the properties of propiconazole and 1,2,4-triazole used in the modelling are given below:

	Propiconazole	**1,2,4-triazole**
Molar mass (g/mol)	342.2	69.1
Soil half-life (days)	43 [i]	6.4 [ii]
K_{FOM} (L/kg)	397 [iii]	51.6 [iv]
1/n	0.88 [iii]	0.92 [iv]
Solubility at 20 °C (mg/L)	100	700,000
Saturated vapour pressure (Pa)	$5.6*10^{-5}$ (25 °C)	0.22 (25 °C)

i) median of 8 values from laboratory studies

ii) arithmetic mean of 3 values from a laboratory study

iii) median of 9 values

iv) arithmetic mean of 4 values

According to FOCUS guidance K_{FOM} was calculated by multiplying Koc by 0.58 and soil half-lives were normalised to 20 °C and also to pF2 (where moisture data available). FOCUS-PEARL is based on the Single First-Order kinetics and the half-life needs to be normalised in terms of temperature and moisture. Therefore, it is acceptable to use a half-life from the laboratory studies in the modelling although there are field studies on propiconazole giving longer half-lives.

For wood preservation use the predicted environmental concentration in groundwater, as represented by the 80th percentile leachate concentration at 1 m soil depth, for propiconazole and 1,2,4-triazole was less than 0.001 µg/l in all nine FOCUS-PEARL scenarios.

IPBC

The fate and behaviour for IPBC suggest that it is not expected to reach groundwater during outdoor service life of treated wood since this compound has been shown to have a T½ of 0.196 days in soil at 12oC. Therefore an exposure assessment for groundwater on IPBC is not considered further for the use phase.

UK CA : A detailed consideration of the potential risks to groundwater was included in the Annex I assessment of propiconazole. This assessment utilised the FOCUS PEARL 3.3.3 model and conservatively assumed 100% loss over a minimum service life period of 5 years. This demonstrated negligible risks to groundwater following use of propiconazole at up to 1.0 g a.s./m^2 based on the 35 house/ha scenario previously agreed at EU level for use in the PT8 groundwater leaching assessment.

The predicted environmental concentration in groundwater, as represented by the 80th percentile leachate concentration at 1 m soil depth, for propiconazole and 1,2,4-triazole was less than 0.001 µg/l in all nine FOCUS-PEARL scenarios.

On the basis of the Annex I assessment, it may be reasonable to conclude that the use of product [redacted] at up to 1.44 g a.s./m^2 will not lead to an exceedence of the 0.1µg/l limit given the relatively large margins of safety associated with the assessment of the Annex I representative use. This large margin of safety would also negate the need to perform additional UK specific modelling with the FOCUS MACRO Châteaudun scenario that would be triggered for parent propiconazole based on the Kf_{oc} > 100ml/g (propiconazole Kf_{oc} for modelling = 684ml/g according to Annex I assessment).

However, the Annex I assessment was based on agreed endpoints available at the time of the EU consideration. As RMS for the 1,2,4-triazole data package being considered under the EU Plant Protection Products legislation, the UK CA is now aware that the soil DT_{50} for this metabolite has been significantly revised in light of the latest assessment approaches following the FOCUS kinetics guidance. The proposed DT_{50} input parameter for exposure assessments such as $FOCUS_g$for this metabolite is now 60.5 d (at 20°C and pF2) compared with only 6.4 d agreed at the time of Annex I consideration of propiconazole as a PT8 biocide. As this increased metabolite DT_{50} could affect the conclusions of the groundwater assessment, the UK CA has chosen to repeat the exposure assessment with the longer value to ensure that the risks posed by product [redacted] are still acceptable even taking into account this more conservative endpoint. The detailed consideration follows the Annex I agreed approach at the first tier, with the exception of the revised 1,2,4-triazole DT_{50} endpoint.

With regard to the FOCUS PEARL modelling, the following assumptions were made for all nine FOCUS scenarios:-

1) Wood is treated with propiconazole at a rate of 1.44 g a.s./m^2 (superficial treatment selected as a reasonable worst case scenario).
2) The housing density is 35 houses per hectare with each house having a treated area of 125 m^2 which results in a total area of 4375 m^2 yielding a total emission of 6300 g a.s./ha assuming 100 % leaching over the service life.
3) An absolute worst case annual loss is 20 % because the shortest assumed service-life of treated wood is 5 years,
   i.e. 0.2*6300 g a.s./ha = 1260 g a.s./ha.
4) All the compound enters the soil compartment in 10 equally spaced events per year to simulate leaching, application dates from February 1st to November 1st , no crop interception and simulation for the grassland scenario
   i.e. 1260/10 = 126 g a.s./ha. in 10 monthly applications

The modelling was performed for the parent compound and the main degradation product in soil, namely 1,2,4-triazole. In one soil study, another degradation product (CGA 118 245) has been identified and quantified >10% of the initial radioactivity. However, in line with the Annex I assessment, CGA 118 245 degraded more rapidly and was only slightly more mobile than 1,2,4-triazole and therefore the EU Review concluded that the modelling results of the latter are considered sufficient to address risks posed by CGA 118 245. Since this additional simulation below has used a significantly longer DT_{50} for 1,2,4-triazole, the same approach can be used and the risk posed by CGA 118 245 are effectively addressed by the

1,2,4-triazole assessment.

The input parameters for the properties of propiconazole and 1,2,4-triazole used in the modelling are given below (as per Annex I agreed endpoints taken from Doc II-B of the propiconazole CAR with the exception of the revised 1,2,4-triazole DT_{50}):

	Propiconazole	**1,2,4-triazole**
Molar mass (g/mol)	342.2	69.1
Soil half-life (days)	43 [i]	60.5 [ii]
K_{FOM} (L/kg)	397 [iii]	51.6 [iv]
1/n	0.88 [iii]	0.92 [iv]
Formation fraction	-	1 [v]
Solubility at 20 °C (mg/L)	100	700,000
Saturated vapour pressure (Pa)	$5.6*10^{-5}$ (25 °C)	0.22 (25 °C)

i) median of 8 values from laboratory studies

ii) geometric mean of DFOP slow phase DT_{50} values (see HSE Ref. 001438175) as previous Annex I agreed endpoint was 6.4 d.

iii) median of 9 values

iv) arithmetic mean of 4 values

v) no formation fraction could be located in the Annex I assessment documents and so the UK CA has therefore conservatively assumed a maximum formation fraction of 1. Since the 1,2,4-triazole peaked at 43% applied radioactivity according to the list of endpoints, the conservative assumption regarding formation fraction in this first tier calculation is considered appropriate.

FOCUS-PEARL is based on the Single First-Order kinetics and the half-life needs to be normalised in terms of temperature and moisture. Therefore, the EU Review concluded that it was acceptable to use a half-life from the laboratory studies in the modelling, although there are field studies on propiconazole giving longer half-lives based on un-normalised data sets. The same approach will be used here for consistency with the EU Review.

The new simulations performed by the UK CA utilised FOCUS PEARL v4.4.4, which is the latest version of the model and it was considered appropriate to use the latest version since new simulation modelling had to be performed. This version of the model also used the most up-to-date activation energy equivalent to a Q10 of 2.58. For wood preservation use, the predicted environmental concentration in groundwater (as represented by the 80th percentile leachate concentration at 1 m soil depth) for propiconazole and 1,2,4-triazole are shown below (UK relevant scenarios have been highlighted).

80th percentile PEC_{gw} (µg/l) for propiconazole and 1,2,4-triazole following use at up to 1.44 g a.s./m^2 and assuming 100% loss over 5 year service life for both top coated and non-topcoated (calculated with FOCUS PEARL 4.4.4)

Scenario	Propiconazole PEC_{gw} (µg/l)	1,2,4-triazole PEC_{gw} (µg/l)
Châteaudun	**0.000**	**2.321**
Hamburg	**0.000**	**4.490**
Jokioinen	**0.000**	**2.808**
Kremsmünster	**0.000**	**2.713**
Okehampton	**0.000**	**3.507**
Piacenza	**0.000**	**2.874**
Porto	**0.000**	**2.163**
Sevilla	**0.000**	**0.824**
Thiva	**0.000**	**1.206**

As can be seen from the results in the table presented above, the leaching risk posed by propiconazole is very low. Therefore no further information is required to assess the risk posed by parent compound. However, concentrations for 1,2,4-triazole (metabolite) now exceed the 0.1µg/l limit in all scenarios, including the 4 pertinent to the UK. Since this represents a conservative first tier approach assuming 100% loss combined with the revised metabolite DT_{50}, some further refinement should be considered.

Two refinements have therefore been considered :-

The first refinement is to reduce the housing density to 16 houses per ha. The original first tier value of 35 houses/ha is based on typical UK urban housing density. However, during the revision of the PT8 ESD, the UK CA is aware that this value for use in groundwater assessments has been lowered to 16 houses per ha to reflect the average percentage of wooden houses in Scandinavia (around 45 %). Since wooden houses are more common in Scandinavia than in the rest of the EU (including the UK), this value is considered a reasonable refinement taken from the revised PT ESD.

Secondly, a reduction in the assumed leaching rate from 100 % loss over 5 year service life down to percentage leaching loss values predicted from supporting semi-field leaching studies (Willems, 2010 & 2011).

With regard to non-topcoated wood, semi-field leaching data (report 11047) gives rise to a

mean annual leaching loss for propiconazole of 15.54% (***Tier 1 approach***) if supporting data is used to first derive an annual leaching loss and then simply extrapolate that value to a 5 yr service life.

However, the leaching profile of propiconazole from the non-topcoated study suggests that after an initial phase of high loss (Year 1 : 22.44%), leaching drops to a much lower, more steady rate (Year 2 : 3.47%). On that basis, it is proposed that leaching loss in Year 2 is more representative of annual loss for the remaining service life of the product during Years 3 – 15 (***Tier 2 approach***). Use of such data is considered to be over-protective due to high initial leaching losses which then reduced over the remainder of the study. Extrapolation of study data for service life indicates high initial losses at the start of Year 1 which then tails off to a much lower and steady rate using semi-field data covering the equivalent of almost 19 months of normalised EU rainfall. Due to limitations with FOCUS modelling, it has not been possible to model different application rates in different years so an average leaching loss covering Years 1- 5 has been calculated :-

$$\frac{(1 \times 22.44\%) + (4 \times 3.47\%)}{5} = 7.264\ \%\ \text{(mean annual leaching loss)}$$

When a 15 yr service life is considered for other superficial methods (excluding brush), the mean annual percentage loss drops from 7.264% to 4.735% - effective monthly application rate for FOCUS PEARL 4.4.4 drops to a value of 13.64 g a.s/ha.

The combined effect of reducing (***Tier 1 : non-topcoated***) leaching loss percentage to an average of 15.54% per year and reducing housing density to 16 per ha will reduce the effective monthly application rate to 44.76 g a.s/ha (based on the first tier monthly figure of 16 * 125 m^2 * 1.440 g m^{-2} * 15.54 % * 10 %).

The combined effect of reducing (***Tier 2 : non-topcoated***) leaching loss percentage to an average of 7.264% per year and reducing housing density to 16 per ha will reduce the effective monthly application rate to 20.92 g a.s/ha (based on the first tier monthly figure of 16 * 125 m^2 * 1.440 g m^{-2} * 7.264 % * 10 %).

80th percentile PEC_{gw} (µg/l) for 1,2,4-triazole following use of 1.440 g a.s./m^2 and assuming mean leaching loss of 77.70% (Tier 1 : non-topcoated) and 36.32% (Tier 2 : non-topcoated) over 5 year service life plus 71.02% (non-topcoated) over 15 year service life along with a refined scenario of 16 houses/ha as per revised PT8 ESD [FOCUS PEARL 4.4.4]

Scenario	1,2,4-triazole	1,2,4-triazole	1,2,4-triazole

	PEC_{gw} (µg/l) [no topcoat] TIER 1 (5 yr)	PEC_{gw} (µg/l) [no topcoat] TIER 2 (5 yr)	PEC_{gw} (µg/l) [no topcoat] (15 yr)
Châteaudun	**>0.63**	**>0.24**	**>0.14**
Hamburg	**>1.29**	**>0.51**	**>0.30**
Jokioinen	>0.75	>0.29	>0.16
Kremsmünster	**>0.77**	**>0.30**	**>0.17**
Okehampton	**>1.00**	**>0.40**	**>0.24**
Piacenza	>0.84	>0.34	>0.20
Porto	>0.65	>0.26	>0.15
Sevilla	>0.19	>0.06	>0.03
Thiva	>0.32	>0.12	>0.07

Note : all values for propiconazole reported as <0.000001 µg l^{-1}

Tier 1 approach (all leaching data used to calculate average daily flux rate) for 5 year service life as worst case to support all superficial methods : all 9 scenarios indicate significant risks to groundwater from metabolite 1,2,4-triazole so must be considered as unacceptable.

