Bilag 2

Product Assessment Report

VKR SC200

Internal registration no:	MST-671-01925
Authorisation/Registration no:	674-1
Granting date/entry into force of authorisation/ registration:	15 June 2012
Expiry date of authorisation/ registration:	31 March 2020
Active ingredient:	4% (w/w) Iodopropinyl butylcarbamate (IPBC) 8% (w/w) Propiconazole 8% (w/w) Tebuconazole
Product type:	Wood preservative - PT8

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

Danish Ministry
of the Environment
Environmental
Protection Agency

Contents

1 General information about the product application

1.1 Applicant

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Fax:	
E-mail address:	

1.1.1 Person authorised for communication on behalf of the applicant

Name:	Ole Henriksen
Function:	R&D Manager
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City:	Hampen
Postal Code:	7362
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E-mail address:	oh@superwood.dk

1.2 Current authorisation holder[1]

VKR Holding A/S

1.3 Proposed authorisation holder after authorisation

Company Name:	(Same as above)
Address:	
City:	
Postal Code:	
Country:	
Telephone:	
Fax:	
E-mail address:	

[1] Applies only to existing authorisations

Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	

1.4 Information about the product application

Application received:	1 July 2010
Application reported complete:	22 December 2010
Type of application:	Product authorisation
Further information:	-

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	VKR SC200
Product type:	PT8
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	4% (w/w) IPBC 8% (w/w) Propiconazole 8% (w/w) Tebuconazole
Formulation type:	Liquid solvent based wood preservative
Ready to use product (yes/no):	The product is produced and used on site
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); **If yes: authorisation/registration no. and product name:** **or** **Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):**	No No

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	For use class 2 and 3. The product is used for industrial impregnation of wood using supercritical CO_2 as a carrier.
Target organisms:	Effective against wood destroying fungi at 120 g a.i./m^3. Effective against both wood

	destroying fungi and wood discolouring fungi (blue-stain) at 160 g a.i./m^3.
Category of users:	For industrial use only
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	120 g a.i./m^3 for wood destroying fungi 160 g a.i./m^3 for wood destroying fungi and wood discolouring fungi
Potential for release into the environment (yes/no):	Potential for release into the environment only during the service life.
Potential for contamination of food/feedingstuff (yes/no)	No
Proposed Label:	Yes

1.5.3 Information on active substance(s)

Active substance chemical name:	IPBC	Propiconazole	Tebuconazole
CAS No:	55406-53-6	60207-90-1	107534-96-3
EC No:	259-627-5	262-104-4	403-640-2
Purity (minimum, g/kg or g/l):	Min. 980 g/kg	Min. 930 g/kg	Min. 950 g/kg
Inclusion directive:	2008/79/EF of 28 July 2008	2008/78/EF of 25 July 2008	2008/86/EF of 5 September 2008
Date of inclusion:	1 July 2010	1 April 2010	1 April 2010
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes	Yes	Yes
Manufacturer of active substance(s) used in the biocidal product:			
Company Name:	Troy Chemical Europe	Janssen Pharmaceutica N.V.	LANXESS Deutschland GmbH
Address:	Uiverlaan 12e, PO Box 132	Turnhoutseweg 30	
City:	Maassluis	Beerse	Leverkusen
Postal Code:	3145	2340	51369
Country:	The Netherlands	Belgium	Germany
Telephone:	+31 0 10 592-7494	+32 14 60 22 22	+49 214 30 65109
Fax:			
E-mail address:			

1.5.4 Information on the substance(s) of concern

No substances of concern are identified for the product VKR SC200.

1.6 Documentation

1.6.1 Data submitted in relation to product application

See annex 1 for complete references.

1.6.2 Access to documentation

The applicant has submitted the following letter of access':

Troy Corporation Inc. authorizes the use of the BPD dossier covering PT8 of Polyphase P100 (IPBC).

JANSSEN authorizes the use of proprietary data on WOCOSEN™ as used for annex I inclusion of propiconazole.

Syngenta Crop Protection AG authorizes the use of data for propiconazole in support of the registration of the specific product.

LANXESS Deutschland GmbH grants to Akzo Nobel DDeco GmbH the right to refer to the BPD 98/8/EC dossier of Tebuconazole.

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

2 Summary of the product assessment

2.1 Identity related issues

The biocidal product contains the active substances IPBC (4% (w/w), purity: min. 980 g/kg), Propiconazole (8% (w/w), purity: min. 930 g/kg) and Tebuconazole (8% (w/w), purity: min. 950 g/kg).

The biocidal product is not identical to the representative product for Annex I inclusion.

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

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification and labelling of the biocidal product

The proposed classification and labelling of VKR SC 200 according to Directive 67/548/EEC is shown here:

Symbols		
Category of danger	Xn N	Harmful Dangerous for the environment
Risk phrases	R63 R43 R36/38 R50/53	Possible risk of harm to the unborn child May cause sensitisation by skin contact Irritating to eyes and skin Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Safety phrases	S2 S13 S26 S28 S36 S37	Keep out of the reach of children Keep away from food, drink and animal feeding stuffs In case of contact with eyes, rinse immediately with plenty of water and seek medical advice After contact with skin, wash immediately with plenty of water Wear suitable protective clothing Wear suitable gloves
Additional labelling	-	

2.2.2 Packaging of the biocidal product

The biocidal product is mixed inside the industrial machine and will therefore not be available in any packages.

2.3 Physico/chemical properties and analytical methods

Physico-chemical properties of the active substance:

A letter of access has been submitted for the active substances. An overview of the physico-chemical properties of the active substances can be found in the CAR[2].

A summary of the physical and chemical properties of VKR SC 200 is given in Table 2.3-1. The available data is evaluated and determined to be of sufficient quality and reliability for use in risk assessment (evaluation at the Document IIIB level).

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

	Method	GLP (Y/N)	Results	Reference
Physical state and nature	Visual inspection	N	Liquid solvent-based concentrate	–
Colour	Visual inspection	N	Pale brown	–
Odour	Olfactory inspection	N	Characteristic odour of ether	–
Explosive properties	Literature	–	The biocidal product is not explosive. Lower: 0,6 volume-% Upper: 20,4 volume-%	III-B2.2.1
Oxidizing properties	Literature	–	The biocidal product has no oxidizing properties.	III-B2.2.1
Flash point	Setaflash Closed cup ASTMD3278	N	>100 ºC	III-B3.4
Autoflammability	Literature	–	194 ºC	III-B2.2.1
Other indications of flammability	Literature	–	None	III-B2.2.1
Acidity / Alkalinity	–	–	Cannot be measured as the product is not water-based.	–
Relative density / bulk density	Pyknometer	N	Relative density: 0.97 g/ml (20 ºC)	III-B3.6
Accelerated storage stability	Accelerated test	N	Storage condition: 40°C for 4 weeks. IPBC content before storage at 40°C for 4 weeks: 3.63% IPBC content after storage at 40°C for 4 weeks: 3.85% Variation: 6.1% Propiconazole content before storage at 40°C for 4 weeks: 6.87% Propiconazole content after storage at 40°C for 4 weeks: 7.03% Variation: 2.3% Tebuconazole content before	III-B3.7

[2] Competent Authority Report

	Method	GLP (Y/N)	Results	Reference
			storage at 40°C for 4 weeks: 7.33% Tebuconazole content after storage at 40°C for 4 weeks: 7.42% Variation: 1.2%	
Reactivity towards container material	–	–	The product must be stored in container made of stainless steel or plastic to avoid corrosion of the material.	–
Technical characteristics in dependence of the formulation type	–	–	The biocidal product has none of the properties mentioned in the TNsG on Data Requirements. Therefore no tests are necessary.	–
Compatibility with other products	–	–	Not applicable since the biocidal product will not be used with other products including other biocidal products.	–
Surface tension	–	–	Supplementary data not required	–
Viscosity	DIN Cup 4 mm	N	ca 12 sek (20 ºC)	III-B3.11
Particle size distribution	–	–	Not applicable because the biocidal product is liquid.	–

2.3.1 Storage stability

The results from the long-term stability study for the product are listed in Table 2.3-2.
The active substance content has been analysed by an in-house non-validated HPLC method.
There has been observed no modification of appearance of the biocidal product during the storage period.

Table 2.3-2: Results from the shelf-life study.

Product	Active substance	Variation	
		Initial	15 months
VKR SC 200	IPBC	3.54 % -	3.89 % 9.9 %
	Propiconazole	6.8 % -	6.93 % 1.9 %
	Tebuconazole	7.23 % -	7.23 % 0.0 %

References for initial and 15 months data are given in III-B3.7.

2.3.2 Analytical methods

2.3.2.1 Formulation analysis

The analytical method used for determining the active substances in the biocidal product is based on a non-validated in-house HPLC method.

A summary of the analytical method for the determination of the active substances IPBC, propiconazole and tebuconazole in the treated wood, used for the assessment of efficacy, is given in Table 2.3-3. The validation parameters is presented under Document III B, Section 4.

Table 2.3-3: Validation parameters for analytical method

Test substance	Analytical method	Linearity	Specificity	Relative Standard deviation (RSD)	Reference
IPBC, propiconazole and tebuconazole	GC-FID	Range from 1 µg/ml to 50 µg/ml (mg/l). 6 concentrations with two determinations performed. Correlation coefficients: 0,99 or higher.	No interferences were observed. Detection limit < 1 mg/kg	Propiconazole: 3,4 % (8-fold measurement of one calibration standard 10 µg/mL) Tebuconazole: 7,0 % (8-fold measurement of one calibration standard 10 µg/mL) IPBC: 4,6 % (9-fold measurement of one calibration standard)	IIIB-B4

2.4 Risk assessment for Physico-chemical properties

The submitted physico-chemical data for the product has been evaluated according to 1999/45/EEC and directive 67/548/EEC.

