Product Assessment Report

Jotun Industri Grunning Visir Hvit

Revised February 2018

Addendum – Storage stability test - added June 2012
Addendum – Minor change of the formulation - added June 2014
Addendum - Minor change of the formulation - added February 2018

Replaces PAR 21 December 2011; see addenda for details

R4BP ref no:	2010/2093/6146/NO/AA/7439
Authorisation/Registration no:	NO-2011-0005
Granting date/entry into force of authorisation/ registration:	21 December 2011
Expiry date of authorisation/ registration:	21 December 2021, provided that the active substance is still included in the Union list of approved substances
Active ingredient:	Tebuconazole
Product type:	PT 8

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

Contents

1 General information about the product application

1.1 Applicant

Company Name:	Jotun AS
Address:	P.O.Box 2021
City:	Sandefjord
Postal Code:	N-3248
Country:	Norway
Telephone:	+47 33 45 70 00
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1.1.1 Person authorised for communication on behalf of the applicant

Name:	Anne Margrete Nes
Function:	Senior Scientist
Address:	P.O.Box 2021
City:	Sandefjord
Postal Code:	N-3248
Country:	Norway
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1.2 Current authorisation holder

Jotun Industri Grunning Visir (JIGV) is currently on the market in Norway. However, no authorisation has been required in Norway prior to the requirements according to the BPD, and therefore, no authorisation exists in Norway. Hence, no current authorisation holder is available.

1.3 Proposed authorisation holder

Company Name:	Jotun AS
Address:	P.O.Box 2021
City:	Sandefjord
Postal Code:	N-3248
Country:	Norway
Telephone:	+47 33 45 70 00
Fax:	+47 33 45 77 10
E-mail address:	anne.margrete.nes@jotun.no
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	Not relevant

1.4 Information about the product application

Application received:	1st April 2010
Application reported complete:	5th July 2010
Type of application:	Authorisation
Further information:	-

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	Jotun Industri Grunning Visir
Manufacturer's development code number(s), if appropriate:	Jotun Industri Grunning Visir (SF2202-7, SF 2202-6)
Product type:	PT 8 (wood preservative)
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Active substance: 0.60 % tebuconazole, CAS-No. 107534-96-3 Substances of concern regarding environment: 0.1-0-5% Cobalt, borate neodecanoate; CAS-No. 68457-13-6 Detailed information regarding the composition of the biocidal product is confidential and can be found in R4BP.
Formulation type:	Alkyd-oil primer for exterior wood with water as main solvent
Ready to use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); **If yes: authorisation/registration no. and product name:** **or** **Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):**	No No

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	Jotun Industri Grunning Visir is an alkyd-oil primer for exterior wooden surfaces like house cladding and fences (use class 3). The primer is applied by airless spray with rotating brushes or flow coating, in both cases in closed chambers.
Target organisms:	Wood destroying fungi (Basidiomycetes)
Category of users:	Professionals (industrial use)
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:	To be applied by automated airless spray with rotating brushes or flow coating. Only one coat (application). One litre of the product covers 8-11 m^2 of wood depending on properties of the wooden surface. Assembled cladding should be coated with a top coat (paint or varnish products) within two months. For treated wood used outdoor in wintertime with temperatures below freezing point the topcoat should be applied in spring (1-3 layers of top-coat)
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/feedingstuff (yes/no)	No (provided that the product is not used on materials which are in direct contact with food or feeding stuff)
Proposed Label:	See chapter 3. Proposal for decision
Use Restrictions:	• For outdoor use only in Use Class 3 • Should only be applied industrially by automated airless spray with rotating brushes or flow coating • Maximum application rate: 0.125 L product /m^2 wood corresponding to 0.83 g tebuconazole /m^2. • Maximum level of the active ingredient tebuconazole in the product: 0.60 % w/w • To comply with the efficacy claim, a topcoat has to be applied. This topcoat should be applied within two months. For treated wood used outdoor in wintertime with temperatures below freezing point the topcoat should be applied in spring

1.5.3 Information on active substance(s)

Active substance chemical name:	Tebuconazole
CAS No:	107534-96-3
EC No:	403-640-2
Purity (minimum, g/kg or g/l):	≥ 95 % w/w
Inclusion directive:	2008/86
Date of inclusion:	1st April 2010
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes
Manufacturer of active substance(s) used in the biocidal product:	
Company Name:	Lanxess Deutschland GmbH
Address:	Chempark Leverkusen, Bldg.Q18
City:	Leverkusen
Postal Code:	D-51369
Country:	Germany
Telephone:	+49 214 30 57344
Fax:	+49 214 30 24278
E-mail address:	Olga.wittmann@lanxess.com