Tier 2 approach (leaching data used to calculate high loss phase in "Year 1" plus lower steady flux rate in "Year 2" onwards) for 5 year service life as worst case to support all superficial methods : 8 out of 9 scenarios (including all 4 pertinent to UK) indicate significant risks to groundwater from metabolite 1,2,4-triazole so must be considered as unacceptable.

Tier 2 approach (leaching data used to calculate high loss phase in "Year 1" plus lower steady flux rate in "Year 2" onwards) for 15 year service life as worst case to support other superficial methods excluding brush application : 7 out of 9 scenarios (including all 4 pertinent to UK) indicate significant risks to groundwater from metabolite 1,2,4-triazole so unacceptable.

Overall, it is clear that, despite several refinements, risks to groundwater from 1,2,4-triazole (formed by degradation of propiconazole emissions from treated wood) are unacceptable if treated wood in UC 3 scenarios has been left unprotected (i.e. topcoat has not been used).

With regard to topcoated wood, semi-field leaching data (report 11050) gives rise to a mean annual leaching loss for propiconazole of 0.89% (***Tier 1 approach***) if supporting data is used to first derive an annual leaching loss and then simply extrapolate that value to a 5 yr service life. The combined effect of reducing (***Tier 1 : topcoated***) leaching loss percentage to an average of 0.89% per year and reducing housing density to 16 per ha will reduce the effective monthly application rate to 2.56032 g a.s/ha (based on the first tier monthly figure of 16 * 125 m^2 * 1.440 g m^{-2} * 0.889 % * 10 %).

80th percentile PEC_{gw} (µg/l) for propiconazole and 1,2,4-triazole following use at up to 1.44 g a.s./m^2 and assuming 4.45 % loss over 5 year service life and a refined scenario of 16 houses/ha as per revised PT8 ESD (calculated with FOCUS PEARL 4.4.4)

Scenario	Propiconazole PEC_{gw} (µg/l)	1,2,4-triazole PEC_{gw} (µg/l)
Châteaudun	**<0.000001**	**0.0166**
Hamburg	**<0.000001**	**0.0380**
Jokioinen	**<0.000001**	**0.0185**
Kremsmünster	**<0.000001**	**0.0210**
Okehampton	**<0.000001**	**0.0326**
Piacenza	**<0.000001**	**0.0268**
Porto	**<0.000001**	**0.0202**
Sevilla	**<0.000001**	**0.0035**
Thiva	**<0.000001**	**0.0084**

Based on these two refinements, it can be demonstrated that leaching losses from the topcoated product clearly give rise to acceptable risks in groundwater when considering the PEC_{gw} for both propiconazole and its metabolite 1,2,4-triazole. Concentrations of metabolite are predicted to be less than 0.1µg/l in all scenarios, including the 4 considered pertinent to the UK.

Overall, it is clear that risks to groundwater from 1,2,4-triazole (formed by degradation of propiconazole emissions from treated wood) are only acceptable if treated wood in UC 3 scenarios have been overcoated with an acrylic based paint (such as Delta Futura Venti satin used in the semi-field studies).

It should be noted that the FOCUS PEARL assessment for both non-topcoated and topcoated product has utilised a much longer metabolite DT_{50} than the one agreed for use at Annex I level for propiconazole. However, the UK CA considered this as an appropriately conservative approach in this specific case since this revised (i.e. longer) value has been agreed for use under the Plant Protection Products legislation. It should also be considered that large areas of wooden housing, all treated with propiconazole treated products are unlikely to be particularly widespread across the UK. The refined assessment above therefore represents an appropriately conservative exposure assessment for the UK.

In addition, it is clear that the modelling scenario used by the UK CA will be over-predictive as it is assumed that 100% of aquifer is covered by treated wood using only this combination

of active substances (and presumes no other actives are available) and that the formation fraction for breakdown of propiconazole to 1,2,4-triazole is 1 : situations that are extremely unlikely to happen in reality. It must also be considered unlikely that large areas of wooden housing, all treated with propiconazole treated products, would be particularly widespread across the UK.

Finally, it should be noted that for the industrial on-site storage scenario (where treated timber is assumed to be stored on bare earth), a groundwater assessment is not considered to be necessary because there is risk identified for the soil compartment in the industrial scenario. This is because where a risk to soil is identified, risk mitigation measures will be required to prevent losses to soil (eg. impermeable hard standing and recovery of leachate) which will, by default, prevent exposure to the groundwater compartment.

8.2 RISK CHARACTERIZATION FOR THE ENVIRONMENT

Risk to the environment is characterized quantitatively by comparing a Predicted Environmental Concentration (PEC) with a Predicted No-Effect Concentration (PNEC) in different environmental compartments and scenarios. In this part of Document II the PEC/PNEC ratios only are presented. Detailed PEC_{local} calculations according to the OECD ESD for wood preservatives and TGD, part II (2003) are presented in Document IIB. All the calculations are based on the recommended maximum retentions (345 g propiconazole./m^3 and 115 g IPBC./m^3 for vacuum-pressure, 1.44 g propiconazole/$m^2$and 0.48 g IPBC/m^2 for dipping/automated spraying/flow-coat, spraying/brushing).

The following PNECs have been determined in the Assessment Reports for the respective active substances.

Propiconazole

$PNEC_{STP}$ = 1 mg a.i./l

$PNEC_{Surfacewater}$ = 1.6 µg a.i./l

$PNEC_{Sediment}$ = 0.054 mg a.i./l

$PNEC_{soil}$ = 0.1 mg a.i./l ww at 3.4% organic matter (see below)

IPBC

$PNEC_{STP}$ = 0.44 mg a.i./l

$PNEC_{Surfacewater}$ = 0.5 µg a.i./l

$PNEC_{Sediment}$ = 0.002 mg a.i./l

$PNEC_{soil}$ = 0.005 mg a.i./l ww at 3.4% organic matter

$PNEC_{soil}$ Propiconazole

The following paragraph from the Competent Authority Report for Propiconazole (December 2007, Rapporteur : Finland) indicates that PNECsoil should be 0.02 mg a.i./kg wet soil.

*"The lowest effect concentration of **propiconazole** in soil is NOEC from earthworm (0.998 mg/kg wet soil, 3.4% organic matter). According to the TGD the assessment factor 50 is applied in the derivation of $PNEC_{soil}$ for propiconazole because there are short-term studies from three trophic levels (microorganisms, earthworms and plants) and long-term studies from two trophic levels (microorganisms and earthworms) in the soil environment available. Hence **$PNEC_{soil}$ = 0.02 mg a.i./kg wet soil at 3.4% organic matter."***

However, following the publication of the CA Report, a further study on the chronic toxicity of propiconazole in higher plants has been carried out . The NOEC derived from this study is 0.96mg/kg dry soil. The corresponding NOEC based on wet soil is 0.84 mg a.i./kg wet soil using the conversion factor of 0.88 as stated in the TGD. Furthermore, the test was conducted with a soil containing 1.7% OM. According to the TGD, the NOEC has to be normalized to a standard soil with an organic matter content of 3.4%. **The revised NOEC is calculated to be 1.69 mg a.i./kg wet soil at 3.4% OM**.

According to the TGD the assessment factor 10 can be applied to the lowest NOEC as there are now long-term studies from three trophic levels (microorganisms, earthworms and plants). Hence **$PNEC_{soil}$ = 0.1 mg a.i./kg wet soil.**

UK CA : [redacted] contains 0.3 % of IPBC plus 0.9 % of propiconazole, with a reported relative density of 1.0022.

It is intended to be applied at a rate of 80 – 160 g of product per m^2.

Product is intended to be applied by the following methods :-

- Industrial operators using double-vacuum impregnation, dip, flowcoat (deluge / Vacumat) and automated spray ;

- Professional operators using brush / roller, dip, spray (coarse low pressure) and injection ;

- Non professionals (i.e. amateurs) using brush / roller and spray (coarse low pressure).

Risk assessment has been undertaken by UK CA on the basis of the above listed information, although this has not included vacuum-pressure impregnation treatment. Leaching data have been provided to support superficial treatment methods but cannot be read-across for penetrative treatments (namely any form of vacuum / pressure impregnation).

8.2.1 STP

Table 8.2 2.1.1. Propiconazole - PEC/PNEC ratios for the STP
(*input: 345 g a.i/ m^3 for vacuum-pressure, 1.44 g a.i./m^2 for professional brushing/spraying, dipping/automated spraying/flow-coat, and amateur brushing/spraying*).
$PNEC_{STP}$ = 1 mg a.i./l.

Scenario **Wood in service**	**Application rate 1.44 g/m2 and 345 g/m^3 propiconazole**	
	TIME 1 (30 days)	**TIME 2 (default service life)**
	PEC/PNEC for the STP	
Noise barrier - treatment professional brushing	0.00036	0.000013
Noise barrier - treatment dipping / automated spraying	0.00036	0.000005
Noise barrier - treatment vacuum-pressure	0.00025	0.0000003

PEC_{STP} = Emission / 2000 m^3 (STP)

PEC/PNEC ratios for the STP are below 1 for all application methods, meaning that there is no unacceptable risk to STP microorganisms.

Table 8. 2.1.2. IPBC - PEC/PNEC ratios for the STP
(*input: 115 g a.i/ m^3 for vacuum-pressure, 0.48 g a.i./m^2 for professional brushing/spraying, dipping/automated spraying/flow-coat, and amateur brushing/spraying*).
$PNEC_{STP}$ = 0.44 mg a.i./l.

Scenario **Wood in service**	**Application rate 0.48 g/m2 and 115 g/m^3 IPBC**	
	TIME 1 (30 days)	**TIME 2 (default service life)**
	PEC/PNEC for the STP	
Noise barrier - treatment professional brushing	0.0218	0.00036
Noise barrier - treatment dipping / automated spraying	0.0218	0.000012
Noise barrier - treatment vacuum-pressure	0.0104	0.0000043

PEC_{STP} = Emission / 2000 m^3 (STP)

PEC/PNEC ratios for the STP are below 1 for all application methods, meaning that there is no unacceptable risk to STP microorganisms.

8.2.2 SURFACE WATER

Table 8.2.2.1 : Propiconazole - PEC/PNEC ratios for the aquatic environment
(*input: 345 g a.i/ m^3 for vacuum-pressure, 1.44 g a.i./m^2 for professional brushing/spraying, dipping/automated spraying/flow-coat, and amateur brushing/spraying*).
$PNEC_{surfacewater}$ = 1.6 µg a.i./l

Scenario **Wood in service**	**Application rate 1.44 g/m2 and 345 g/m^3 propiconazole**	
	TIME 1 (30 days)	**TIME 2 (default service life)**
	PEC/PNEC for the aquatic environment	
Noise barrier - treatment professional brushing	0.023	0.0005
Noise barrier - treatment dipping / automated spraying	0.023	0.0005
Noise barrier - treatment vacuum-pressure	0.016	0.0002
Bridge over pond - treatment professional brushing	0.04	0.003
Bridge over pond - treatment dipping / automated spraying	0.4	0.0006
Bridge over pond - treatment vacuum-pressure	0.03	0.0006

PEC/PNEC ratios are below 1 for all scenarios and application methods, meaning that there is no unacceptable risk to the aquatic environment.

Table 8.2.2.2 : IPBC - PEC/PNEC ratios for the aquatic environment
(*input: 115 g a.i/ m^3 for vacuum-pressure, 0.48 g a.i./m^2 for professional brushing/spraying, dipping/automated spraying/flow-coat, and amateur brushing/spraying*).
$PNEC_{surfacewater}$ = 0.5 µg a.i./l

Scenario **Wood in service**	**Application rate 0.48 g/m2 and 115 g/m^3 IPBC**	
	TIME 1 (30 days)	**TIME 2 (default service life)**
	PEC/PNEC for the aquatic environment	
Noise barrier - treatment professional brushing	1.92	0.031
Noise barrier - treatment dipping / automated spraying	1.92	0.010
Noise barrier - treatment vacuum-pressure	0.92	0.004
Bridge over pond - treatment professional brushing	2.96	0.05
Bridge over pond - treatment dipping / automated spraying	2.96	0.02
Bridge over pond - treatment vacuum-pressure	1.42	0.01

There is unacceptable risk to the aquatic environment from wood in service in the bridge over pond scenario after TIME 1 (30 days). The risk is acceptable after the longer assessment period TIME 2 (default service life) for all treatments.
There is unacceptable risk to the aquatic environment from wood in service in the noise barrier scenario after TIME 1 (30 days) for wood treated by brushing or spraying/dipping. The risk is acceptable after the longer assessment period TIME 2 (default service life) for all treatments.