The results for VKR SC 200 indicate that the formulation is stable with regards to the active substance contents and the visual properties of the product at room temperature.
Furthermore, the other physico-chemical properties are considered acceptable.

Concerning long-term storage stability (shelf life), Denmark has up until now allowed a 15% deviation from the specified content for homogenous products containing less than 2.5% a.i., in line with the FAO recommendations. Due to EU harmonisation, the GIFAP monograph no. 17 may be followed in the future. However, this awaits a final agreement between the Member States. It should be mentioned that an EU harmonisation of long-term stability has been discussed very late in the process without a final decision. Therefore, we accept a 15% deviation in our evaluations of wood preservatives in progress.
It should also be noted that the results from the accelerated studies are overruled by the results from the long-term storage stability studies, if such studies are available.

The results for VKR SC 200 from the accelerated study shows that the degradation of IPBC after 4 weeks at 40ºC is 6.1 %, which is above the allowed 5 % (according to OECD 113: Screening test for thermal stability and stability in air). Propiconazole and tebuconazole have degraded by 2.3 % and 1.2 %, respectively.

According to the 15 months results from the shelf-life study, the active substance contents in the product varies with 9.9 %, 1.9 % and 0.0 % for IPBC, propiconazole and tebuconazole, respectively.

Conclusion:

On the basis of the results from the long-term stability study, it can be concluded that the product is stable with regards to its contents of both IPBC, propiconazole and tebuconazole as well as the other physico-chemical properties during the investigated period. A claim for 15 months shelf-life can therefore be accepted on the basis of the available stability data and the level of variation.
The overall conclusion of the risk-assessment for physico-chemical properties is that no unacceptable risk is identified after 15 months.

2.5 Effectiveness against target organisms

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

VKR SC200 is recommended to be approved as a biocide product to protect against wood destroying fungi in use class 2 and 3 at 120 g a.i./m^3, a top coat is not required.

VKR SC200 is also recommended to be approved as a biocide product to protect against wood destroying fungi and wood discolouring fungi blue stain in use class 2 and 3 at 160 g a.i./m^3. In this case a top coat is required to be applied after treatment with the product.

2.5.1 Dose / mode of action / known limitations / resistance

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

Propiconazole belongs to the triazole fungicides. As other triazole fungicides propiconazole inhibits the C14 demethylation step in the ergosterol biosynthesis of fungi.

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

Due to the unspecific mode of action a development of resistance is neither to be expected nor has been ever observed.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

VKR SC200 is a solvent-based formulation for industrial use.

The concentrate of the product contains 4%, 8%, and 8% (w/w) IPBC, propiconazole, and tebuconazole, respectively. However, in the final product used in the application process, the concentrate is diluted to a final concentration of 0.012%, 0.025%, and 0.025% (w/w) IPBC, propiconazole, and tebuconazole, respectively.

It is used as wood preservative (BPD Product Type 8) for wood outdoors, which is not covered, not in direct contact with the ground or water (for use class 2 and 3), and exposed to frequent weathering. Timber treatment is conducted industrially by vacuum impregnation using supercritical CO_2 as a carrier. The use rate is 160 g a.i./m^3 for wood discolouring fungi and wood destroying fungi, and 120 g a.i./m^3 for wood destroying fungi only.

After application of VKR SC200 the timber is finally treated with a top coat if protection against wood discolouring fungi is claimed.

The intended use is covered by the CAR's for IPBC, propiconazole and tebuconazole.

2.6.2 Assessment of exposure to humans and the environment

A leaching study has been submitted, an evaluation of this and flux rates used for the environmental risk assessment is presented in Annex 4.

No new studies on human health have been submitted.

2.7 Risk assessment for human health

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR. The threshold limits and labelling regarding human health risks listed in Annex 2 „Toxicology and metabolism" must be taken into consideration.

2.7.1.2 Toxicology of the substance(s) of concern

The b.p. does not contain substances of concern in the definition of Directive 1998/8/EC.

2.7.1.3 Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The product was not a dummy product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC.

2.7.1.3.1 Percutaneous absorption

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

As very low concentrations of the a.s. are used in the final product (< 0.01), a dermal absorption of 100% will be used for all the calculations.

2.7.1.3.2 Acute toxicity

Studies for skin irritation and sensitisation have been performed for the end-use product. In compliance with the provisions of Council Directive 1999/45/EEC on the classification, packaging and labelling of dangerous preparations, the acute toxicological profile for the other end-points for the end-use product can be deduced from available data of its main ingredients.

The exact application of these classification methods can be found in Doc. IIIB, Section 6. The results of the classification are given in Table 2.7-1.

Table 2.7-1: Classification for acute health effects of Rubbol WP 167

Endpoint	DPD classification
Acute oral toxicity	None
Acute dermal toxicity	None
Acute inhalation toxicity	Inhalation is not a relevant route of exposure
Skin irritation	**Xi, R38**
Eye irritation	**Xi, R36**
Skin sensitisation	**Xi, R43**
Other	**Repr.Cat.3, R63**

IPBC is classified with R23 (Toxic by inhalation). As the b.p. contains 4 % IPBC, the product would normally be classified as R20 (Harmful by inhalation). However, considering the production and application of the product, which takes place in a closed system, the classification for inhalation toxicity is not relevant.

All three active ingredients are classified as harmful if swallowed (R22). However, the combined concentration only amounts to 20%, which is below the limit triggering classification with R22 for the product (> 25%). Hence, the product is not classified for acute oral toxicity.

In the skin irritation study, an irritative effect was found, for which the product is classified as R38 (Irritating to skin). No eye irritation study was performed for animal welfare reasons, so the product is classified as R36 (Irritating to eyes) as a result of the skin irritative properties.

The b.p. contains >1% of the active ingredients propiconazole (8.0%) and IPBC (4.0%), which are classified and proposed classified as skin sensitisers. This warrants a classification for skin sensitising effects for the product (R43). Furthermore, the classification with R43 is substantiated in a Maximisation test performed on the product, which showed a sensitising effect. Therefore, the product is classified as a sensitiser.

2.7.1.3.3 Other

Tebuconazole is classified as a Repr.Cat.3 with R63. This classification pertains to the classification of the b.p. because the tebuconazole content is 8.0%, and as classification of the b.p. according to the criteria of the DPD is necessary at a tebuconazole concentration of ≥5%.

2.7.2 Exposure

The biocidal product contains the active substances IPBC (4% (w/w), purity: min. 980 g/kg), Propiconazole (8% (w/w), purity: min. 930 g/kg) and Tebuconazole (8% (w/w), purity: min. 950 g/kg). However, in the final product used in the application process, the concentrate is diluted to a final concentration of 0.012%, 0.025%, and 0.025% (w/w) IPBC, propiconazole, and tebuconazole, respectively. The risk assessment will thus be carried out using the concentrations in the diluted product.

Exposure of industrial and professional workers to the active substances while handling VKR SC 200 is estimated. VKR SC 200 is not intended or sold for the treatment of indoor housing areas with the exception of pre-treated window frames to be used indoors. An exposure assessment of residents inhaling volatile residues indoors has been included to estimate potential exposure from this source.

In an skin irritation study, the product was found irritating and therefore given a classification as R36/38 (Irritating to eyes and skin). Furthermore, the product is classified as sensitizing (R43) on basis of a Maximisation study.
Due to the local effects of the product, the risk is considered to be negligible when appropriate personal protective equipment (PPE) is worn by the professional user. Furthermore, exposure is considered negligible due to the closed system facilities during production and application.

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

During and after the application of VKR SC 200, operator exposure could theoretically occur by dermal and inhalation routes.

However, the potential of exposure for operators through ingestion of the b.p. during these processes is negligible. The inhalation route is of minimal concern due to the low vapour pressure of the active substances (IPBC / propiconazole: 4.5×10^{-3} / 5.6×10^{-5} Pa at 25°C; tebuconazole: 1.7×10^{-6} Pa at 20°C) and the kind of application (no open spray application).

Post-application exposure can occur to professionals handling treated wood and maintaining the treatment equipment.

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

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

Infants may be exposed via mouthing of treated wood chips.

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

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

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

The main routes of exposure are summarised in Table 2.7-2.

Table 2.7-2: Summary of human exposure paths to IPBC / propiconazole

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

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

2.7.2.2 Summary of primary exposure

The overall summary of primary systemic exposure is given in Table 2.7-3.

Table 2.7-3: Summary of primary exposure

Scenario	Systemic dose [mg/kg bw/day]		
	Propiconazole	**IPBC**	**Tebuconazole**
Vacuum impregnation using super critical CO2 (Handling model 1)	Inhalation: 0.00003 Dermal: 0.00262 **Total: 0.00264**	Inhalation: 0.00001 Dermal: 0.0013 **Total: 0.0013**	Inhalation: 0.00003 Dermal: 0.00262 **Total: 0.00264**

2.7.2.3 Summary of secondary exposure

The overall summary of secondary systemic exposure is given in Table 2.7-4.

Table 2.7-4: Summary of secondary exposure

Scenario	Systemic dose [mg/kg bw/day]		
	Propiconazole	**IPBC**	**Tebuconazole**
Acute: sanding of treated wood, amateur	**0.000003**	**0.000002**	**0.000003**
Acute: chewing treated wood chip, infant	**0.000010**	**0.0000051**	**0.000010**
Chronic: sanding of treated wood, professional	**0.000018**	**0.000012**	**0.000018**
Chronic, intermittent: adult laundering work clothes at home	**0.00047**	**0.00023**	**0.00047**
Chronic: Inhalation of volatile residues, indoors	**Inhalation:** Infant: 0.000039 Child: 0.000033 Adult: 0.000029	**Inhalation:** Infant: 0.0012 Child: 0.0011 Adult: 0.0010	**Inhalation:** Infant: 0.000009 Child: 0.000009 Adult: 0.000008

2.7.2.4 Exposure to residues in food

Not relevant, as contact with food is not predicted.