8.2.3 SEDIMENT

Table 8.2.3.1 : Propiconazole - PEC/PNEC ratios for the sediment
(*input: 345 g a.i/ m^3 for vacuum-pressure, 1.44 g a.i./m^2 for professional brushing/spraying, dipping/automated spraying/flow-coat, and amateur brushing/spraying*).
$PNEC_{sediment}$ = 0.054 mg a.i./kg wet sediment.

Scenario **Wood in service**	**Application rate 1.44 g/m2 and 345 g/m^3 propiconazole**	
	TIME 1 (30 days)	**TIME 2 (default service life)**
	PEC/PNEC for the sediment (mg/kg)	
Noise barrier - treatment professional brushing	0.014	0.0006
Noise barrier - treatment dipping / automated spraying	0.014	0.0002
Noise barrier - treatment vacuum-pressure	0.010	0.0001
Bridge over pond - treatment professional brushing	2.54	3.52
Bridge over pond - treatment dipping / automated spraying	2.54	1.96
Bridge over pond - treatment vacuum-pressure	1.76	1.09

There is unacceptable risk to sediment dwelling organisms from wood in service in the bridge over pond scenario after TIME 1 (30 days). The risk is still unacceptable after the longer assessment period TIME 2 (default service life) for all treatments.
Concerning emission due to leaching from the noise barrier via the STP to surface water , risk is acceptable risk at TIME 1 (30 days). Risk is also acceptable after the longer assessment period (default service life).

Table 8.2.3.2 : IPBC - PEC/PNEC ratios for the sediment
(*input: 115 g a.i/ m^3 for vacuum-pressure, 0.48 g a.i./m^2 for professional brushing/spraying, dipping/automated spraying/flow-coat, and amateur brushing/spraying*).

$PNEC_{sediment}$ = 0.002 mg a.i./kg wet sediment.

Scenario **Wood in service**	**Application rate 0.48 g/m2 and 115 g/m^3 IPBC**	
	TIME 1 (30 days)	**TIME 2 (default service life)**
	PEC/PNEC for the sediment (mg/kg)	
Noise barrier - treatment professional brushing	1.75	0.03
Noise barrier - treatment dipping / automated spraying	1.75	0.01
Noise barrier - treatment vacuum-pressure	0.8	0.004
Bridge over pond - treatment professional brushing	56	0.9
Bridge over pond - treatment dipping / automated spraying	56	0.3
Bridge over pond - treatment vacuum-pressure	27	0.1

There is unacceptable risk to sediment dwelling organisms from wood in service in the bridge over pond scenario after TIME 1 (30 days). The risk is acceptable after the longer assessment period TIME 2 (default service life) for all treatments.
Concerning emission due to leaching from the noise barrier via the STP to surface water , risk is unacceptable risk at TIME 1 (30 days) for wood treated by brushing or spraying/dipping.
Risk is acceptable after the longer assessment period (default service life).

8.2.4 GROUNDWATER USED AS DRINKING WATER

Propiconazole

TGD does not contain a detailed approach to calculate PEC in groundwater but only the equation 67 to calculate concentration in pore water. Because this is a worst-case assumption, neglecting transformation and dilution in deeper soil layers, a PEARL 3.3.3 modelling with nine different FOCUS scenarios was carried out with the assumption of 35 houses of treated wood per hectare.

The predicted environmental concentration in groundwater, as represented by the 80th percentile leachate concentration at 1 m soil depth, for propiconazole and 1,2,4-triazole was less than 0.001 µg/l in all nine FOCUS-PEARL scenarios. None of these concentrations exceeds the maximum permissible concentration of 0.1 µg/l given for groundwater in Directive 80/778/EEC (amended by 98/83/EC).

IPBC

The fate and behaviour for IPBC suggest that it is not expected to reach groundwater during outdoor service life of treated wood since this compound has been shown to have a T½ of 0.196 days in soil at 12^{o}C. Therefore an exposure assessment for groundwater on IPBC is not considered further for the use phase

8.2.5 ATMOSPHERE

Propiconazole is only slightly volatile and not persistent in air and therefore no risk characterization for air is needed.

8.2.6 SOIL

Table 8.2.6.1 : Wood in-situ and in-service: Summary of calculated PEC/PNEC ratios (*input: 345 g propiconazole./m^3 and 115 g IPBC./m^3 for vacuum-pressure, 1.44 g propiconazole/m^{2}and 0.48 g IPBC/m^2 for dipping/automated spraying/flow-coat, spraying/brushing*).

$PNEC_{soil}$ = 0.1 mg a.i./kg wet soil (Propiconazole)

$PNEC_{soil}$ = 0.005 mg a.i./kg wet soil (IPBC)

Scenario	Application rate 1.44 g/m^2 and 345 g/m^3 propiconazole			Application rate 0.48 g/m^2 and 115 g/m^3 IPBC		
	Day of application	Time 1 (30 days)	Time 2 (default service life)	Day of application	Time 1 (30 days)	Time 2 (default service life)
Scenarios related to professional brushing treatment – in-situ + in-service combined						
	PEC/PNEC for soil					
Fence	2.0	2.2	0.3	13.6	4.4	0.08
House	2.4	2.6	0.4	16.2	5.2	0.08
Scenarios related to professional brushing treatment –in-service only						
	PEC/PNEC for soil					
Fence	n/a	0.3	0.1	n/a	4.2	0.08
House	n/a	0.4	0.2	n/a	5.0	0.08
Noise Barrier	n/a	0.1	0.005	n/a	1.9	0.04
Scenarios related to amateur brushing treatment – in-situ + in-service combined						
	PEC/PNEC for soil					
Fence	3.4	3.4	0.5	22.6	4.4	0.08
House	4.1	4.1	0.6	27.2	5.4	0.08
Scenarios related to amateur brushing treatment –in-service only						
	PEC/PNEC for soil					
Fence	n/a	0.3	0.1	n/a	4.2	0.08
House	n/a	0.4	0.2	n/a	5.0	0.08
Noise Barrier	n/a	0.1	0.005	n/a	1.9	0.04
Scenarios related to spraying treatment – in-situ + in-service combined						
	PEC/PNEC for soil					
Façade / House – adjacent soil	16.3	15.4	0.62	108.6	6.2	0.04

Scenario	Application rate 1.44 g/m^2 and 345 g/m^3 propiconazole			Application rate 0.48 g/m^2 and 115 g/m^3 IPBC		
	Day of application	Time 1 (30 days)	Time 2 (default service life)	Day of application	Time 1 (30 days)	Time 2 (default service life)
Façade / House – distant soil	0.87	0.80	0.03	5.8	0.06	0.0004
Scenarios related to dipping / spraying /flow-coat – in-service only						
	PEC/PNEC for soil					
Fence	n/a	0.29	0.05	n/a	4.2	0.02
House	n/a	0.35	0.06	n/a	5.0	0.02
Noise Barrier	n/a	0.13	0.002	n/a	1.9	0.01
Scenarios related to vacuum pressure – in-service only						
	PEC/PNEC for soil					
Fence	n/a	0.20	0.03	n/a	2.0	0.008
House	n/a	0.24	0.03	n/a	2.4	0.01
Noise Barrier	n/a	0.09	0.001	n/a	0.9	0.004

TREATED WOOD IN SERVICE

The OECD ESD for wood in service assumes 10 cm horizontal and vertical distance in soil. However, it was decided by the 23rd Competent Authority Meeting to consider soil volumes representing 50 cm horizontal and vertical distances in the risk assessment, and it was confirmed by the 24th Competent Authority Meeting that the 50 cm horizontal and vertical distances should apply at product authorisation stage as well as the Annex 1 entry. All PEC/PNEC calculations for in-service scenarios listed in Tables 2.6.1 were carried out based on 50 cm horizontal and vertical distance. In the scenario 'house' the horizontal distance is 50 cm symmetrically to all four directions around the house (see ESD page 75 figure 5-3).
At an application level of 115 g IPBC/m^3 (vacuum pressure treatment), there is unacceptable risk to the terrestrial environment in the in-service scenarios fence and house after TIME 1 (30 days). Risk is acceptable at an application level of 345 g Propiconazole/m^3. Risk is

acceptable in all in-service scenarios after TIME 2 (default service life), for both active substances.

At an application level of 0.48 g IPBC/m2 (dip / spray / brush treatment), there is unacceptable risk to the terrestrial environment after TIME 1 (30 days) for the in-service scenarios fence, house and noise barrier. Risk is acceptable at an application level of 1.44 g Propiconazole/m^2. Risk is acceptable in all in-service scenarios after TIME 2 (default service life), for both active substances

IN-SITU TREATMENT COMBINED WITH TREATED WOOD IN SERVICE

When in-situ treatments by brush or spray are considered, at an application level of 1.44 g Propiconazole/m^2 and 0.48 g IPBC/m^2, there is unacceptable risk to the terrestrial environment adjacent to the treated structure immediately after treatment and also after TIME 1 . After TIME 2 (default service life), however, risk is acceptable for both active substances. For the distant soil compartment in the façade/house scenario, risk is acceptable immediately after application for Propiconazole, but unacceptable for IPBC. With degradation processes, risk is acceptable for both active substances at TIME 2.

APPLICATION OF SEWAGE TREATMENT PLANT SLUDGE TO AGRICULTURAL SOIL AND GRASSLAND

$PNEC_{soil}$ = 0.1 mg a.i./kg wet soil (Propiconazole)

$PNEC_{soil}$ = 0.005 mg a.i./kg wet soil (IPBC)

Table 8.2.6.2. STP sludge to agricultural soil and grassland: Summary of calculated PEC/PNEC ratios

	PEC/PNEC in agricultural soil averaged over 30 days		PEC/PNEC in agricultural soil averaged over 180 days		PEC/PNEC in grassland averaged over 30 days		PEC/PNEC in grassland averaged over 180 days	
	Propi	**IPBC**	**Propi**	**IPBC**	**Propi**	**IPBC**	**Propi**	**IPBC**
Wood in service: noise barrier – based on highest emission to facility drain	0.0037	0.028	0.0025	0.0046	0.0015	0.01	0.0010	0.0018

The highest emission to the drain is due to leaching from treated noise barrier.

There is no unacceptable risk to soil organisms over 30 days or 180 days if STP sludge containing propiconazole and IPBC as a result of emissions from a noise barrier is applied to agricultural soil or grassland.

UK CA : The results from the CEN/TS 15119-1 laboratory based leaching study are considered unreliable and therefore the PEC/PNEC values determined by the Applicant cannot be supported when leaching loss / flux rates from this short-term study are used.

However, an additional semi-field (NT Build 509) study was undertaken for propiconazole and results submitted to the UK CA are considered acceptable for use in risk assessment. It must be noted that low levels of leaching have been demonstrated only when the [redacted] product has been overcoated with a proprietary non-biocidal acrylic dispersion (non-biocidal in terms of no active substances being present in the topcoat with the intention of protecting / preserving wood under PT 8).

As additional leaching data have been made available, the UK CA has performed new emissions assessments based upon leaching loss flux rates calculated from semi-field data (see section 8.1.2 for further detail). However, new data have only been provided to support application by superficial treatment methods (and **not** vacuum-pressure impregnation).

However, the AR for propiconazole does indicate concerns related to risks posed to soil and/or sediment and/or surface waters. Although the applicant has full access to the active substance data package (including higher plant toxicity data submitted to RMS to support lowering of the soil PNEC with reduced AF), some risks need assessment to demonstrate that [redacted] may be safely applied to timber intended for UC 3. It should be noted that all

data protection issues have been considered as part of this application and we consider that this applicant has provided sufficient information to perform a full assessment in accordance with Uniform Principles to satisfy the requirements of BPD/R.

All assessments utilise agreed endpoints for propiconazole relating to degradation and ecotoxicity for soil, sediment, STP and surface water which have been taken from its AR (including revised soil PNEC which takes account of additional higher plant toxicity data). Emissions from treated wood have been based upon flux rates and leaching loss demonstrated in the NT Build 509 semi-field test which has been discussed in detail within 8.1.2.2.1 where results have been presented.