2.7.3 Risk Characterisation

2.7.3.1 Industrial

Exposure of industrial users involved in wood treatment by vacuum impregnation using super critical CO_2 are displayed in Table 2.7-5. All scenarios are assessed using the respective long-term AELs.

Table 2.7-5: Risk characterisation for primary exposure

Scenario	AEL [mg/kg bw/day]	Systemic dose [mg/kg bw/day]	% AEL	NOAEL [mg/kg bw/day]	MoE
Propiconazole					
Vacuum impregnation using super critical CO_2 (Handling model 1)	0.08	0.00264	3.3%	8	3030
IPBC					
Vacuum impregnation using super critical CO_2 (Handling model 1)	0.2	0.00127	0.6%	20	15750
Tebuconazole					
Vacuum impregnation using super critical CO_2 (Handling model 1)	0.03	0.00264	8.8%	3	1136

Based on the risk assessment of the active substance, a risk for industrial users resulting from the intended use is unlikely. Regarding occupational safety, there are no objections against the intended use.

2.7.3.2 Non-professional users

The b.p. is not sold to non-professional users.

2.7.3.3 Indirect exposure as a result of use

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

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

It is noteworthy that for tebuconazole only a long-term AEL exists, based on a chronic dog study. Thus, the risk characterisation for acute exposure scenarios (e.g., amateur sanding, infant chewing wood) is highly conservative.

Long-term, but intermittent (once per week) exposure can be envisaged for individuals laundering contaminated work clothing at home. Children may have repeated contact to treated wood, e.g., on

playgrounds. For infants, dermal contact and oral absorption after hand-to-mouth contact are possible routes of exposure.

Inhalation of volatile residues indoors may be relevant for residents.

The risk characterisation for secondary exposure is summarised in Table 2.7-6.

Table 2.7-6: Risk characterisation for secondary exposure

Scenario	AEL [mg/kg bw/day]	Systemic dose [mg/kg bw/day]	% AEL	NOAEL [mg/kg bw/day]	MoE
Propiconazole					
amateur sanding	0.3	0.000003	0.001%	30	10,000,000
infant chewing wood	0.3	0.000010	0.003%	30	3,000,000
professional sanding	0.08	0.000018	0.023%	8	444,444
laundry	0.08	0.00047	0.6%	8	17,000
Inhalation of volatile residues, indoors. Infant	0.08	0.000039	0.04%	8	235988
Inhalation of volatile residues, indoors. Child	0.08	0.000033	0.04%	8	242424
Inhalation of volatile residues, indoors. Adult	0.08	0.000029	0.04%	8	272109
IPBC					
amateur sanding	0.35	0.000002	0.001%	35	17,500,000
infant chewing wood	0.35	0.0000051	0.001%	35	7,000,000
professional sanding	0.2	0.000012	0.006%	20	1,700,000
laundry	0.2	0.00023	0.12%	20	87,000
Inhalation of volatile residues, indoors. Infant	0.2	0.0012	0.51%	20	16949
Inhalation of volatile residues, indoors. Child	0.2	0.0011	0.57%	20	17544
Inhalation of volatile residues, indoors. Adult	0.2	0.0010	0.59%	20	19608
Tebuconazole					

amateur sanding	0.03	0.000003	0.0001%	3	100,000,000
infant chewing wood	0.03	0.000010	0.0003%	3	30,000,000
professional sanding	0.03	0.000018	0.06%	3	170,000
laundry	0.03	0.00047	1.6%	3	6500
Inhalation of volatile residues, indoors. Infant	0.03	0.00000924	0.03%	3	324575
Inhalation of volatile residues, indoors. Child	0.03	0.00000899	0.03%	3	333704
Inhalation of volatile residues, indoors. Adult	0.03	0.00000803	0.03%	3	373599

The direct exposure, exposure via the environment or to other residues resulting from the intended use is unlikely to cause any unacceptable acute or chronic risk to consumers (bystanders and residents). Regarding consumer health protection, there are no objections against the intended uses.

2.7.3.4 Risk for consumers via residues

Not relevant, as contact with food is not predicted.

2.8 Risk assessment for the environment

2.8.1 Environmental classification

2.8.1.1 Environmental classification of the active substances

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

Substance	Env. classification	Effect concentration (mg/L)	Concentration of a.s. in the product
IPBC	N; R50	0.053 (algae)	4
Propiconazole	N; R50/53	0.88 (algae)	8
Tebuconazole	N; R51/53	2.8 (daphnia)	8

2.8.1.2 Environmental classification of the substance(s) of concern

The biocidal product does not contain any other substances with an environmental classification.

2.8.1.3 Environmental classification of the biocidal product

Calculations regarding the environmental classification have been performed for the product:

N; R50/53:	8/25 = 0.32	<1
N; R50:	4/2.5+8/25= 1.92	>1
N; R51/53:	8/2.5+8/25= 3.52	>1

The resulting classification for the product is the following: N; R50/53

2.8.2 Environmental exposure assessment

The environmental exposure assessment is based on the OECD series on emission scenario documents (OECD ESD) "Emission Scenario Document for Wood Preservatives (Part 1 and 2)" (OECD, 2003[3]). Where necessary the "Technical Guidance Document (TGD) for Risk Assessment" (European Commission, 2003) is also taken into consideration.

Emissions to the environment is not expected to occur during the industrial application and subsequent storage, as the industrial process is performed in a closed system and the wood is dry when it exits the industrial machine. Emissions to the environment can occur during the service life of the treated wood.
For the envisaged fields of use for VKR SC200 one main scenario with the following sub-categories have been addressed (Table 2.8-1). The fence scenario has not been included as the timber cladded house is a worst case scenario for the terrestrial compartment.

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

Table 2.8-1: Relevant exposure scenarios for use of VKR SC200

Main exposure scenario	Subcategory
In-service leaching from treated wood	- Bridge over pond - Timber cladded house - Noise barrier

The product contains no substances of concern which will be included in the environmental risk assessment. Also there are no ecotoxicological tests with the product, the environmental risk assessment will therefore be based on the active substances within the product.

2.8.2.1 Assessment of service life

During the Arona Leaching Workshop in June 2005 (ECB, 2005)[4], it was agreed that a long-term assessment of in-service uses of wood should be carried out. For vacuum pressure treatments an assessment of cumulative leaching from treated wood in-service over a 20 year period was applied. Hence, the assessment times are 30 days (TIME 1) for short term consideration and 20 years for the longer time period (TIME 2).

2.8.2.2 Leaching rates used for environmental risk assessment

A semi-field leaching study has been submitted for the product SC100. Bridging to the product VKR SC200 is accepted. The study has been evaluated and leaching rates for the emission calculation have been calculated, see annex 4 and 5. Leaching rates are calculated for the maximum application rate of 160 g a.i./m^3.

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

Table 2.8-2: Leaching rates for VKR SC200

Active substance	Leaching rates (mg/m^2/day)	
	TIME1 (30 days)	TIME2 (20 years)
IPBC	25.8*	0.106*
Propiconazole	4.04	0.0295
Tebuconazole	5.60	0.0130

* Calculated based on the assumption that 100% of the active ingredient leaches within Time1 and Time2, respectively.

2.8.2.3 PEC calculations

The PECs for IPBC, propiconazole and tebuconazole in the environmental compartments derived in the following sections are calculated on the basis of the emission scenarios available for Product Type 8. The PEC values presented are rounded values from EXCEL spread sheets. The calculations for the different PECs within EXCEL are always carried out with unrounded values.

For the general assessment of the environmental fate and behaviour of the active substances refer to the Section on "Fate and Distribution in the Environment" in Doc. II-A of the CAR's.

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

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

Table 2.8-3: Input parameters for the active substances

	IPBC	Propiconazole	Tebuconazole
Half-life in the aquatic compartment (12°C)	3.1 hour (31.2 days)*	1206 days** 6.4 days	198 days** 43 days
Half-life in the terrestrial compartment (12°C)	4.7 hour (9.5 days)*	129 days	77 days
Fraction staying in the water phase in the STP	0.97* IPBC is completely degraded to PBC in the STP	0.895	0.891
Koc	113.25 (198.1)*	944	992

* Value for PBC
** This value will be used for all calculations of sediment concentration

PEC for sewage treatment plant

Losses to sewage treatment plants (STP) are calculated for in-service leaching from the surfaces of noise barriers (constructed from pre-treated timber).

In the Competent Authority Report for IPBC, the influent concentration of IPBC is considered to be relevant in order to assess predicted environmental concentrations in sewage treatment plants. For further modelling surface water concentrations it is assumed, that the whole IPBC in the STP is transformed into PBC. Hence, the STP risk assessment is based on IPBC influent concentration with no removal/degradation or translocation processes.

For propiconazole and tebuconazole, the STP effluent concentrations do represent predicted environmental concentrations for this compartment.

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

PEC for surface water

During outdoor service life PECs for industrial pre-treated wood are calculated. The target compartments are pond water (scenario “bridge over pond”) and surface water (scenario “noise barrier”).

Further refinements of the initial PECs for surface water were done (only for direct emissions to the surface water) taking into account degradation of the active ingredients (Chapter 7: Removal processes in the receiving compartment, p.119).

PEC for sediment

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

For propiconazole and tebuconazole $PEC_{sediment}$ values are calculated for the bridge over pond scenario and the noise barrier scenario. The predicted concentration in sediment is deduced from the PEC_{sw} by a partition of the active between suspended matter and the water phase (TGD, equation 50, p.78).