Due to changes in the data set of 1,2,4-triazole (metabolite of propiconazole) such that the soil half-life increases significantly from 6.4 d to 60.5 d, then it is prudent to undertake groundwater assessment to ensure that modelling still confirms safe use of this active (and product). New assessment particularly looking at groundwater levels for 1,2,4-triazole from breakdown of propiconazole has therefore been required.

1) Risk to STP

Based upon flux rates and leaching loss from the semi-field study, the following table contains PEC/PNEC ratios which have been determined for levels of propiconazole in the [redacted] product. PEC values have been derived using modelling outlined in the ESD for PT8 using flux rates calculated from leaching loss in the semi-field study and PNEC values are those which have been agreed in the relevant AR.

No assessment of metabolites such as 1,2,4-triazole has been undertaken as high margins of safety are predicted in the AR for propiconazole and application rates are comparable (with leaching losses significantly reduced based on 2011 semi-field data).

Output to STP : PEC / PNEC values for propiconazole in [redacted]

Scenario	Propiconazole PEC / PNEC	
	Non-topcoated (Tier 1)	Topcoated (Tier 1)
Industrial application		
Dipping daily	1.71E-1	1.71E-1
Automated spray (large) daily	8.96E-3	8.96E-3
Automated spray (small) daily	8.96E-4	8.96E-4
In-service : noise barrier		
Dipping : Time 1	3.18E-2	3.90E-5
Dipping : Time 2	2.18E-4	2.91E-5
Automated spray : Time 1	3.18E-2	3.90E-5
Automated spray : Time 2	2.18E-4	2.91E-5

Risk to local STP from use of the product is considered to be acceptable.

2) Risk to surface waters

Based upon flux rates and leaching loss from the Megner (2011) study, the following table contains PEC/PNEC ratios have been determined for levels of propiconazole in the [redacted] product. PEC values have been derived using modelling outlined in the ESD for PT8 using flux rates calculated from leaching loss in the 2011 study and PNEC values are those which have been agreed in the relevant AR.

Output to surface waters: PEC /PNEC values for propiconazole in [redacted]

Scenario	Propiconazole PEC / PNEC	
	Non-topcoated (Tier 1)	Topcoated (Tier 1)
Industrial application (with degradation)		
Dipping - daily	**5.21E+0**	**5.21E+0**
Automated spray (large) - daily	2.73E-1	2.73E-1
Automated spray (small) - daily	2.73E-2	2.73E-2
Industrial storage (with degradation)		
Dipping - daily	**1.78E+0**	2.18E-3
Automated spray (large) - daily	**2.00E+0**	2.45E-3
Automated spray (small) - daily	2.00E-1	2.45E-4
Industrial application and storage (with degradation)		
Dipping - daily	**6.98E+0**	**5.21E+0**
Automated spray (large) - daily	**2.27E+0**	2.76E-1
Automated spray (small) - daily	2.27E-1	2.76E-2
In-service : BRIDGE (with degradation)		
Dipping : Time 1	1.44E-1	1.77E-4
Dipping : Time 2	1.23E-5	1.65E-6
Automated spray : Time 1	1.44E-1	1.77E-4
Automated spray : Time 2	1.23E-5	1.65E-6
Brush : Time 1	1.44E-1	1.77E-4
Brush : Time 2	5.26E-5	3.01E-6
Application : BRIDGE (with degradation)		
Amateur - initial	2.06E-1	2.06E-1
Professional - initial	1.23E-1	1.23E-1
Application & in-service : BRIDGE (with degradation)		
Amateur – Time 1	1.47E-1	2.65E-3
Amateur – Time 2	1.46E-1	1.66E-3
Professional – Time 1	1.46E-1	1.66E-3
Professional – Time 2	5.40E-4	2.30E-4
In-service : NOISE BARRIER (with degradation)		
Dipping : Time 1	**1.39E+0**	1.70E-3
Dipping : Time 2	9.51E-3	1.27E-3
Automated spray : Time 1	**1.39E+0**	1.70E-3
Automated spray : Time 2	9.51E-3	1.27E-3

Risk to surface waters following release of propiconazole from treated wood is generally

considered acceptable, with the exception of emissions from industrial dipping applications with / without storage. Such risks can be mitigated by ensuring that labels and safety data sheets state that *freshly treated timber must be stored after treatment under shelter or on an impermeable hard standing to prevent direct losses to water and that any losses must be collected for reuse or disposal*.

In addition, an assessment of metabolite risk (specifically 1,2,4-triazole) has been undertaken using available degradation data on propiconazole plus available data on 1,2,4-triazole (aquatic degradation DT_{50} of 144 d at 25 °C plus aquatic PNEC of 320 µg l^{-1}) from the relevant AR, the following PEC/PNEC ratios have been determined following degradation of emissions of propiconazole from the [redacted] product :-

Output to surface waters: PEC /PNEC values for 1,2,4-triazole from [redacted]

Scenario	**1,2,4-T from Propiconazole PEC / PNEC**	
	Non-topcoated (Tier 1)	**Topcoated (Tier 1)**
Industrial application (with degradation)		
Dipping - daily	3.22E-3	3.22E-3
Automated spray (large) - daily	1.69E-4	1.69E-4
Automated spray (small) - daily	1.69E-5	1.69E-5
Industrial storage (with degradation)		
Dipping - daily	4.23E-4	5.20E-7
Automated spray (large) - daily	4.76E-4	5.84E-7
Automated spray (small) - daily	4.76E-5	5.84E-8
Industrial application and storage (with degradation)		
Dipping - daily	3.64E-3	3.22E-3
Automated spray (large) - daily	6.45E-4	1.69E-4
Automated spray (small) - daily	6.45E-5	1.69E-5
In-service : BRIDGE (with degradation)		
Dipping : Time 1	8.96E-5	1.10E-7
Dipping : Time 2	1.73E-8	2.31E-9
Automated spray : Time 1	8.96E-5	1.10E-7
Automated spray : Time 2	1.73E-8	2.31E-9
Brush : Time 1	8.96E-5	1.10E-7
Brush : Time 2	4.02E-8	2.30E-9
Application : BRIDGE (with degradation)		
Amateur - initial	4.90E-5	4.90E-5
Professional - initial	2.94E-5	2.94E-5
Application & in-service : BRIDGE (with degradation)		
Amateur – Time 1	9.11E-5	1.65E-6
Amateur – Time 2	1.13E-7	6.18E-8
Professional – Time 1	9.05E-5	1.03E-6
Professional – Time 2	8.99E-8	3.83E-8
In-service : NOISE BARRIER (with degradation)		
Dipping : Time 1	3.30E-4	4.05E-7
Dipping : Time 2	2.27E-6	3.02E-7
Automated spray : Time 1	3.30E-4	4.05E-7

Automated spray : Time 2	2.27E-6	3.02E-7

Risks posed to surface waters by metabolite 1,2,4-triazole following leaching of propiconazole from treated wood are considered acceptable.

3) Risk to sediment

Based upon flux rates and leaching loss from the 2011 study, the following table contains PEC/PNEC ratios have been determined for levels of propiconazole in the [redacted] product. PEC values have been derived using modelling outlined in the ESD for PT8 using flux rates calculated from leaching loss in the 2011 study and PNEC values are those which have been agreed in the relevant AR.

Output to sediment: PEC /PNEC values for propiconazole in [redacted]

Scenario	**Propiconazole PEC / PNEC**	
	Non topcoated (Tier 1)	**Topcoated (Tier 1)**
Industrial application (with degradation)		
Dipping - daily	**2.42E+0**	**2.42E+0**
Automated spray (large) - daily	1.27E-1	1.27E-1
Automated spray (small) - daily	1.27E-2	1.27E-2
Industrial storage (with degradation)		
Dipping - daily	8.25E-1	1.01E-3
Automated spray (large) - daily	9.28E-1	1.14E-3
Automated spray (small) - daily	9.28E-2	1.14E-4
Industrial application and storage (with degradation)		
Dipping - daily	**3.24E+0**	**2.42E+0**
Automated spray (large) - daily	**1.05E+0**	1.28E-1
Automated spray (small) - daily	1.05E-1	1.28E-2
In-service : BRIDGE (with degradation)		
Dipping : Time 1	6.69E-2	8.21E-5
Dipping : Time 2	5.73E-6	7.65E-7
Automated spray : Time 1	6.69E-2	8.21E-5
Automated spray : Time 2	5.73E-6	7.65E-7
Brush : Time 1	6.69E-2	8.21E-5
Brush : Time 2	2.44E-5	1.40E-6
Application : BRIDGE (with degradation)		
Amateur - initial	9.54E-2	9.54E-2
Professional - initial	5.72E-2	5.72E-2
Application & in-service : BRIDGE (with degradation)		
Amateur – Time 1	6.81E-2	1.23E-3
Amateur – Time 2	2.22E-3	1.21E-3
Professional – Time 1	6.76E-2	7.72E-4
Professional – Time 2	2.51E-4	1.07E-4
In-service : NOISE BARRIER (with degradation)		
Dipping : Time 1	6.43E-1	7.89E-4
Dipping : Time 2	4.41E-3	5.89E-4
Automated spray : Time 1	6.43E-1	7.89E-4

Automated spray : Time 2	4.41E-3	5.89E-4

Risk to sediment from use of the product is generally considered acceptable, with the exception of emissions from industrial application with /without storage. Such risks can be mitigated by ensuring that labels and safety data sheets state that *freshly treated timber must be stored after treatment under shelter or on an impermeable hard standing to prevent direct losses to water and that any losses must be collected for reuse or disposal*.

No assessment of the metabolite 1,2,4-triazole has been undertaken due to its high water solubility (700 g l^{-1} at 20 °C), low molecular weight (69.1 g mol^{-1}) plus low K_{oc} (89 l kg^{-1}) - as such, the compound is not expected to bind to soil / sludge / sediment and therefore be highly mobile. On this basis, only risk of 1,2,4-triazole to surface water and groundwater have been considered relevant.

4) Risk to soil

In the Assessment Report for Annex I inclusion of Propiconazole under PT 8, toxicity to terrestrial species was considered in micro-organisms, plants and earthworms. The RMS (Finland) concluded that the $PNEC_{soil}$ should be 0.02 mg a.i./kg wet soil, based on the lowest NOEC from long-term studies at two trophic levels with an assessment factor of 50. However, a further long-term higher plant toxicity study has since been completed by the applicant for Propiconazole in support of use in PT 9 and this has been submitted to and accepted by the RMS. This additional study allows reduction of the assessment factor (AF) to 10, resulting in a revised $PNEC_{soil}$ of 0.1 mg/kg wwt.

The PEC values determined for this product have been compared against PNEC values agreed during the EU Review of propiconazole (under PT 8) with the exception of soil, where a revised PNEC of 0.1 mg/kg has been proposed based on a new higher plant toxicity study considered as part of the EU Review of propiconazole (PT 9).

Original $PNEC_{soil}$ (PT 8 CAR) of 0.02 mg a.s. kg^{-1} wet weight

This PNEC has been derived from acute endpoints for earthworms, micro-organisms plus plants and chronic endpoints for earthworms and micro-organisms, applying an AF of 50 to the lowest chronic value to earthworms (0.998 mg a.s. kg^{-1} wwt) - decision based upon discussion and agreement at Technical Meeting (TM).

Revised $PNEC_{soil}$ (PT 9 CAR) of 0.10 mg a.s. kg^{-1} wet weight

This PNEC is proposed in the propiconazole CAR for its use in PT 9 as a result of additional chronic higher plant toxicity data being submitted in order to reduce AF to 10. At this point in time (November 2011), the CAR has not been presented at a TM so the extra toxicity data

have not been discussed and thus the revised PNEC has not been agreed to.

UK view on revised PNEC soil for propiconazole

The $PNEC_{soil}$ has been revised in the PT 9 CAR by inclusion of an additional long-term toxicity endpoint from a plant toxicity study. Plants were found to be the second most sensitive group in the short term toxicity tests, with earthworms being the least sensitive. Using the long term data, earthworms are considered the most sensitive group, even when the new long- term plant endpoint is considered. Lowering of the AF may be permitted if the uncertainty of predicting ecosystem effects from laboratory data is lowered by the existence of further toxicity data. The NOEC from the plant long-term toxicity test is lower than the EC_{50} derived from the plant short term toxicity test, but is not lower than the NOEC derived from the earthworm toxicity test. It is the view of the UK CA that there are sufficient data available to be more certain that the most sensitive group of organisms is covered by the available data and thus the AF can be lowered to reflect this. It is considered that the AF of 10 is sufficient to allow for inter-special variation, i.e. to be protective of earthworm species that were not tested in the laboratory so the revised $PNEC_{soil}$ is acceptable.

In summary, it is the conclusion of the UK CA that the revised $PNEC_{soil}$ of 0.1 mg a.s. kg^{-1} wwt can be considered acceptable for use in assessment of this product application, on the proviso that this value is accepted at the TM when propiconazole for use in PT 9 is discussed and agreed. However, **if the revised PNEC is not agreed at TM,** then this could adversely impact on the application for [redacted] n that risk to soil (denoted by PEC/PNEC values) would increase by a factor of 5 if assessment reverted to use of the original PNEC.

Based upon flux rates and leaching loss from the 2011 study, the following PEC/PNEC ratios have been determined for levels of propiconazole in the [redacted] product :-

Output to soil: PEC /PNEC values for propiconazole in [redacted]

Scenario	Propiconazole PEC / PNEC (no topcoat) : Tier 1	Propiconazole PEC / PNEC (no topcoat) : Tier 2	Propiconazole PEC / PNEC (with topcoat) : Tier 1
Industrial storage (initial)			
Dipping : Time 1	**8.42E+1**	**8.42E+1**	1.03E-1
Dipping : Time 2	**1.54E+4**	**1.54E+4**	**1.89E+1**
Automated spray (large) : Time 1	**8.42E+1**	**8.42E+1**	1.03E-1
Automated spray (large) : Time 2	**1.54E+4**	**1.54E+4**	**1.89E+1**
Automated spray (small) : Time 1	**8.42E+1**	**8.42E+1**	1.03E-1
Automated spray (small) : Time 2	**1.54E+4**	**1.54E+4**	**1.89E+1**
In-service : FENCE (with degradation)			
Dipping : Time 1	**2.82E+1**	**2.82E+1**	3.46E-2
Dipping : Time 2	**1.61E+0**	**1.15E+0**	2.15E-1
Automated spray : Time 1	**2.82E+1**	**2.82E+1**	3.46E-2

Automated spray : Time 2	**1.61E+0**	**1.15E+0**	2.15E-1
Brushing : Time 1	**2.82E+1**	**2.82E+1**	3.46E-2
Brushing : Time 2	**3.76E+0**	**1.76E+0**	2.15E-1

Application : FENCE (with degradation)			
Amateur : Initial	3.50E-2	3.50E-2	3.50E-2
Professional : Initial	2.10E-2	2.10E-2	2.10E-2
Application & in-service : FENCE (with degradation)			
Amateur : Time 1	**2.82E+1**	**2.82E+1**	6.55E-2
Amateur : Time 2	**3.60E+0**	**1.68E+0**	2.08E-1
Professional : Time 1	**2.82E+1**	**2.82E+1**	5.31E-2
Professional : Time 2	**3.60E+0**	**1.68E+0**	2.07E-1
In-service : HOUSE (with degradation)			
Dipping : Time 1	**3.39E+1**	**3.39E+1**	4.15E-2
Dipping : Time 2	**1.94E+0**	**1.38E+0**	2.59E-1
Automated spray : Time 1	**3.39E+1**	**3.39E+1**	4.15E-2
Automated spray : Time 2	**1.94E+0**	**1.38E+0**	2.59E-1
Brushing : Time 1	**3.39E+1**	**3.39E+1**	4.15E-2
Brushing : Time 2	**4.52E+0**	**2.11E+0**	2.59E-1
Application : HOUSE (with degradation)			
Amateur : Initial	3.50E-2	3.50E-2	3.50E-2
Professional : Initial	2.10E-2	2.10E-2	2.10E-2
Application & in-service : HOUSE (with degradation)			
Amateur : Time 1	**3.39E+1**	**3.39E+1**	7.25E-2
Amateur : Time 2	**4.32E+0**	**2.02E+0**	2.50E-1
Professional : Time 1	**3.39E+1**	**3.39E+1**	6.01E-2
Professional : Time 2	**4.32E+0**	**2.02E+0**	2.49E-1
In-service : NOISE BARRIER (with degradation)			
Dipping : Time 1	**4.23E+1**	**4.23E+1**	5.18E-2
Dipping : Time 2	**2.42E+0**	**1.72E+0**	3.23E-1
Automated spray : Time 1	**4.23E+1**	**4.23E+1**	5.18E-2
Automated spray : Time 2	**2.42E+0**	**1.72E+0**	3.23E-1

PEC values have been derived using modelling outlined in the ESD for PT8 using flux rates calculated from leaching loss in the 2011 study and PNEC values are those which have been agreed in the relevant AR (and take account of the revised soil PNEC for propiconazole based on additional higher plant toxicity data).

Risk to soil from use of the product is generally considered acceptable when [redacted] is used in conjunction with a top coat, with the exception of emissions from industrial storage. Such risks can be mitigated by ensuring that labels and safety data sheets state that *freshly treated timber must be stored after treatment under shelter or on an impermeable hard standing to prevent direct losses to soil and that any losses must be collected for reuse or disposal*.

At present, interpretation of leaching losses from the NT 509 semi-field study (without topcoat) give rise to the following long term flux rates used by UK CA in risk assessment :-

	Tier 1 flux rate (mg m^{-2} d^{-1})	Tier 2 flux rate (mg m^{-2} d^{-1})
TIME 2 (day 1825)	6.130E-1	2.865E-1
TIME 2 (day 5475)	2.630E-1	1.868E-1

However, it should be noted that the Applicant has subsequently proposed an additional level of refinement (taken to be Tier 3) for setting of long term flux rate as both existing approaches (Tier 1 and Tier 2) taken by the UK CA indicate the potential for unacceptable risks to soil in all scenarios (industrial pre-treatment sites, noise barrier, house and fence).

The Applicant has further investigated leaching losses within the semi-field study (no topcoat applied : report 11047) and proposes a revised daily flux rate at TIME 2 based upon their calculation of the lowest daily flux rate during the entire study. This is estimated to be 3.00E-2 mg m^{-2} d^{-1} derived from the results observed between collection of 520 – 620 mm of rain (i.e. during notional Year 1 of study). By contrast, when leaching loss had reduced to a more steady state in notional Year 2 of the study, the UK CA has derived a "lowest" mean flux rate from study data of 4.99E-2 mg m^{-2} d^{-1}.

As means of support for use of a lower flux rate at TIME 2, leaching losses in the NT 509 study for the second year (results covering 700 mm to 1099.7 mm rainfall) suggest losses of 28.53 mg m^{-2} after 399.7 mm of rain. If 700 mm is taken to represent normalised annual rainfall, this is equivalent to 28.53 mg m^{-2} being lost in 208.4 days and a resultant mean flux rate of 1.369E-1 mg m^{-2} d^{-1}. This in itself is already a significant drop in mean flux rate from Year 1 (323.1 mg m^{-2} in 365 days so 8.85E-1 mg m^{-2} d^{-1}) and it has been agreed at the Arona 2005 Workshop that flux rate can be expected to continually reduce over time to the end of service life.

Use of "lowest" daily flux rate from the semi-field study to predict losses at TIME 2 (i.e. on day 1825 and day 5475) does give rise to significantly reduced emissions of propiconazole at that point. Based upon the value of 4.99E-2 mg m^{-2} d^{-1} derived by UK CA as lowest daily flux rate during Year 2 of the study, it is noted that PEC/PNEC values in soil at TIME 2 drop the acceptable levels for the house, fence and noise barrier scenarios but unacceptable risks still exist at industrial sites.

Revised soil PEC / PNEC values for propiconazole at TIME 2 using "lowest" daily flux rate (4.99E-2 mg m^{-2} d^{-1}) derived once steady state leaching reached in Year 2 : proposed TIER 3 approach by Applicant

Scenario	Propiconazole PEC / PNEC (TIER 3)
Industrial storage (initial)	
Dipping : Time 2	**1.54E+4**
Automated spray (large) : Time 2	**1.54E+4**
Automated spray (small) : Time 2	**1.54E+4**

In-service : FENCE (with degradation)	
Dipping : Time 2	3.06E-1
Automated spray : Time 2	3.06E-1
Brush : Time 2	3.06E-1
Application & in-service : FENCE (with degradation)	
Amateur : Time 2	2.95E-1
Professional : Time 2	2.94E-1
In-service : HOUSE (with degradation)	
Dipping : Time 2	3.68E-1
Automated spray : Time 2	3.68E-1
Brush : Time 2	3.68E-1
Application & in-service : HOUSE (with degradation)	
Amateur : Time 2	3.54E-1
Professional : Time 2	3.53E-1
In-service : NOISE BARRIER (with degradation)	
Dipping : Time 2	4.59E-1
Automated spray : Time 2	4.59E-1

Some uncertainty exists over choice of appropriate flux rates at TIME 2 from semi-field studies and whilst several proposals / suggestions were made at the Arona Leaching Workshop in 2005, no clear conclusion appears to have been reached to support either the UK CA or Applicant's approach. Furthermore, where studies demonstrate the potential for total leaching of active substance before the end of service life, it has been agreed to assume linear leaching loss to derive flux rates by dividing total applied active substance by service life. However, it would not be considered acceptable to base long-term flux rate on the lowest measurable flux rate value during the study in these instances.

On that basis and to maintain a "realistic worst case" approach to risk assessment, the UK CA considers that unacceptable risks to soil are potentially possible using both Tier 1 and Tier 2 evaluations when timber has not been topcoated following application of [redacted]

No assessment of the metabolite 1,2,4-triazole has been undertaken due to its high water solubility (700 g l^{-1} at 20 °C), low molecular weight (69.1 g mol^{-1}) plus low K_{oc} (89 l kg^{-1}). As such, the compound is not expected to bind to soil / sludge / sediment and therefore be highly mobile. On this basis, only risk of 1,2,4-triazole to surface water and groundwater have been considered relevant.

5) Risk to groundwater

As outlined in section 8.1.9, leaching risk posed to groundwater by propiconazole in all assessments has been shown to be very low (actual PEC_{gw} values were all reported to be <0.00001µg/l for all scenarios). However, concentrations for 1,2,4-triazole (metabolite)

significantly exceed the 0.1µg/l limit in all scenarios (including the 4 pertinent to the UK) when it is assumed that all applied propiconazole will leach from treated wood during a 5 year service life (associated with brush application). Such results in FOCUS PEARL 4.4.4 modelling make use of new soil degradation data under PPPR on the metabolite which predicts that the compound is significantly more persistent that considered in the AR for propiconazole.

When refinements are applied to FOCUS modelling, the following outcomes are noted :-

Use of leaching losses derived from non-topcoated leaching study when it is assumed that losses demonstrated during study continue at a linear rate until end of 5 year service life - **Tier 1 approach** : concentrations for 1,2,4-triazole (metabolite) significantly exceed the 0.1µg/l limit in all 9 scenarios including the 4 pertinent to the UK, even when calculated with reduced number of houses (16 per ha) and use of daily flux rates derived from the semi-field study. Predicted levels of metabolite in groundwater are considered unacceptable.

Use of leaching losses derived from non-topcoated leaching study when it is assumed that leaching losses are high in Year 1 but decrease to a lower, steady rate in Year 2 onwards for 5 year service life - **Tier 2 approach** : concentrations for 1,2,4-triazole (metabolite) exceed the 0.1µg/l limit in 8 out of 9 scenarios including all 4 pertinent to the UK, even when refined for reduced number of houses (16 per ha) and use of daily flux rates derived from the semi-field study. Predicted levels of metabolite in groundwater are considered unacceptable as significant risks are identified.

Use of leaching losses derived from non-topcoated leaching study when it is assumed that leaching losses are high in Year 1 but decrease to a lower, steady rate in Year 2 onwards for 15 year service life - **Tier 2 approach** : concentrations for 1,2,4-triazole (metabolite) exceed the 0.1µg/l limit in 7 out of 9 scenarios including all 4 pertinent to the UK, even when refined for reduced number of houses (16 per ha) and use of daily flux rates derived from the semi-field study. Predicted levels of metabolite in groundwater are considered unacceptable as significant risks are identified.

Use of leaching losses derived from topcoated leaching study when it is assumed that losses demonstrated during study continue at a linear rate until end of 5 year service life - **Tier 1 approach** : concentrations for 1,2,4-triazole (metabolite) all drop significantly below the 0.1µg/l limit in all scenarios including the 4 pertinent to the UK. As a consequence, predicted levels of metabolite in groundwater are considered acceptable.