PEC for soil

Emissions into soil are assumed to occur only during the service life. For use class 3 outdoor service life the OECD models “timber house” and “noise barrier” are used. The OECD model “noise barrier” assumes that 30 % of the emissions from wood will reach the soil.

A 50 cm distance and soil depth from the treated wood is defined as the receiving soil compartment in the models "timber house" and "noise barrier".

Further refinements of the initial PECs for soil were done taking into account degradation of the active ingredients (OECD 2003; page 118, equation 7.7 and 7.8).

PEC for groundwater

The environmental fate and behaviour of IPBC indicate that the substance is not expected to migrate to groundwater during outdoor service life of treated wood since it is rapidly degraded in soil (DT_{50} = 0.196 days (at 12°C)). Thus, the calculation of potential concentrations in groundwater is not considered relevant for the proposed used pattern (*cf.* Danish CAR, p.17).

In the Finnish CA report for propiconazole and in the Danish CA report for tebuconazole, FOCUS-PEARL-3.3.3 groundwater modelling for the compounds is described, which was carried out using a worst case scenario of 35 simultaneously treated wooden houses per hectare. The calculations were undertaken for propiconazole and tebuconazole releases of 1000 mg/m^2 treated wood over a period of 5 years. For wood preservation use the predicted environmental concentration of propiconazole and tebuconazole in groundwater, as represented by the 80th percentile leachate concentration at 1 m soil depth, were lower than the legal Drinking Water Limit of 0.1 µg/l in all FOCUS-PEARL scenarios. For the intended use of VKR SC200 groundwater concentrations below 0.1 µg/l can also be expected because the estimated maximum total releases are less than that investigated in the CA-reports. This demonstrates that the use of propiconazole and tebuconazole in the wood preservative should not lead to unacceptable concentrations in groundwater.

PEC for atmosphere

Based on the vapour pressure (5.6 x 10^{-5} Pa×m^3 at 25°C) and the Henry`s Law constant (9.2 x 10^{-5} Pa×m^3/mol), volatilisation of propiconazole can be regarded as negligible. Calculations of the chemical lifetime in the troposphere resulted in a half life between 10.2 and 42 hours (*cf.* Document II-A). According to these results (DT_{50} < 2 days), propiconazole is rapidly degraded by photochemical processes and no accumulation of propiconazole in air is to be expected. Therefore, calculation of PEC values for the atmosphere (PEC_{air}) is of no relevance and air is not regarded as a compartment of concern for this Product Type and proposed use patterns.

The second active substance contemplated in this risk assessment, IPBC, will not be a subject of concern likewise. IPBC, has a low vapour pressure of 2.36 – 4.5 x 10^{-3} Pa at 25°C combined with a Henry`s Law constant of 3.38 – 6.45 x 10^{-3} Pa×m^3/mol. This indicates a very low risk of volatilisation. With regard to the fact that IPBC half-life in air is only about 15 hours, the substance is not considered persistent in air (as stated in the Danish CAR). Thus no assessment for a possible risk of the atmosphere (PEC_{air}) is conducted.

Based on the vapour pressure (1.7 x 10^{-6} Pa×m^3) and the Henry`s Law constant (1 x 10^{-5} Pa×m^3/mol at 25 °C), volatilisation of tebuconazole can be regarded as negligible. Therefore, calculation of PEC values for the atmosphere (PEC_{air}) is of no relevance and air is not regarded as a compartment of concern for this Product Type and proposed use patterns.

PEC for biota

According to the TGD (EC, 2003) the calculation of a possible risk to man via the food chain ($PECoral_{predator}$) should be conducted if the a.s. shows a potential for bioaccumulation, indicated by a log K_{ow} value >3.
IPBC reveals a log K_{ow} of 2.81 and PBC a log K_{ow} of 1.64 indicating that no risk for bioaccumulation of the substances to man via the food chain is given.

Although the log K_{ow} of propiconazole (log K_{ow} = 3.7) reveals a slight potential for bioaccumulation, an assessment of secondary poisoning is not requested in the Finnish CAR (2007, p.18) for the use of propiconazole in wood preservatives.

According to the CA report for tebuconazole there is no risk for bioaccumulation of tebuconazole in wood preservatives.

Calculated PEC values are summarised in Table 2.8-4. For IPBC either IPBC or PBC values are shown for the compartments surface water and soil, dependent on what result in highest PEC/PNEC values. PEC values including degradation are shown in cases where there is a direct discharge to the compartment; this is shown by a symbol.

Table 2.8-4: Summary of PEC values for IPBC/PBC, propiconazole and tebuconazole.

IPBC/PBC	**PEC_{STP} (µg/L)**	**$PEC_{surface\ water}$ (µg/L)**	**$PEC_{sediment}$ (mg/kg wwt)**	**PEC_{soil} (mg/kg wwt)**
In-service				
Noise Barrier (30 days)	27.1	1.45*	-	0.0153#
Noise Barrier (20 years)	0.111	5.94×10^{-3}*	-	6.41×10^{-5}#
House (30 days)	-	-	-	0.0409#
House (20 years)	-	-	-	1.71×10^{-4}#
Bridge over pond (30 days)	-	86.6*#	-	-
Bridge over pond (20 years)	-	1.31*#	-	-
Propiconazole	**PEC_{STP} (µg/L)**	**$PEC_{surface\ water}$ (µg/L)**	**$PEC_{sediment}$ (mg/kg wwt)**	**PEC_{soil} (mg/kg wwt)**
In-service				
Noise Barrier (30 days)	3.80	0.379	8.08×10^{-3}	0.122#
Noise Barrier (20 years)	0.0277	2.77×10^{-3}	5.89×10^{-5}	0.0144#
House (30 days)	-	-	-	0.325#
House (20 years)	-	-	-	0.0385#
Bridge over pond (30 days)	-	13.1#	0.642##	-
Bridge over pond (20 years)	-	0.136#	0.417##	-
Tebuconazole	**PEC_{STP} (µg/L)**	**$PEC_{surface\ water}$ (µg/L)**	**$PEC_{sediment}$ (mg/kg wwt)**	**PEC_{soil} (mg/kg wwt)**
In-service				
Noise Barrier (30 days)	4.26	0.426	9.52×10^{-3}	0.163#
Noise Barrier (20 years)	9.91×10^{-3}	9.90×10^{-4}	2.21×10^{-5}	5.51×10^{-3}#
House (30 days)	-	-	-	0.435#
House (20 years)	-	-	-	0.0147#
Bridge over pond (30 days)	-	36.0#	0.804##	-
Bridge over pond (20 years)	-	0.400#	8.95×10^{-3}##	-

* Values for PBC
# Value including degradation
Based on value including degradation

2.8.3 Environmental risk characterisation

The environmental risk characterization for biocidal active substances in the context of Article 5 and Annex VI of Directive 98/8 involves the comparison of PEC and PNEC values for each relevant environmental compartment as well as for non-target organisms. For this purpose Risk Characterisation Ratios (PEC/PNEC) are derived for the use of the wood preservative. The calculated PEC/PNEC ratios are provided for the STP, the aquatic and terrestrial compartment in the following.

If the PEC/PNEC ratio is equal to or below 1.0, this is interpreted as an acceptable risk to the environment.

The PNEC values shown in Table 2.8-5 are used for the risk characterisation

Table 2.8-5: PNEC values used for risk characterisation

	IPBC/PBC	Propiconazole	Tebuconazole
$PNEC_{STP}$ (µg/L)	440/-	1000	320
$PNEC_{surface\ water}$ (µg/L)	0.5/41.3	1.6	1.0
$PNEC_{sediment}$ (mg/kg wwt)	Covered by surface water	0.054	0.55
$PNEC_{soil}$ (mg/kg wwt)	0.00434/0.149	0.1	0.1

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

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

IPBC/PBC	**$(PEC/PNEC)_{STP}$**	**$(PEC/PNEC)_{surface\ water}$**	**$PEC/PNEC)_{sediment}$**	**$(PEC/PNEC)_{soil}$**
In-service				
Noise Barrier (30 days)	0.0616	0.0350*	-	**3.53**#
Noise Barrier (20 years)	2.53×10^{-4}	1.44×10^{-4}*	-	0.0148#
House (30 days)	-	-	-	**9.42**#
House (20 years)	-	-	-	0.0394#
Bridge over pond (30 days)	-	**41.3***#	-	-
Bridge over pond (20 years)	-	0.0317*#	-	-
Propiconazole	**$(PEC/PNEC)_{STP}$**	**$(PEC/PNEC)_{surface\ water}$**	**$(PEC/PNEC)_{sediment}$**	**$(PEC/PNEC)_{soil}$**
In-service				
Noise Barrier (30 days)	3.80×10^{-3}	0.237	0.150	**1.22**#
Noise Barrier (20 years)	2.77×10^{-5}	1.73×10^{-3}	1.09×10^{-3}	0.144#
House (30 days)	-	-	-	**3.25**#
House (20 years)	-	-	-	0.385#
Bridge over pond (30 days)	-	**8.21**#	**11.9**##	-
Bridge over pond (20 years)	-	0.0849#	**7.73**##	-
Tebuconazole	**$(PEC/PNEC)_{STP}$**	**$(PEC/PNEC)_{surface\ water}$**	**$(PEC/PNEC)_{sediment}$**	**$(PEC/PNEC)_{soil}$**
In-service				
Noise Barrier (30 days)	0.0133	0.426	0.0173	**1.63**#
Noise Barrier (20 years)	3.10×10^{-5}	9.90×10^{-4}	4.02×10^{-5}	0.0551#
House (30 days)	-	-	-	**4.35**#
House (20 years)	-	-	-	0.147#
Bridge over pond (30 days)	-	**36.0**#	**1.46**##	-
Bridge over pond (20 years)	-	0.400#	0.0163##	-

* Values for PBC
# Value including degradation
Based on value including degradation

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

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

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

In Table 2.8-7 $(PEC/PNEC)_{product}$ values for each environmental compartment are summarised.

Table 2.8-7: Summary of PEC/PNEC values (with and without degradation) for the product.

VKR SC200	$(PEC/PNEC)_{STP}$	$(PEC/PNEC)_{surface\ water}$	$(PEC/PNEC)_{sediment}$	$(PEC/PNEC)_{soil}$
In-service				
Noise Barrier (30 days)	0.0787	0.698	0.167	**6.37**
Noise Barrier (20 years)	3.12×10^{-4}	2.86×10^{-3}	1.13×10^{-3}	0.214
House (30 days)	-	-	-	**17.0**
House (20 years)	-	-	-	0.572
Bridge over pond (30 days)	-	**85.5**	**13.4**	-
Bridge over pond (20 years)	-	0.517	**7.75**	-

For the noise barrier environmental risk is identified for the soil compartment for the initial time period this is however accepted as the risk is reduced below the trigger value of 1 for 20 years. Also for the house scenario the risk is reduced below the trigger value of 1 for the soil compartment for 20 years. For the bridge over pond scenario risk is identified for the surface water within the initial time period, however the risk is reduced below the trigger of 1 for 20 years, but for the sediment compartment risk is identified both for 30 days and 20 years. The treated wood can therefore not be used close to water.

As stated in section 2.8.1.3, groundwater and air are not regarded as compartments of concern for this product with the proposed use patterns; also, there are no concerns of secondary poisoning (section 2.8.1.3).

Conclusion: The overall conclusion of the environmental risk assessment for the product VKR SC200 applied by vacuum impregnation using super critical CO_2 for use class 2 and 3, is that no unacceptable risk is identified for secondary poisoning, STP, surface water, soil, air and the groundwater compartment. However, risk is identified for the sediment compartment when used in the vicinity of water. **As a consequence the treated wood can not be used close to water.**

2.9 Measures to protect man, animals and the environment

Methods and precautions concerning handling and use

Due to the organic solvents content of the preparation:

Vapours are heavier than air and may spread along floors. Vapours may form explosive mixtures with air. Prevent the creation of flammable or explosive concentrations of vapours in air and avoid vapour concentrations higher than the occupational exposure limits. In addition, the product should only be used in areas from which all naked lights and other sources of ignition have been excluded. Electrical equipment should be protected to the appropriate standard.

Keep container tightly closed. Keep away from heat, sparks and flame. No sparking tools should be used.

Avoid contact with skin and eyes. Avoid the inhalation of dust, particulates, spray or mist arising from the application of this preparation. Avoid inhalation of dust from sanding.

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed.

Never use pressure to empty. Container is not a pressure vessel. Always keep in containers made from the same material as the original one. Comply with the health and safety at work laws.

Exposure controls: Provide adequate ventilation. Where reasonably practicable, this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and solvent vapours below the OEL, suitable respiratory protection must be worn.

Personal protection equipment:

Respiratory system: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. Dry sanding, flame cutting and/or welding of the dry paint film will give rise to dust and/or hazardous fumes. Wet sanding/flatting should be used wherever possible. If exposure cannot be avoided by the provision of local exhaust ventilation, suitable respiratory protective equipment should be used.

Skin and body: Personnel should wear antistatic clothing made of natural fibres or of high-temperature-resistant synthetic fibres.

Hands: For prolonged or repeated handling, use the following type of gloves: Recommended: nitrile rubber. Barrier creams may help to protect the exposed areas of the skin but should not be applied once exposure has occurred.
The user must check that the final choice of type of glove selected for handling this product is the most appropriate and takes into account the particular conditions of use, as included in the user's risk assessment.

Eyes: Use safety eyewear designed to protect against splash of liquids.

Methods and precautions concerning storage

Store in accordance with local regulations. Observe label precautions. Store in a dry, cool, well-ventilated area. Keep away from heat and direct sunlight.

Keep away from sources of ignition. Keep away from: oxidising agents, strong alkalis, strong acids.

No smoking. Prevent unauthorised access. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

Methods and precautions concerning transport

Transport information: Always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

No marine pollutant.

Methods and precautions concerning fire

Extinguishing media: Recommended: alcohol-resistant foam, CO_2, powders, water spray. Do not use water jet.

Special exposure hazards: Fire will produce dense black smoke. Exposure to decomposition products may cause a health hazard. Appropriate breathing apparatus may be required. Cool closed containers exposed to fire with water. Do not release runoff from fire to drains or watercourses.

Identity of relevant combustion products in cases of fire: Carbon monoxide, carbon dioxide, smoke, oxides of nitrogen.

Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available

First aid measures:

General: In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and seek medical advice.

Inhalation: Remove to fresh air. Keep person warm and at rest. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel.

Skin contact: Remove contaminated clothing and shoes. Wash skin thoroughly with soap and water or use recognised skin cleanser. Do not use solvents or thinners.

Eye contact: Check for and remove any contact lenses. Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open.

Ingestion: If swallowed, seek medical advice immediately and show the container or label. Keep person warm and at rest. Do not induce vomiting.

Emergency measures to protect the environment

Accidental release measures:

Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Environmental exposure controls: Do not allow to enter drains or watercourses. If the product contaminates lakes, rivers, or sewers, inform the appropriate authorities in accordance with local regulations.

Cleaning of equipment

Used equipment should be cleaned with white spirit.

Waste management

Do not allow to enter drains or watercourses. Dispose of according to all federal, state and local applicable regulations.

3 Proposal for decision

3.1 Background for decision

Physico-chemical properties:
The overall conclusion of the risk-assessment for physico-chemical properties is that no unacceptable risk is identified after 15 months.
On the basis of the available stability data and the level of variation a claim for 15 months shelf-life can be accepted.

Efficacy evaluation:
VKR SC200 is recommended to be approved as a biocide product to protect against wood discolouring fungi as well as wood destroying fungi in use class 2 and 3 by a penetration process at an application rate of 160 g a.i./m^3. A top coat is required to be applied after treatment with the product.

If the product is only used for protection against wood destroying fungi an application rate of 120 g a.i./m^3 is used. No top coat is needed for this purpose.

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

Environmental assessment:
The overall conclusion of the environmental risk assessment for the product VKR SC200 applied by vacuum impregnation using super critical CO_2 for use class 2 and 3, is that no unacceptable risk is identified for secondary poisoning, STP, surface water, soil, air and the groundwater compartment. However, risk is identified for the sediment compartment when used in the vicinity of water. **As a consequence the treated wood can not be used close to water.**

3.2 Decision regarding Authorisation of the biocidal product

The Danish CA proposes the authorisation of the biocidal product VKR SC200 as a wood preservative (PT 8) for use by vacuum impregnation using super critical CO_2. The use rate is 120 or 160 g a.i./m^3, depending on the wanted protection.

Identity of the Biocidal Product

The biocidal concentrated product under PT8 Wood preservatives VKR SC200 contains 4% (w/w) IPBC, 8% (w/w) propiconazole and 8% (w/w) tebuconazole. The diluted final product contains 0.012% (w/w) IPBC, 0.025% (w/w) propiconazole and 0.025% (w/w) tebuconazole.

Particular Conditions

Purity of the Active Substance

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

IPBC: 980 g/kg

Propiconazole: 930 g/kg

Tebuconazole: 950 g/kg

Product Type

PT8: Wood preservatives

Expiry Date of the Authorisation:

The authorisation of the product VKR SC200 expires on 31 March 2020, which is the expiry date of Annex I listing of the active substances propiconazole and tebuconazole.

4 Annex:

1. **List of studies reviewed**
2. **Toxicology and metabolism –active substance**
3. **Human exposure assessment**
4. **Leaching calculations**
5. **Calculation of leaching rates – general procedures**

Annex 1: List of studies reviewed

List of new data[5] submitted in support of the evaluation of the active substance: None

List of new data submitted in support of the evaluation of the biocidal product

Section No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
					Yes	No	Yes	No
B2.2.1	Dow Chemicals	2008	Data for Glycolether, DOW Chemicals, offentliggjort	Dow Chemicals	☐	☒	☐	☒
B3.4	Henriksen, Ole	2010	Bestemmelse af flammepunkt	VKR Holding	☐	☒	☐	☒
B3.6	Henriksen, Ole	2010	Bestemmelse af densitet	VKR Holding	☐	☒	☐	☒
B3.7	Spetmann, P	2002	Preparation of Tebuconazole, Propiconazole and 3-Iodo-2-propynyl-butylcarbamate (IPBC) in Dowanol DPnB - Storage stability. Bayer AG. Report nr : - . Ikke GLP, Ikke offentliggjort	VKR Holding	☐	☒	☐	☒
B3.11	Henriksen, Ole	2010	Bestemmelse af viskositet	VKR Holding	☐	☒	☐	☒

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

Section No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
B5.10.2.1	Fennert, E.M., Wessely, S.	2002	Bestimmung der Grenze der Wirksamkeit gegen holzzerstörende Basidiomyceten gemäss EN113	VKR Holding	☐	☒	☒	☐
B5.10.2.2	Fennert, E.M., Wessely, S.	2002	Bestimmung der Grenze der Wirksamkeit gegen holzzerstörende Basidiomyceten gemäss EN113 in Kombination mit einer Auswaschbeanspruchung gemäss EN 84	VKR Holding	☐	☒	☒	☐
B5.10.2.3	Schumacher, P., Fennert, E.M., Wessely, S.	2002	Bestimmung der Grenze der Wirksamkeit gegen holzzerstörende Basidiomyceten gemäss EN113 in Kombination mit einer Verdunstungsbeanspruchung gemäss EN 73	VKR Holding	☐	☒	☒	☐
B5.10.2.4	Venås, T. M., Morsing, N.	2007	Test of the protective effectivness of various Gori SC200 products as reference systems as a wood preservative out-of ground contact after 3 years of exposure	VKR Holding	☐	☒	☒	☐
	Klamer, M., Venås, T. M.	2010	Test report – semi-field leaching of wood preserrvative GORE SC100	VKR Holding	☐	☒	☒	☐