However, it should be noted that the Applicant has proposed an additional level of refinement (taken to be Tier 3) for deriving long term (TIME 2) flux rate by assuming it to be the lowest daily flux rate from the semi-field study. Furthermore, it has been proposed that once

sampling of leachate in rainwater ceased at 19 months, the flux rate for the reminder of service life dropped to this daily rate (3.00E-2 mg m^{-2} d^{-1}) even though daily leaching rates during Year 2 of the study varied between 4.99E-2 to 3.44E-1 mg m^{-2} d^{-1}.

Due to the extremely high leaching losses of propiconazole during the first year of the semi-field study and new soil degradation data on the breakdown of its metabolite 1,2,4-triazole, the UK CA cannot accept any further refinement of groundwater assessment beyond the Tier 1 and Tier 2 approach already taken. On that basis, levels of 1,2,4-triazole in groundwater can only be considered acceptable if timber treated with [redacted] has then been topcoated with an acrylic dispersion wood finish.

UK CA : Whilst no leaching data have been submitted for IPBC, flux rates based upon service life have been demonstrated by the Applicant and these fall significantly below those found acceptable within its Assessment Report (AR). Although significant PEC/PNEC values have been calculated by the Applicant in this section of 8.2, they conflict with values presented in the AR based on greater flux rates. It is clear that the summation of PEC/PNEC's as a screening process to assess mixed active risk will not identify additional risks to those presented for propiconazole alone. The introduction of mitigation measures at industrial sites to prevent contamination of water and ground from emissions of both active substances from treated wood will provide sufficient protection.

UK CA : In summary, it is considered that risks to all environmental compartments from leaching of both IPBC and propiconazole following use of the product on timber intended for UC 2 - 3 can be considered acceptable, provided that :-

- As leaching data have only been provided where [redacted] was applied to wood by superficial methods, then application by penetrative methods (such as vacuum / pressure impregnation) cannot be supported. This is in line with decisions arising from the Arona leaching Workshop in 2005. However, all other superficial application methods are considered acceptable ;
- Application of the [redacted] product at rates up to a maximum of 160 g per m^2 to timber must be followed by application of appropriate topcoat at coverage rates in line with those used in the semi-field study. As leaching study data have only been shown to be acceptable for soil and groundwater provided that overcoating is undertaken as part of the treatment process, then labels must indicate that the product must always

be overcoated in this manner prior to use of the treated timber in situations where it would be exposed to weathering (UC 3) ;

- Mitigation measures are undertaken as there is potential for risk to surface waters plus risk to sediment plus risk to soil from emissions of propiconazole following industrial application with/without storage. Labels and safety data sheets must state that freshly treated timber must be stored after treatment under shelter or on an impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

Endocrine disruption

Propiconazole has undergone a comprehensive battery of in vivo mammalian toxicology and ecotoxicology testing that cover a broad spectrum of endocrine-sensitive endpoints that are sufficient to detect potential endocrine disruption. This testing included a tiered battery of acute, sub-acute, sub-chronic, chronic/carcinogenicity and reproductive mammalian toxicology tests, in addition to acute, chronic and lifecycle ecotoxicology tests. Furthermore, these studies have robust experimental designs, follow internationally accepted protocols, have a high level of replication and a long history of use in hazard identification and risk assessment. The results from these studies show no clear and unambiguous evidence of endocrine-mediated adverse effects on endocrine organs, reproduction or development with propiconazole. It is possible that the changes in adrenal, testis and epididymis weights observed in the rat are secondary to generalised toxicity and that the low incidence of cleft palate identified in the rat is due to a non-endocrine disruptive mechanism. Therefore, although the evidence suggests no obvious concern for endocrine disruption, there remains an uncertainty as to whether further investigation would be appropriate. However, at present, there are no clear criteria agreed at EU level to identify endocrine disrupters for regulatory purposes. In addition, currently, the BPD does not specify any regulatory implications of identifying a substance as an endocrine disrupter. Therefore, it is proposed that this assessment is revisited once EU-agreed criteria for endocrine disrupters are established and the new Biocidal Product Regulation which stipulates regulatory consequences for substances identified as endocrine disrupters is implemented.

8.2.7 EFFECT OF RE-APPLICATION

For those intended uses for which re-application is possible (i.e. spraying or brushing), PEC/PNEC values for the soil compartment at TIME 2 are low, indicating that re-application would not give rise to any unacceptable risk.

9. Unacceptable Effects of the Biocidal Product
None to report.

10 DECISION

10.1 Summary of decisions and restrictions

It is concluded that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the product Holzschutz-Imprägnierung aq. 9005 supported according to the following:

1) Industrial use

The following methods of application have been found to be acceptable for Industrial use of the products.
Automated dipping
Automated spraying
Flow coating (deluge)
Manual dipping

2) Professional use

The following methods of application have been found to be acceptable for Professional use of the products.
Brush/Roller (indoors and outdoors)
Spraying (indoors and outdoors)
Manual dipping
Surface injection/treatment (indoor only)

3) Non-professional users

The following method of application has been found to be acceptable for non-professional use of the products.
Brush/Roller (indoors and outdoors)
Spraying (indoors and outdoors)

4) The following application methods could not be authorised:
Industrial: Vacuum pressure

The applicant also requested the application method vacuum pressure. However, leaching data have only been submitted to support superficial treatment and in line with guidelines

drawn up following the Arona Leaching Workshop in 2005, superficial leaching data cannot be used to support penetrative treatment methods. Therefore, application by penetrative methods (such as vacuum impregnation) is considered unacceptable.

5) The following conditions must be applied to the product:-

Authorisation is granted for Use Class 2 and Use Class 3. The product is for use on timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting.

Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.

For industrial use application processes must be carried out within a contained area, situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).

For industrial use storage of freshly treated wood must be either undercover with a recovery system in place (e.g. sump) or on impermeable hard standing and bunded to prevent run-off with a recovery system in place (e.g. sump).

Authorisation is only granted on the basis that the product must have an appropriate top-coat (minimum total application of 240 ml/ m^2, achieved by 1-3 applications or minimum dry film thickness in total of 100 µm,) applied to treated timber in situations where it would be exposed to weathering. The topcoat should either be applied prior to the use of the treated timber in situations exposed to weathering, or in the case of ‘new build’ scenarios or *in situ* applications of this product, prior to the weathering events themselves (e.g. rainfall). The top-coat should not contain a triazole fungicide. This information must be included on the product label..

At present, there are no clear criteria agreed at EU level to identify endocrine disrupters for regulatory purposes. In addition, currently, the BPD does not specify any regulatory implications of identifying a substance as an endocrine disrupter. Therefore, it is proposed that once EU-agreed test guidelines, associated definitions and criteria for endocrine disruption are established for biocides and the new Biocidal Product Regulation which stipulates regulatory consequences for substances identified as endocrine disrupters is implemented, then relevant information should be provided to the UK CA by the authorisation holder so that appropriate reassessment of the product authorisation can be carried out

As a condition, in the absence of supporting efficacy data on hardwood, suitable information post-authorisation supporting the efficacy as a superficial treatment against wood rotting fungi

on hardwood, will need to be provided. It is intended that these data will be provided to support the lead product dossier [redacted]

6*)* Authorisation is granted for use of the product at a minimum application rate of the product is 80 g product m^{-2} (0.72 g propiconazole m^{-2} and 0.24 g IPBC m^{-2}). Efficacy data against wood rotting fungi, wood discolouring fungi and dry rot has shown the product to be effective when used at this minimum application rate.
Application by surface injection is only authorised for the treatment of dry rot..

For applications against blue stain, decay fungi, sapstain and molds the acceptable application rate of the product is 80 – 160 g of product per m^2 which can be achieved by 1-2 applications.

For injection/surface treatment against dry rot the acceptable application rate of the product is 80 – 160 g of product per m^2 which can be achieved by 1-3 applications.

In all cases it should be ensured that the maximum application of product would only reach 160 g m^{-2}.

6) Authorisation is granted for Use Class 2 and Use Class 3.

The product is for use on internal timbers that are at risk of wetting and timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting.

7) Based on the data provided with this application authorisation is only granted on the basis that the product must have a top-coat applied (minimum total volume of 240 ml/ m², achieved by 1-3 applications or minimum dry film thickness in total of 100 µm, achieved by 1-3 applications) and this information will be included on the product label. The use of a specific top-coat is not required at this stage. However, please be aware that the UK CA are currently working towards establishing a more formal position as regards the use of top-coats which will include what generic positions can be viewed as acceptable, and what data are required to support these. In formulating and establishing this position discussion with both Member States and UK stakeholders will need to take place. If, once the final position is agreed, amendments to this product authorisation are required, then Concerned Member States will be informed.

8) The maximum level of active ingredient Propiconazole in the product is 0.9 % w/w. The source of the active is Syngenta Crop Protection AG, Basel, minimum purity 93% w/w.

9) The maximum level of active ingredient IPBC in the product is 0.3% w/w. The source of the active is Troy Corporation, USA, minimum purity 98% w/w.

10) The maximum shelf life of the product is 18 months.

10.2 NECESSARY ISSUES ACCOUNTED FOR IN THE PRODUCT LABEL

It is conceivable that a label in UK or other MS that there may have more than one user group on the same label, particularly on packaging of the same container size. In this regard we recommend that in circumstances where more than one user group (industrial, professional or non-professional) is included on the same label, the necessary issues accounted for on the relevant product labels (as indicated below), should be accounted for on any multi-user group label.

Industrial label

R 52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

***Contains Propiconazole and IPBC. May cause an allergic reaction*.**

S61 – Avoid release to the environment. Refer to special instructions/Safety data sheets

The product is for use on timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting.

Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.

Application processes must be carried out within a contained area, situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).

Storage of freshly treated wood must be either undercover with a recovery system in place (e.g. sump) or on impermeable hard standing and bunded to prevent run-off with a recovery system in place (e.g. sump).

A top-coat (minimum total volume of 240 ml/ m², achieved by 1-3 applications or minimum dry film thickness in total of 100 µm, achieved by 1-3 applications,) must be applied to treated timber in situations where it would be exposed to weathering. The topcoat should either be applied prior to the use of the treated timber in situations exposed to weathering, or in the case of 'new build' scenarios or *in situ* applications of this product, prior to the weathering events themselves (e.g. rainfall). The top-coat should not contain a triazole fungicide.

The COSHH (Control of Substances Hazardous to Health) Regulations 2002 (as amended) apply to the use of this product at work.

Guidance on the safe use of wood preservatives is provided in leaflet WIS 29 ("Occupational hygiene and health surveillance at industrial treatment plants") at www.hse.gsi.gov.uk.

Wear suitable protective clothing (coveralls, gloves, footwear) when applying the product and when handling freshly treated timber. Avoid excessive contamination of overalls

Do not contaminate ground, waterbodies or watercourses with chemicals or used container.

DISPOSE OF SURPLUS CHEMICAL, CONTAMINATED MATERIALS (INCLUDING SAWDUST) AND THE EMPTY CONTAINER SAFELY using a method approved by the WASTE DISPOSAL AUTHORITY.

WASH HANDS AND EXPOSED SKIN before meals and after use.

KEEP IN A SAFE PLACE.

3-IODO-2-PROPYNYL-N-BUTYL CARBAMATE is a carbamate compound which has weak anticholinesterase activity. DO NOT USE if under medical advice not to work with anticholinesterase compounds.

Professional label

R 52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

***Contains Propiconazole and IPBC. May cause an allergic reaction*.**

S2 – Keep out of reach of children

S61 – Avoid release to the environment. Refer to special instructions/Safety data sheets

For professional use only

The product is for use on timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting.

Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.
Application by manual dipping must be carried out within a contained area, and situated on an impermeable surface.
Storage of treated wood must either be undercover with a recovery system in place or on an impermeable surface.

A top-coat (minimum total volume of 240 ml/ m², achieved by 1-3 applications or minimum dry film thickness in total of 100 µm, achieved by 1-3 applications) must be applied to treated timber in situations where it would be exposed to weathering. The topcoat should either be applied prior to the use of the treated timber in situations exposed to weathering, or in the case of *in situ* applications, prior to the weathering events themselves (e.g. rainfall). The top-coat should not contain a triazole fungicide.

The COSHH (Control of Substances Hazardous to Health) Regulations 2002 (as amended) apply to the use of this product at work.

Wear suitable protective clothing (coveralls, gloves, footwear) when applying product and when handling freshly treated timber. Avoid excessive contamination of coveralls.