Annex 2: Toxicology and metabolism –active substance

Active Substance: IPBC

Threshold Limits and other Values for Human Health Risk Assessment

Summary			
	Value	Study	AF
AEL long-term	0.2 mg/kg bw/day	2 yr rat	100
AEL medium-term	0.35 mg/kg bw/day	90-day gavage rat	100
AEL acute	0.35 mg/kg bw/day	90-day gavage rat	100

Inhalative absorption	Default: 100%
Oral absorption	>90% based on urinary excretion (~57-71%) and exhaled air (~18-24%) within 72 hours.
Dermal absorption	1.6, 10, and 30% for solutions containing 17, 2.4 and 0.6% IPBC 100% default for solutions containing <0.5%-0.6% IPBC (based on in vitro human skin study with solvent based on model product)

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

Active substance: propiconazole

Threshold Limits and other Values for Human Health Risk Assessment

Summary			
	Value	Study	AF
AEL long-term	0.08 mg/kg bw/day	2-generation rat	100
AEL medium-term	-	-	-
AEL acute	0.3 mg/kg bw/day	Developmental study in rat	100

Inhalative absorption	Default: 100%
Oral absorption	86% within 48 h
Dermal absorption	The estimated dermal absorption in humans is 1% for the Wocosen 100 SL product (water based product with 10% propiconazole) and 2% for the 1% Wocosen 100 SL dilution and the 1.2% Solvent based Wocosen 12 OL product, based on an in vivo study in rat and a comparative in vitro dermal penetration study using rat and human skin. Furthermore, for dilute solutions of propiconazole (0.006% – 1.4%), a dermal absorption values of app. 2% has been set in the CAR.

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

Active substance: tebuconazole

Threshold Limits and other Values for Human Health Risk Assessment

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

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

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

Annex 3: Human exposure assessment

VKR SC200

Human exposure assessment calculations

Exposure scenarios for intended uses (Annex IIIB, point 6.6)

To estimate dermal exposure, a **clothing penetration** for coated coveralls of **10%** was assumed, as suggested by the HEEG opinion ”Default protection factors for protective clothing and gloves” (2010).

As very low concentrations of the a.s. are used in the final product (< 0.01), a dermal absorption of 100% will be used for all the calculations.

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

1. Exposure assessment of automated processes

1.1. Industrial automated vacuum impregnation

VKR SC200 is used for industrial timber treatment conducted by vacuum impregnation using supercritical CO_2 as a carrier. During the automated application phase, the exposure of the operator is assumed to be negligible.

The activities of the industrial users are:

Mixing/loading:
Loading is a fully automated process in closed systems, without any need for manual interaction by the operator. The concentration of a.s. may be checked from time to time and adjusted, all within the same automated, closed system.
No exposure calculation is provided for this activity.

Application:
The application process itself occurs in a large closed system, in which wood is loaded on a conveyer belt and is removed again when the final treated wood comes out dry after the treatment process.
The application process during the vacuum impregnation in industrial premises is not associated with significant exposure of the operator, neither by inhalation nor via dermal contact. No separate exposure calculation is provided for this activity. However, the model applied for post-application handling as described below may partly also cover potential exposure during the treatment process itself. This model may be best described as "Industrial wood preservation" (Handling model 1, TNsG 2002 part 2).

Post-application:
Post-application exposure to the product may occur during manual contact during handling of treated wood. Usually, there is no manual contact with treated wood as the process with using supercritical CO_2 as a carrier leaves the wood dry. However, as a worst case scenario, the Handling model 1 is applied to the risk assessment of the product.

Any sort of maintenance/repair work on the system (hoses, valves etc.) may potentially lead to exposure. However, such activities are of short duration (few minutes to few hours) and occur only occasionally (once to a few times a year or even less). Potential contamination is expected to be limited to hands.

Cleaning of the system is not a relevant task, as the product is recycled in the system and the process runs continuously. So this activity may never or very rarely occur.

Unfortunately, there is no adequate model to estimate these types of exposure, so no exposure calculation is provided for the activities. The use of PPE is recommended during these tasks.

Exposure assessment

As there is no model describing the exposure during the vacuum impregnation process, the Industrial wood preservation scenario described in the Handling model 1 (TNsG 2002, p. 162) has been used as a worst case to estimate the potential exposure during and after the application process.
The duration of a cycle is assumed to be 3.5 h based on information from the applicant. It is assumed that 2 cycles can be completed pr day, and the dermal exposure is based on the combined exposure from one operator handling 3 vacuum impregnation vessels pr day, that is 6 cycles pr day.
It is assumed that the inhalation exposure during the application process can occur during a 7 h working day.

Applied parameters:

Hands	**88.8 mg/cycle** (actual, 75th percentile)
Glove penetration	**not considered for actual hand exposure values**
Body	**158 mg/cycle** (potential, 75th percentile)
Clothing penetration	**10%** (HEEG opinion, 2010)
Inhalation	**0.75 mg/m³** (potential, 75th percentile, n=49)
Inhalation rate	**1.25 m³/h** (default)
Duration	**420 min (2 x 3.5 h cycle)** (based on information from applicant)
Body weight	**60 kg** (default)

Estimated Exposure:

The estimated systemic exposure to propiconazole, tebuconazole and IPBC is **0.0026, 0.0026** and **0.0013** mg/kg bw/day, respectively (Table A4-1).

Table A4-1: Exposure assessment for Handling model 1

Handling Model 1 - solvent based			
	Propiconazole	**IPBC**	**Tebuconazole**
active substance % (w/w)	0,025%	0,012%	0,025%
Potential body exposure			
Indicative value mg/cycle	158	158	158
No. of cycles per day	6	6	6
Potential dermal deposit mg	948	948	948
Clothing type	Coated coveralls	Coated coveralls	Coated coveralls
Clothing penetration %	10%	10%	10%
Actual dermal deposit [product] mg	94,8	94,8	94,8
Hand exposure			
Indicative value mg/cycle (actual)	88,8	88,8	88,8
No. of cycles per day	6	6	6
Hand deposit mg	532,8	532,8	532,8
Mitigation by gloves	Not applicable	Not applicable	Not applicable
Actual hand deposit [product] mg	532,8	532,8	532,8
Total dermal exposure			
Total dermal deposit [product] mg	627,6	627,6	627,6
Active substance mg	0,16	0,08	0,16
Dermal absorption %	100%	100%	100%
Systemic exposure via dermal route mg	0,1569	0,0753	0,1569
Exposure by inhalation			
Indicative value mg/m3	0,75	0,75	0,75
Duration	420	420	420
Inhalation rate m^3/h	1,25	1,25	1,25
Mitigation by RPE (PF)	1	1	1
Inhaled [product] mg	6,56	6,56	6,56
Systemic exposure via inhalation route	0,002	0,001	0,002
Systemic exposure			
Total systemic exposure a.s. mg	0,1585	0,0761	0,1585
Body weight kg	60	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0,00264**	**0,00127**	**0,00264**

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

2.1. Acute phase: Adult – sanding treated wood posts

Inhalation route

A person (non professional) is sanding the surface of treated wood posts (4 cm x 4 cm x 2.5 m, surface area of 4032 cm^2) for an outdoor play area.

Exposure of adults towards VKR SC200 dust during sanding of treated wood was estimated using the example calculation provided in the TNsG, 2002, part 3 (worked examples, page 50).

As preserved wood is not placed on the market until the product is dry, dermal exposure during handling of wood treated with VKR SC200 is assumed to be negligible.

An adult sands industrial treated wood with a sander for one hour. The sander generates 5 mg/m^3 wood dust during this one hour work with a density of 0.4 g/cm^3 (TM III 2008, MOTA) The resulting wood dust is inhaled with a inhalation rate of 1.25 m^3/hour.

When exposure is estimated for a piece of wood treated by vacuum impregnation, the results listed in table A4-2 is obtained:

Table A4-2: Exposure assessment for Handling model 1

Surface area of the treated wood Volume of wooden post*	(4 x 4 cm x 2.5 m) + (2 x 4 cm x 4 cm) = 4032 cm^2 0.004 m^3
Active substance concentration in dilution	0.025% Propiconazole 0.012% IPBC 0.025% tebuconazole
Active substance concentration on the outer 1 cm layer (double vacuum impregnated wood) **	0.0125 mg/cm^3 (propiconazole) 0.006 mg/cm^3 (IPBC) 0.0125 mg/cm^3 (tebuconazole)
Inhalation rate*	1.25 m^3/h
Exposure for wood dust during sanding for 60 min*	5 mg/m^3
Inhaled wood dust amount	1.25 m^3/h x 5 mg/m^3= 6.25 mg
Density of soft wood	0.4 g/cm^3
Volume of wood dust	6.25 mg / 0.4 g/cm^3 = 0.0156 cm^3
Concentration of active substance in the wood dust	0.0125 mg/cm^3 x 0.016 cm^3= 0.0002 mg (propi) 0.006 mg/cm^3 x 0.016 cm^3= 0.0001 mg (IPBC) 0.0125 mg/cm^3 x 0.016 cm^3= 0.0002 mg (tebu)
Inhalation exposure of 60 kg adult	**0.000003 mg a.s./kg bw/day (propiconazole)** **0.000002 mg a.s./kg bw/day (IPBC)** **0.000003 mg a.s./kg bw/day (tebuconazole)**

* Parameters given in the Technical Notes for Guidance – Human exposure to biocidal products, User Guidance
** Wood absorbs 50 L/m^3 of product in double vacuum pressure process (default value given in User Guidance), and is adapted for the vacuum impregnation process: 50 L/m^3 x 0.025% x 0.004 m^3 = 0.05 g propiconazole per 4000 cm^3 wood = 0.0125 mg/cm^3, 50 L/m^3 x 0.025% x 0.004 m^3 = 0.05 g tebuconazole per 4000 cm^3 wood = 0.0125 mg/cm^3 and 50 L/m^3 x 0.012% x 0.004 m^3 =0.024 g IPBC per 4000 cm^3 wood = 0.006 mg/cm^3.