Handle product and dry freshly treated wood in areas with good ventilation

DO NOT CONTAMINATE FOODSTUFFS, EATING UTENSILS OR FOOD CONTACT SURFACES.

WASH HANDS AND EXPOSED SKIN before meals and after use.

KEEP IN A SAFE PLACE.

Do not empty into drains

Do not contaminate ground, waterbodies or watercourses with chemicals or used container.

For *in situ* use do not contaminate plant life and remove or cover aquariums/fish bowls/ponds before application.

This material and its container must be disposed of in a safe way.

UNPROTECTED PERSONS AND ANIMALS SHOULD BE KEPT AWAY FROM TREATED AREAS FOR 48 HOURS OR UNTIL SURFACES ARE DRY.

COVER ALL WATER STORAGE TANKS before application.

Dangerous to Bats. All bats are protected under the Wildlife and Countryside Act 1981. Before treating any structure used by bats, consult Natural England, Scottish Natural Heritage or the Countryside Council for Wales.

3-IODO-2-PROPYNYL-N-BUTYL CARBAMATE is a carbamate compound which has weak anticholinesterase activity. DO NOT USE if under medical advice not to work with anticholinesterase compounds.

Non-professional label

R 52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

***Contains Propiconazole and IPBC. May cause an allergic reaction*.**

S2 – Keep out of reach of children

S61 – Avoid release to the environment. Refer to special instructions/Safety data sheets

The product is for use on timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting.

Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.

During application to *in situ* timbers do not contaminate soil and surface waters with product A top-coat (minimum total volume of 240 ml/ m², achieved by 1-3 applications or minimum dry film thickness in total of 100 µm, achieved by 1-3 applications) must be applied to treated timber in situations where it would be exposed to weathering. The topcoat should either be applied prior to the use of the treated timber in situations exposed to weathering, or in the case of *in situ* applications, prior to the weathering events themselves (e.g. rainfall). The top-coat should not contain a triazole fungicide.

This material and its container must be disposed of in a safe way.

DO NOT CONTAMINATE FOODSTUFFS, EATING UTENSILS OR FOOD CONTACT SURFACES.

*WASH HANDS AND EXPOSED SKIN before meals and after use.

*KEEP IN A SAFE PLACE.

Do not empty into drains

Do not contaminate ground, waterbodies or watercourses with chemicals or used container.

For *in situ* use do not contaminate plant life and remove or cover aquariums/fish bowls/ponds before application.

UNPROTECTED PERSONS AND ANIMALS SHOULD BE KEPT AWAY FROM TREATED AREAS FOR 48 HOURS OR UNTIL SURFACES ARE DRY.

COVER ALL WATER STORAGE TANKS before application.

Dangerous to Bats. All bats are protected under the Wildlife and Countryside Act 1981. Before treating any structure used by bats, consult Natural England, Scottish Natural Heritage or the Countryside Council for Wales.

3-IODO-2-PROPYNYL-N-BUTYL CARBAMATE is a carbamate compound which has weak anticholinesterase activity. DO NOT USE if under medical advice not to work with anticholinesterase compounds.

10.3 REQUIREMENT FOR FURTHER INFORMATION

1. As a condition, in the absence of supporting efficacy data on hardwood, suitable information post-authorisation supporting the efficacy as a superficial treatment against wood rotting fungi on hardwood, will need to be provided. It is intended that these data will be provided to support the lead product dossier [redacted]

2. Based on the data provided with this application authorisation is only granted on the basis that the product must have a top-coat applied (minimum total 240 ml/ m², achieved by 1-3 applications, or minimum dry film thickness in total of 100 µm, achieved by 1-3 applications) and this information will be included on the product label. The use of a specific top-coat is not required at this stage. However, please be aware that the UK CA are currently working towards establishing a more formal position as regards the use of top-coats which will include what generic positions can be viewed as acceptable, and what data are required to support these. In formulating and establishing this position discussion with both Member States and UK stakeholders will need to take place. If, once the final position is agreed, amendments to this product authorisation are required, then Concerned Member States will be informed.

3. At present, there are no clear criteria agreed at EU level to identify endocrine disrupters for regulatory purposes. In addition, currently, the BPD does not specify any regulatory implications of identifying a substance as an endocrine disrupter. Therefore, it is proposed that once EU-agreed test guidelines, associated definitions and criteria for endocrine disruption are established for biocides and the new Biocidal Product Regulation which stipulates regulatory consequences for substances identified as endocrine disrupters is implemented, then relevant information should be provided to the UK CA by the authorisation holder so that appropriate reassessment of the product authorisation can be carried out.

4. There is currently no agreed methodology for performing a combined risk assessment of multi-active biocidal products. A proposal from the French CA is due to be discussed and agreed at TM level. Once a methodology is agreed by all Member States and included in the manual for Product Authorisation, a harmonised approach on how to implement this requirement for multi-active products already authorised should be considered.

5. The revised PNEC is acceptable for use in this product application, with the proviso that this is accepted at the TM when propiconazole as a PT9 is discussed. If the revised PNEC is not agreed to at the TM, the implications of this as regards the product authorisation of Holzschutz-Imprägnierung aq. 9005 will be evaluated.

UK Competent Authority
May 2012

Annex A Human health exposure assessment for [redacted]

Annex A
Table A1.1 Industrial Application of [redacted] containing 0.3% w/w IPBC by vacuum pressure – Using cycle method. PPE = coated coveralls (10% penetration), gloves and boots

Exposure Descriptor	Value
Hand in-glove exposure	
Indicative value [mg of in-use product/cycle]	1080.00
Task duration [number of cycles: 1 cycle equivalent to 180 minutes per day]	1
Amount of in-use product on hands [mg in-use product]	1080.0000
Rest Of Body Exposure	
Indicative value [mg in-use product/minute]	8570.00
Task duration [number of cycles]	1
Potential dermal exposure to in-use product [mg in-use product]	8570.0000
Clothing penetration [%]	10.00
Amount of in-use product on rest of body [mg in-use product]	857.0000
Total amount of in-use product on skin[mg in-use product]	1937.0000
Total amount of active substance on skin [mg a.s.]	5.8110
Skin penetration [%]	30.00
Total systemic dermal exp. to the active substance [mg a.s.]	***1.7433***
Inhalation Exposure	
Indicative value [mg of in-use product/m^3]	1.90
Task duration [minutes]	180
Volume of air inhaled over task duration [m^3]	3.7500
Inhalation rate of person applying the in-use product [m^3/h]	1.25
Potential amount of in-use product inhaled over task duration [mg in-use product]	7.13
Systemic inhalation exp. to the a.s., assuming 100 % absorption - no RPE worn [mg a.s.]	***0.0214***
Number of task cycles	3
Task cycle multiplier	3
Systemic exp. via skin and inhalation to the active substance - no RPE worn [mg a.s./d]	5.2940
Body weight of person applying the in-use product [kg]	60.00
Total systemic dose of the a.s. - no RPE worn [mg a.s./kg/d]	***0.0882***
Concentration of the active substance in the in-use product [% w/w]	0.30
Density of the in-use product [g/ml]	1.00

Table A1.2 Industrial Application of [redacted] containing 0.9% w/w propiconazole by vacuum pressure – Using cycle method. PPE = coated coveralls (10% penetration), gloves and boots	
Exposure Descriptor	**Value**
Hand in-glove exposure	
Indicative value [mg of in-use product/cycle]	1080.00
Task duration	1
Amount of in-use product on hands [mg in-use product]	1080.0000
Rest Of Body Exposure	
Indicative value [mg in-use product/minute]	8570.00
Task duration [number of cycles]	1
Potential dermal exposure to in-use product [mg in-use product]	8570.0000
Clothing penetration [%]	10.00
Amount of in-use product on rest of body [mg in-use product]	857.0000
Total amount of in-use product on skin[mg in-use product]	1937.0000
Total amount of active substance on skin [mg a.s.]	17.4330
Skin penetration [%]	2.00
Total systemic dermal exp. to the active substance [mg a.s.]	***0.3487***
Inhalation Exposure	
Indicative value [mg of in-use product/m^3]	1.90
Task duration [minutes]	180
Volume of air inhaled over task duration [m^3]	3.7500
Inhalation rate of person applying the in-use product [m^3/h]	1.25
Potential amount of in-use product inhaled over task duration [mg in-use product]	7.13
Systemic inhalation exp. to the a.s., assuming 100 % absorption - no RPE worn [mg a.s.]	**0.0641**
Number of task cycles	3
Task cycle multiplier	3
Systemic exp. via skin and inhalation to the active substance - no RPE worn [mg a.s./d]	1.2384
Body weight of person applying the in-use product [kg]	60.00
Total systemic dose of the a.s. - no RPE worn [mg a.s./kg/d]	***0.0206***
Concentration of the active substance in the in-use product [% w/w]	0.30
Density of the in-use product [g/ml]	1.00

Table A1.3 Industrial exposure during automated dipping of timber with in-use dipping fluid containing 0.3% w/w IPBC. PPE = coated coveralls (penetration 10%), gloves and boots	
Exposure Descriptor	**Value**
Hand Exposure	
Indicative value (in-glove) [mg of in-use product/minute]	1080.00
Task duration [minutes]	1
Glove penetration [%]	100.00
Amount of in-use product on hands [mg in-use product]	1080.0000
Rest Of Body Exposure	
Indicative value (on clothing) [mg in-use product/minute]	8570.00
Task duration [minutes]	1
Potential amount of in-use product on the rest of body [mg in-use product]	8570.0000
Clothing penetration [%]	10.00
Amount of in-use product on rest of body [mg in-use product]	857.0000
Total amount of in-use product on feet, hands and rest of body [mg in-use product]	1937.0000
Total amount of active substance on feet, hands and rest of body [mg a.s.]	5.8110
Skin penetration [%]	30.00
Systemic dermal exp. to the active substance via feet, hands and body [mg a.s.]	***1.7433***
Inhalation Exposure	**n/a**
Number of task cycles	4
Systemic exp. via skin and inhalation to the active substance - no RPE worn [mg a.s./d]	6.9732
Body weight of person applying the in-use product [kg]	60.00
Total systemic dose of the a.s. - no RPE worn [mg a.s./kg/d]	***0.1162***
Concentration of the active substance in the in-use product [% w/w]	0.30
Density of the in-use product [g/ml]	1.00

Table A1.4 Industrial exposure during automated dipping of timber with in-use dipping fluid containing 0.9% w/w propiconazole. PPE = coated coveralls (penetration 10%), gloves and boots	
Exposure Descriptor	**Value**
Hand Exposure	
Indicative value (in-glove) [mg of in-use product/cycle]	1080
Glove penetration [%]	100.00
Amount of in-use product on hands [mg in-use product]	1080
Rest Of Body Exposure	
Indicative value (on clothing) [mg in-use product/cycle]	8570
Potential amount of in-use product on the rest of body [mg in-use product]	8570
Clothing penetration [%]	10.00
Amount of in-use product on rest of body [mg in-use product]	857
Total amount of in-use product on feet, hands and rest of body [mg in-use product]	1937
Total amount of active substance on feet, hands and rest of body [mg a.s.]	17.433
Skin penetration [%]	2.00
Systemic dermal exp. to the active substance via feet, hands and body [mg a.s.]	***0.3487***
Number of task cycles	4
Systemic exp. via skin to the active substance [mg a.s./d]	1.3946
Body weight of person applying the in-use product [kg]	60.00
Total systemic dose of the a.s.[mg a.s./kg/d]	***0.0232***
Inhalation Exposure	**n/a**
Concentration of the active substance in the in-use product [% w/w]	0.90

Table A1.5 Non Professional brush application (indoors) of [redacted] containing 0.3% w/w IPBC, 50% clothing protection (shirt, trousers and shoes) assumed	
Exposure Descriptor	**Value**
Hand Exposure	
Indicative value [mg of in-use product/minute]	150.00
Task duration [minutes]	150
Glove penetration [%]	100.00
Amount of in-use product on hands [mg in-use product]	22500.0000
Rest Of Body Exposure	
Indicative value [mg in-use product/minute]	35.70
Task duration [minutes]	150
Potential amount of in-use product on the rest of body [mg in-use product]	5355.0000
Clothing penetration [%]	50.00
Amount of in-use product on rest of body [mg in-use product]	2677.5000
Total amount of in-use product on feet, hands and rest of body [mg in-use product]	25177.5000
Total amount of active substance on feet, hands and rest of body [mg a.s.]	75.5325
Skin penetration [%]	30.00
Systemic dermal exp. to the active substance via feet, hands and body [mg a.s.]	***22.6598***
Inhalation Exposure	
Indicative value [mg of in-use product/m^3]	3.10
Task duration [minutes]	150
Volume of air inhaled over task duration [m^3]	3.1250
Inhalation rate of person applying the in-use product [m^3/h]	1.25
Potential amount of in-use product inhaled over task duration [mg in-use product]	9.69
Systemic inhalation exp. to the a.s., assuming 100 % absorption - no RPE worn [mg a.s.]	***0.0291***
Number of task cycles	1
Task cycle multiplier	1
Systemic exp. via skin and inhalation to the active substance - no RPE worn [mg a.s./d]	22.6888
Body weight of person applying the in-use product [kg]	60.00
Total systemic dose of the a.s. - no RPE worn [mg a.s./kg/d]	***0.3781***
Concentration of the active substance in the in-use product [% w/w]	0.30
Density of the in-use product [g/ml]	1.00

Annex B Human health risk assessment for [redacted]

Please see Member State Confidential Annex.

Annex C
SUMMARY OF PRODUCT CHARACTERISTICS

(a) Product trade name: Holzschutz-Imprägnierung aq. 9005

(b) (i) Qualitative and quantitative information on the composition of the biocidal product

NB: This information is confidential and should not be disclosed to third parties

Active substance(s)				Contents				
Common name	**IUPAC name**	**CAS number**	**EC number**	**Concentration**	**Unit[1]**	**w/w (%)**	**Minimum purity (% w/w)**	**Same source as for Annex I inclusion**
IPBC	3-iodi-2-propynyl butylcarbamate	55406-53-6	259-627-5	Not reported	g/l	0.3	98.0	Yes
Propiconazole	1-((2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl)methyl)-1H-1,2,4-triazole	60207-90-1	262-104-4	Not reported	g/l	0.9	93.0	Yes

Co-formulants					Contents				
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Concentration**	**Unit**	**w/w (%)**	**Classification**	**Substance of concern**
Confidential - see R4BP (2011/14669/7626/UK/AA/24825)									

1 g/l, g/kg, other. For biological products, the concentration should state the number of activity units/units of potency (as appropriate) per defined unit of formulation (e.g. per gramme or per litre).

(b) (ii) Is the product identical to the representative product, assessed for the purpose of the Annex I inclusion?

NO

If not, briefly describe the difference.

ADDITION OF A SECOND ACTIVE SUBSTANCE AND DIFFERENCES IN THE CONTENT OF THE NON-ACTIVE SUBSTANCES

(b) (iii) Does the biocidal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?

NO

If yes, does the product comply with Directive 2001/18/EC?

N/A

(c) Manufacturer(s) of the active substance(s) (name(s) and address(es) including location of plant(s))

Name of the active substance: **IPBC**

Manufacturer: Troy Chemical Company
For manufacturing address please see Member State Confidential Annex

Name of the active substance: **Propiconazole**

Manufacturer: Syngenta Crop Protection AG
For manufacturing address please see Member State Confidential Annex

(d) Formulator(s) of the biocidal product (name(s) and address(es) including location of plant(s))

Company Name: Saicos Colour GmbH
Address: Carl-Zeiss Str. 3, 48336 Sassenberg, Germany
Telephone: [redacted]
Fax: + [redacted]

Physical state and nature of the biocidal product:

(e) Type of formulation: **Water based**

(f) Ready-to-use product: **Yes**

Classification and labelling statements of the biocidal product:

(g) Product classification:

(h) Risk and Safety Phrases:

Risk phrases:

R52/53

Safety phrases:
S2: Keep out of reach of children*.
S23: do not breathe vapour and spray**
S61: Avoid release to the environment. Refer to specialist instruction/safety data sheets

*** For professional and non-professional users only**
** Relevant for spray applications only

(i) Product classification according to GHS: **Not included**

(j) Hazard statement according to GHS: **Not included**

Intended uses and efficacy:

(k) PT: **8 (Wood Preservative)**

(l) Target harmful organisms:

I.1.1 Wood rotting fungi (decay fungi)

I.1.2 Wood disfiguring fungi (blue stain, sapstain and molds)

I.1.3 Dry rot

(m) Development stage of target organisms:

II.1 Not applicable

(n) Function/mode of action:

III.2 Preventive

(o) Field of use:

IV.1 Use category 2

IV.2 Use category 3

Application aim:

VII.1 Preventive

(p) User category

V.1 Non-professional

V.2 Professional and Industrial

(q) Application method:

VI1.1 Non-Professional – Brush/Roller (indoors and outdoors). Spraying (indoors and outdoors)

VI1.1 Professional – Brush/Roller (indoors and outdoors). Spraying (indoors and outdoors). Manual dipping, Surface injection/treatment (indoor only).

VI.2.1 and VI.2.2 Industrial – Automated spraying, Flow coating (deluge) and dipping (automated and manual),

(r) Manner and area of use:

Authorisation is granted for Use Class 2 and Use Class 3. The product is for use on timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting.
For treatment of dry rot only applications by surface injection are authorised.

For applications against blue stain, decay fungi, sapstain and molds the acceptable application rate of the product is 80 – 160 g of product per m^2 which can be achieved by 1-2 applications.

For injection/surface treatment against dry rot the acceptable application rate of the product is 80 – 160 g of product per m^2 which can be achieved by 1-3 applications.

In each case it should be ensured that the maximum application of product would only reach 160 g m^{-2}.

(s) Conditions of use:

Industrial use

For Industrial use only

The product is for use on timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting.

Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.

Application processes must be carried out within a contained area, situated on impermeable hard standing, with bunding to prevent run-off and a recovery system in place (e.g. sump).

Storage of treated wood must either be undercover with a recovery system in place (e.g. sump) or on impermeable hard standing and bunded to prevent run-off with a recovery system in place (e.g. sump).

A top-coat (minimum total 240 ml/ m², achieved by 1-3 applications, or minimum dry film thickness in total of 100 µm, achieved by 1-3 applications) must be applied to treated timber in situations where it would be exposed to weathering. The topcoat should either be applied prior to the use of the treated timber in situations exposed to weathering, or in the case of 'new build' scenarios or *in situ* applications of this product, prior to the weathering events themselves (e.g. rainfall). The top-coat should not contain a triazole fungicide.

The COSHH (Control of Substances Hazardous to Health) Regulations 2002 (as amended) apply to the use of this product at work.

Guidance on the safe use of wood preservatives is provided in leaflet WIS 29 ("Occupational hygiene and health surveillance at industrial treatment plants") at www.hse.gsi.gov.uk.

Wear suitable protective clothing (coveralls, gloves, footwear) when applying the product and when handling freshly treated timber. Avoid excessive contamination of overalls

Do not contaminate ground, waterbodies or watercourses with chemicals or used container.

DISPOSE OF SURPLUS CHEMICAL, CONTAMINATED MATERIALS (INCLUDING SAWDUST) AND THE EMPTY CONTAINER SAFELY using a method approved by the WASTE DISPOSAL AUTHORITY.

WASH HANDS AND EXPOSED SKIN before meals and after use.

KEEP IN A SAFE PLACE.

3-IODO-2-PROPYNYL-N-BUTYL CARBAMATE is a carbamate compound which has weak anticholinesterase activity. DO NOT USE if under medical advice not to work with anticholinesterase compounds.

Professional use

For Professional use only

The product is for use on timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting.

Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.

Application via manual dipping must be carried out within a contained area and situated on an impermeable surface.

Storage of treated wood must either be undercover with a recovery system in place, or on an impermeable surface.

A top-coat (minimum total 240 ml/ m², achieved by 1-3 applications, or minimum dry film thickness in total of 100 µm, achieved by 1-3 applications) must be applied to treated timber in situations where it would be exposed to weathering. The topcoat should either be applied prior to the use of the treated timber in situations exposed to weathering, or in the case of *in situ* applications, prior to the weathering events themselves (e.g. rainfall). The top-coat should not contain a triazole fungicide.

The COSHH (Control of Substances Hazardous to Health) Regulations 2002 (as amended) apply to the use of this product at work.

Wear suitable protective clothing (coveralls, gloves, footwear) when applying product and when handling freshly treated timber. Avoid excessive contamination of coveralls.

Handle product and dry freshly treated wood in areas with good ventilation.

DO NOT CONTAMINATE FOODSTUFFS, EATING UTENSILS OR FOOD CONTACT SURFACES.

This material and its container must be disposed of in a safe way.

WASH HANDS AND EXPOSED SKIN before meals and after use.

KEEP IN A SAFE PLACE.

Do not empty into drains.

Do not contaminate ground, waterbodies or watercourses with chemicals or used container.

For *in situ* use do not contaminate plant life and remove or cover aquariums/fish bowls/ponds before application.

UNPROTECTED PERSONS AND ANIMALS SHOULD BE KEPT AWAY FROM TREATED AREAS FOR 48 HOURS OR UNTIL SURFACES ARE DRY.

COVER ALL WATER STORAGE TANKS before application.

Dangerous to Bats. All bats are protected under the Wildlife and Countryside Act 1981. Before treating any structure used by bats, consult Natural England, Scottish Natural Heritage or the Countryside Council for Wales.

3-IODO-2-PROPYNYL-N-BUTYL CARBAMATE is a carbamate compound which has weak anticholinesterase activity. DO NOT USE if under medical advice not to work with anticholinesterase compounds.

Non - Professional use

The product is for use on timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting.

Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.

Handle product and dry freshly treated wood in areas with good ventilation.

A top-coat (minimum total 240 ml/ m², achieved by 1-3 applications, or minimum dry film thickness in total of 100 µm, achieved by 1-3 applications) must be applied to treated timber in situations where it would be exposed to weathering. The topcoat should either be applied prior to the use of the treated timber in situations exposed to weathering, or in the case of *in situ* applications, prior to the weathering events themselves (e.g. rainfall). The top-coat should not contain a triazole fungicide.

This material and its container must be disposed of in a safe way.

DO NOT CONTAMINATE FOODSTUFFS, EATING UTENSILS OR FOOD CONTACT SURFACES.

WASH HANDS AND EXPOSED SKIN before meals and after use.

KEEP IN A SAFE PLACE.

Do not empty into drains.

Do not contaminate ground, waterbodies or watercourses with chemicals or used container.

For *in situ* use do not contaminate plant life and remove or cover aquariums/fish bowls/ponds before application

UNPROTECTED PERSONS AND ANIMALS SHOULD BE KEPT AWAY FROM TREATED AREAS FOR 48 HOURS OR UNTIL SURFACES ARE DRY.

COVER ALL WATER STORAGE TANKS before application.

Dangerous to Bats. All bats are protected under the Wildlife and Countryside Act 1981. Before treating any structure used by bats, consult Natural England, Scottish Natural Heritage or the Countryside Council for Wales.

3-IODO-2-PROPYNYL-N-BUTYL CARBAMATE is a carbamate compound which has weak anticholinesterase activity. DO NOT USE if under medical advice not to work with anticholinesterase compounds.

(t) Instructions for safe use of the product:

See section h, r and s.

(u) Particulars of likely direct or indirect adverse effects and first aid instructions

After skin contact: Take off all contaminated clothing and wash skin with plenty of water and soap. Seek medical attention if symptoms occur.

After eye contact: Rinse immediately with plenty of water. Seek medical attention if symptoms occur.

If swallowed: Do not induce vomiting unless expressly instructed by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Seek medical attention.

If inhaled: Move the affected person into fresh air. Keep person warm and rest. Provide artificial respiration by a trained person if breathing is irregular or arrested. Seek medical attention if symptoms are severe or long lasting. If unconscious place in recovery position and seek medical attention immediately.

(v) Instructions on the safe disposal of the product and its packaging

Industrial

DISPOSE OF SURPLUS CHEMICAL, CONTAMINATED MATERIALS (INCLUDING SAWDUST) AND THE EMPTY CONTAINER SAFELY using a method approved by the WASTE DISPOSAL AUTHORITY.

Professional and non professional

This material and its container must be disposed of in a safe way.

Do not empty into drains

Do not contaminate ground, waterbodies or watercourses with chemicals or used container.

(w) Conditions of storage and shelf-life of the product under normal conditions of storage

Store product in tightly closed original containers

Shelf-life of at least 18 months.

(x) Additional information:

a) Packaging information

Non-professionals: **Lined metal or HDPE container– Up to 5 Litres**

Professionals: **Lined metal or HDPE container – Up to 25 Litres**

Industrial: **Lined metal or HDPE container – Up to 1000 Litres**