The exposure estimation revealed a systemic exposure of 0.000002 mg IPBC/ kg bw and 0.000003 propiconazole/ kg bw and tebuconazole/ kg bw for an adult during sanding of treated wood.

2.2. Acute phase: Infant chewing treated wood chip

Exposure of infants towards VKR SC200 resulting from chewing of treated wood was estimated using the example calculation provided in the TNsG, 2002, part 3 (worked examples, page 50).

It is assumed that an infant plays nearby persons who are handling and sawing VKR SC200 pre-treated wood. The infant chews on one of the pieces of wood, thereby extracting 10% of the IPBC, Tebuconazole and Propiconazole contained in the cut-off.

When exposure is estimated for a piece of wood treated by double vacuum, and assuming the highest use rate of 160 g a.i./ m^3 sapwood (32 g IPBC/ m^3 sapwood (20%), 64 g Tebuconazole/ m^3 sapwood (40%) and 64 g Propiconazole/ m^3 sapwood (40%)), the following result is obtained:

Assumptions:

- Infant (10 kg bw) chewing piece of wood of the following dimensions:
  1 cm × 4 cm × 4 cm (area: $4.8x10^{-3}$ m^2, volume: 1.6×10^{-5} m^3)
- IPBC: 32 g/ m^3 sapwood
- Propiconazole: 64 g/ m^3 sapwood
- Tebuconazole: 64 g / m^3 sapwood

Results:

- Amount in treated wood:
  IPBC: 32 g IPBC/m^3 x $1.6x10^{-5}$ m^3 = 0.51 mg IPBC
  Propiconazole: 64 g Propiconazole/ m^3 x $1.6x10^{-5}$ m^3 = 1.02 mg Propiconazole
  Tebuconazole: 64 g Propiconazole/ m^3 x $1.6x10^{-5}$ m^3 = 1.02 mg Tebuconazole
- Amount extracted by chewing:
  IPBC: 0.51 mg IPBC x 10% = 0.051 mg IPBC
  Propiconazole: 1.02 mg Propiconazole x 10% = 0.10 mg Propiconazole
  Tebuconazole: 1.02 mg Propiconazole x 10% = 0.10 mg Tebuconazole
- Systemic dose:
  IPBC: 0.051 mg IPBC/10 kg = **5.1 µg IPBC/kg bw**
  Propiconazole: 0.10 mg Propiconazole /10 kg = **10 µg Propiconazole/kg bw**
  Tebuconazole: 0.10 mg Propiconazole /10 kg = **10 µg Tebuconazole/kg bw**

The exposure of an infant after oral ingestion of VKR SC200 via chewing of treated wood is estimated at 5.1 µg IPBC/kg bw/day, 10 µg Tebuconazole/kg bw/day and 10 µg Propiconazole/kg bw/day respectively.

An exposure assessment of infant playing on playground has not been included, as it is assumed that exposure will be negligible and considering the low exposure following the child chewing wood scenario.

2.3. Chronic phase: Adult – professional sanding

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

Inhalation route

The inhalation exposure is six times higher than for the one-hour task of an amateur (see Section 2.1, p.38). Accordingly, **systemic exposure estimates** for propiconazole, IPBC, and tebuconazole are **0.000018, 0.000012**, and **0.000018 mg/kg bw/day**, respectively.

2.4. Chronic (intermittent): Adults - cleaning work clothes at home

This scenario was adopted from the CAR for propiconazole (RMS FI, 2007). Persons at risk are adults. The relevant exposure route is dermal. Exposure duration is acute to short-term. An activity with the potential for some contamination is the laundering of contaminated work clothing (e.g. a coverall). Laundering is assumed to occur mechanically without any exposure risk to humans. Contact with effluent is unlikely to occur. The only likely exposure can occur during handling of the dirty clothing while preparing it for laundry. The exposure route is dermal (mainly to hands) and is dependent on the area concentration of dislodgeable residues on the surface of the clothing and the transfer coefficient to the human skin. For the following it is assumed, that the clothing to be washed is a coverall used by an industrial operator (considered to represent the worst case). The total surface of a medium size coverall was determined to be 22,700 cm². Body contamination (without hands and feet) was calculated to be 628 mg for above described industrial exposure scenarios (see **Fejl! Henvisningskilde ikke fundet.**1) are re-expressed as mg a.s./cm².
It is assumed that the coverall is washed after one working week, corresponding to 5 working days, and the total residues accumulate during this time and account for 5 times the daily deposits.
The transfer coefficient (TC) is determined by estimating how many times the coverall is touched with the hands. Assuming that this happens three times, twice with the inner side of both hands and once with the total hands surface, the TC would account for 1640 cm^2 (total surface of both hands = 820 cm^2). As another worst case assumption, 100% of the dislodgeable residues in the touched area are considered to be transferred to the skin. The results of the estimation are given in Table A4-4.
Systemic exposure estimates for propiconazole, IPBC, and tebuconazole are **0.00047**, **0.00023**, and **0.00047 mg/kg bw/day**, respectively.

Table A4-4: Exposure during laundry of contaminated clothing

Laundry of contaminated clothing			
	Propiconazole	**IPBC**	**Tebuconazole**
active substance % (w/w)	0,025%	0,01%	0,025%
Clothing contamination			
Actual dermal deposit [product] mg/day	628	628	628
Actual dermal deposit [a.s.] mg/day	0,16	0,08	0,16
Overall surface cm²	22.700	22.700	22.700
Surface concentration mg a.s./cm²/day	6,91E-06	3,32E-06	6,91E-06
No of working days before washing	5	5	5
Percentage dislodgeable	50%	50%	50%
Dislodgeable residues mg a.s./cm²	0,00002	0,00001	0,00002
Hand exposure			
Transfer coefficient cm²/day	1640	1640	1640
Hand deposit mg a.s./day	0,03	0,01	0,03
Percentage transferred to skin	100%	100%	100%
Dermal absorption %	100%	100%	100,0%
Systemic exposure via dermal route mg a.s.	0,0283	0,0136	0,0283
Body weight kg	60	60	60
Systemic exposure mg kg^{-1} day^{-1}	**0,00047**	**0,00023**	**0,00047**

2.5. Adult, child and infant: Inhalation of volatised residues, indoors

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

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

Assumptions:

- Adult: 60 kg bw, residential time 18 hours, inhaling 1.25 m^3 air/h (TNsG on HE, 2007, p 61)
- Child: 15 kg bw, residential time 18 hours, inhaling 0.35 m^3 air/h (TGD, page 274)
- Infant: 10 kg bw, residential time 18 hours, inhaling 0.24 m^3 air/h (TGD, page 274)
- Vapour pressure IPBC : 2.36 x 10^{-3} Pa (at 20°C)
- Vapour pressure Propiconazole : 5.6 x 10^{-5} Pa (at 25°C)
- Vapour pressure Tebuconazole : 1.7 x 10^{-6} Pa (at 20°C)

- Molecular weight of IPBC : 281 g/mol
- Molecular weight of Propiconazole : 342.2 g/mol
- Molecular weight of Tebuconazole : 307.8 g/mol
- 1 atmosphere (or 1 bar) is equivalent to 101325 Pa
- Molar volume of gas at room temperature: 24.1L

Results:

- Airborne concentration:
  IPBC : 2.36×10^{-3} Pa x 1%/101325 x 10^{6} = 2.33×10^{-4} ppm (mL/m^3)
  Propiconazole : 5.6×10^{-5} Pa x 1%/101325 x 10^{6} = 5.53×10^{-6} ppm (mL/m^3)
  Tebuconazole : 1.7×10^{-6} Pa x 1%/101325 x 10^{6} = 1.68×10^{-6} ppm (mL/m^3)
- SVC:
  IPBC: 2.33×10^{-4} ppm x 281 g/mol/24.1L = 2.72×10^{-3} mg/m^3
  Propiconazole: 5.53×10^{-6} ppm x 342.2 g/mol/24.1L = 7.85×10^{-5} mg/m^3
  Tebuconazole: 1.68×10^{-6} ppm x 307.8 g/mol/24.1L = 2.14×10^{-5} mg/m^3
- Systemic dose:
  IPBC
  Adult: 2.72×10^{-3} mg/m^3 x 1.25 m^3/h x 18 h/60 kg bw = 1.02×10^{-3} mg/kg bw/day
  Child: 2.72×10^{-3} mg/m^3 x 0.35 m^3/h x 18 h/15 kg bw = 1.14×10^{-3} mg/kg bw/day
  Infant: 2.72×10^{-3} mg/m^3 x 0.24 m^3/h x 18 h/10 kg bw = 1.18×10^{-3} mg/kg bw/day
  Propiconazole
  Adult: 7.85×10^{-5} mg/m^3 x 1.25 m^3/h x 18 h/60 kg bw = 2.94×10^{-5} mg/kg bw/day
  Child: 7.85×10^{-5} mg/m^3 x 0.35 m^3/h x 18 h/15 kg bw = 3.30×10^{-5} mg/kg bw/day
  Infant: 7.85×10^{-5} mg/m^3 x 0.24 m^3/h x 18 h/10 kg bw = 3.39×10^{-5} mg/kg bw/day
  Tebuconazole
  Adult: 2.14×10^{-5} mg/m^3 x 1.25 m^3/h x 18 h/60 kg bw = 8.03×10^{-6} mg/kg bw/day
  Child: 2.14×10^{-5} mg/m^3 x 0.35 m^3/h x 18 h/15 kg bw = 8.99×10^{-6} mg/kg bw/day
  Infant: 2.14×10^{-5} mg/m^3 x 0.24 m^3/h x 18 h/10 kg bw = 9.24×10^{-6} mg/kg bw/day

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

2.6. Exposure to residues in food

Not relevant, as contact with food is not predicted.

Annex 4: Leaching calculations

A semi-field leaching study for SC100 (comparable to VKR SC200) was conducted in accordance with NT Build 509 (approved 2005-03) "Leaching of active components from preservative treated timber – semi-field testing".

The product SC100 contains IPBC, propiconazole and tebuconazole. However, analytical measurements of IPBC were not performed due to stability problems of IPBC; 100% leaching throughout TIME 1 and 2 is therefore assumed.

The average daily leaching rate for each time interval was plotted versus the mean time of the time interval considered. A detailed description of this procedure can be found in Appendix 1 of the ESD for PT 8 (OECD, 2003).
For fitting the experimental FLUX(Δt)=f(t) curve a polynomial regression of second order was employed:

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

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

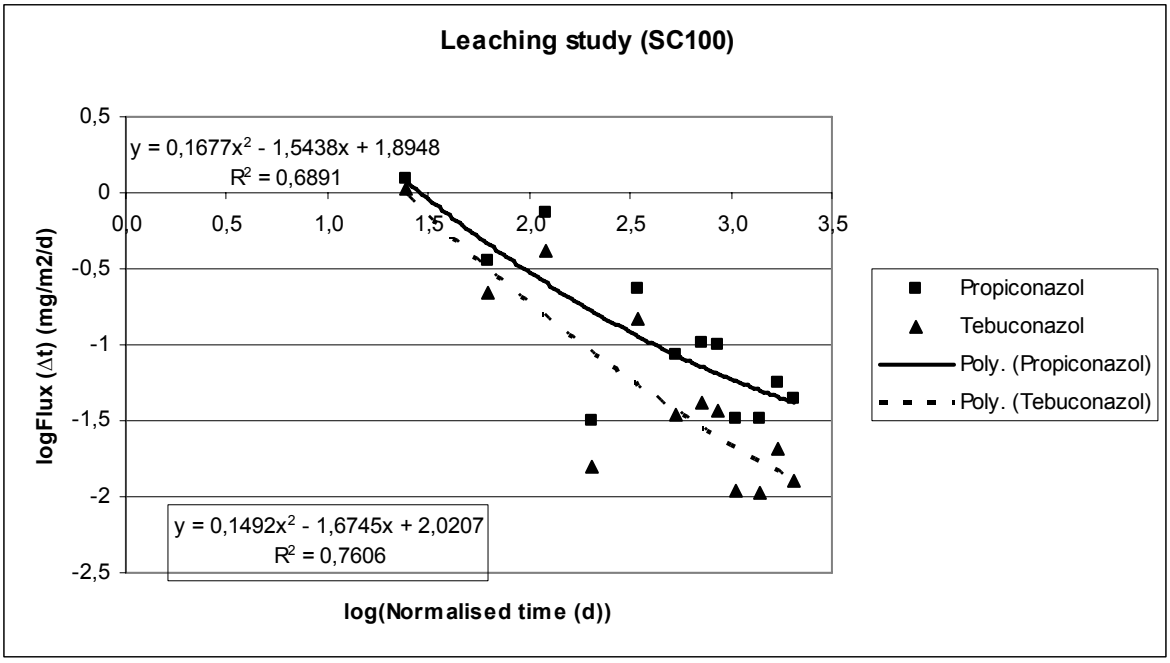

Figure 1 Fitted daily FLUX(Δt) of propiconazole and tebuconazole versus time. For tebuconazole a box is made around the fitted equation.

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

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

With the aid of the second equation leaching rates for the short- and long-term risk assessments (TIME 1 - 30 days and TIME 2 – 20 years) can be derived. For this purpose daily leaching rates for day 1 up to day 30 are summed up and divided by 30 for TIME 1 and for TIME 2 leaching rates for day 31 up to day 7300 are summed and divided by 7270. With this approach the following leaching rates are derived:

Propiconazole:	TIME 1	6.52 mg/m^2/day ((196 mg/m^2))/30 days)
	TIME 2	0.0475 mg/m^2/day ((346 mg/m^2))/(7300-30) days)
Tebuconazole:	TIME 1	7.57 mg/m^2/day ((227 mg/m^2))/30 days)
	TIME 2	0.0176 mg/m^2/day ((128 mg/m^2))/(7300-30) days)

The leaching rates calculated by extrapolation are in the same range as the leaching rates within the test period. It is therefore preferred to use the calculated leaching rates as these values are based on data within the whole test period.

When bridging between the two products with different content of active substance and different retention, extrapolation will be used as suggested below:

Active substance	VKR SC200 (g/m^3)	SC100 (g/m^3)	Part of a.s. for VKR SC200	Suggested extrapolation
Propiconazole	64	204	31%	Linear extrapolation x 2
Tebuconazole	64	86	74%	Linear extrapolation

The following corrected short- and long-term leaching rates are used as input parameter for the different exposure scenarios:

Propiconazole:	TIME 1	**4.04 mg/m^2/day** (6.52 mg/m^2/day x 2 x 0.31)
	TIME 2	**0.0295 mg/m^2/day** (0.0475 mg/m^2/day x 2 x 0.31)
Tebuconazole:	TIME 1	**5.60 mg/m^2/day** (7.57 mg/m^2/day x 0.74)
	TIME 2	**0.0130 mg/m^2/day** (0.0176 mg/m^2/day x 0.74)

For IPBC leaching rates are calculated based on the total amount that is applied, i.e. 32 g IPBC/m^3. The amount of IPBC per volume is converted to IPBC per surface area by using the volume and area of the wood panels from the semi-field leaching test.

IPBC:	TIME 1	**25.8 mg/m^2/day** (32 g/m^3/(41.32 m^2/m^3 x 30 days))
	TIME 2	**0.106 mg/m^2/day** (32 g/m^3/(41.32 m^2/m^3 x 7300 days))

Annex 5: Calculation of leaching rates from a leaching experiment

Introduction
For the environmental risk assessment of wood preservatives, emission calculations are performed based on leaching rates of the active ingredients and if relevant also for substances of concern.
Leaching rates are calculated according to guidance given in "OECD ESD for wood preservatives" and "Report of the leaching workshop". However, in the "OECD ESD for wood preservatives" several possibilities are stated for how to calculate leaching rates. Moreover, the guidance documents do not cover how to deal with leaching experiments where a top coat is applied.

In this document it is described how DK has approached the calculation of leaching rates also in cases where a top coat has been applied on the surface of the treated wood.

Calculation of leaching rates
For the calculation of leaching rates it is preferred to use all measurements within the leaching experiment. This has been done by fitting the experimental FLUX(Δt)=*f(t)* curve using a polynomial regression of second order:

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

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

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

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

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

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

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

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

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

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

Available leaching study	Claim on the biocidal product	How to perform emission calculations?	Requirement regarding top coat
No study	No top coat or any top coat	Use: a) 100% leaching	None
Study with no top coat	No top coat or any top coat	Use: a) calculated leaching rates b) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	None
Study with top coat	No top coat	Use: a) 100% leaching	None
	With top coat which is "stable" according to EN927-2* **Amateur use**	Use: a) calculated leaching rates **x 10,** both for time1 and time2 b) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	a) Treated timber should receive a top coat … b) Top coat should be maintained
	With top coat which is "stable" according to EN927-2* **Industrial/professional use**	Use: a) calculated leaching rate for time1. For time2 use calculated leaching rate **x 5** b) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	a) Treated timber should receive a top coat which is "stable" according to EN927-2… b) Top coat should be maintained
	With any top coat **Amateur, professional or industrial use**	Use: a) calculated leaching rates **x 10,** both for time1 and time2 b) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	a) Treated timber should receive a top coat … b) Top coat should be maintained

* The top coat used in the leaching study should also be "stable" according to EN927-2
** This can either be for time1, time2 or for both time1 and time2

Available leaching study	Claim on the biocidal product	How to perform emission calculations?	Requirement regarding top coat
Studies both with and without top coat	No top coat	Use: a) calculated leaching rates (study without top coat) b) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	None
	With top coat which is "stable" according to EN927-2* **Amateur use**	Use: a) calculated leaching rates **x 10,** both for time1 and time2 (study with top coat) b) leaching rates from study without top coat if calculated leaching rates from a) exceed the ones from study without top coat ** c) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	a) Treated timber should receive a top coat … b) Top coat should be maintained
	With top coat which is "stable" according to EN927-2* **Industrial or professional use**	Use: a) calculated leaching rate for time1. For time2 use calculated leaching rate **x 5** (study with top coat) b) leaching rates from study without top coat if calculated leaching rates from a) exceed the ones from study without top coat** c) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	a) Treated timber should receive a top coat which is "stable" according to EN927-2… b) Top coat should be maintained
	With any top coat **Amateur, professional or industrial use**	Use: a) calculated leaching rates **x 10,** both for time1 and time2 (study with top coat) b) leaching rates from study without top coat if calculated leaching rates from a) exceed the ones from study without top coat** c) 100% leaching if calculated leaching rates from a) exceed 100% leaching**	a) Treated timber should receive a top coat … b) Top coat should be maintained

* The top coat used in the leaching study should also be "stable" according to EN927-2
** This can either be for time1 or time2 or for both