1.5.4 Information on the substance(s) of concern

Substance chemical name	Cobalt, borate neodecanoate complexes
CAS No:	68457-13-6
EC No :	270-601-2
Purity (minimum, g/kg or g/l):	n.a.
Typical concentration (minimum and maximum, g/kg, or g/l):	0.1-0-5%
Relevant toxicological/ecotoxicological information:	Xn; R22 Xi; R38, R43 N; R50/53
Original ingredient (trade name):	Confidential information – see R4BP

1.6 Documentation

1.6.1 Data submitted in relation to product application

No new data on the active substance has been submitted in relation to the product application.

Data for the relevant formulation has been submitted on physical-chemical properties. Moreover, an analytical method for determination of the active substance in the product, efficacy and leaching data has been submitted with the product application. All this data has been accepted and evaluated. The evaluation of these study summaries can be found in Appendix 2.

Jotun Industri Grunning Visir contains 0.6 % tebuconazole as wood preservative and 0.3 % IPBC as film preservative. In the formulations tested in the phys-chem., the efficacy and leaching studies, concentrations of tebuconazole and IPBC were slightly different. However, this is not anticipated to have influenced the test results as the formulations otherwise were more or less identical to the formulation applied for. Concentrations of tebuconazole and IPBC were the following:

- Phys-chem study: nominal 0.40% tebuconazole[1] (0.37 % measured)
- Effectivity: nominal 0.60 % tebuconazole (measured 0.41 %) and nominal 0.30 % IPBC (measured 0.19 %)
- Leaching laboratory study: 0.60 % tebuconazole and 0.30 % IBPC (both nominal)
- Leaching semi-field study: 0.60 % tebuconazole (nominal and measured) and 0.30 % IPBC (nominal and measured)

1.6.2 Access to documentation

A Letter of Access to the BPD 98/8/EC dossier for Tebuconazole, including all underlying studies and reports, is granted from Lanxess Deutschland GmbH to Jotun AS for support of the product dossier of Jotun Industri Grunning Visir. This Letter of Access is valid for the Norwegian market and has been submitted to the Norwegian CA.

[1] Information on nominal concentration not contained in Doc IV; personal communication applicant 17 October 2011

2 Summary of the product assessment

2.1 Identity related issues

The active ingredient tebuconazole is purchased from Lanxess GmbH Deutschland, which is also the supplier of the active substance evaluated for Annex I inclusion, and a Letter of Access is granted to Jotun AS. Jotun Industri Grunning Visir is an alkyd primer, containing 0.6 % tebuconazole as a PT 8 active substance and IPBC as film preservative. It contains further cobalt borate neodecanoate as a substance of concern for the environment. The main solvent is water.

Information concerning the composition of the biocidal product can be found in R4BP.

Jotun Industri Grunning Visir is an existing biocidal product (wood preservative) that has been on the Norwegian market for many years.

2.2 Classification, labelling and packaging

2.2.1 Classification of the biocidal product

On the basis of study results on the product and the concentration and properties of the active substance and formulants in the product, classification and labelling of Jotun Industri Grunning Visir according to the principles detailed in Council Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and the Council is detailed in the table below. The harmonised classification given in Regulation (EC) 1272/2008, Annex VI, Part 3, has been taken into account.

Category of danger:	Dangerous for the environment	
Risk phrases:	R52/53	Harmful to aquatic organisms, may cause long term adverse effects in the aquatic environment
Safety phrases:	S23	Do not breathe vapour/spray Contains 3-iodo-2-propynyl-butylcarbamate and cobalt borate neodecanoate complexes. May produce an allergic reaction.

2.2.2 Labelling of the biocidal product

The labelling of Jotun Industri Grunning Visir according to Directive 67/548/EEC and Directive 1999/45/EC (with amendments and adaptations) is shown in the following table:

Symbols:	No symbol
Indications of danger:	-
Risk phrases:	R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Safety phrases:	S23 Do not breathe vapour/spray Contains 3-iodo-2-propynyl-butylcarbamate and cobalt borate neodecanoate complexes. May produce an allergic reaction.

2.2.3 Packaging of the biocidal product

Jotun Industri Grunning Visir is packed in containers made of clear coated steel or plastic (PP/PE) and is supplied to the end market in 20 litre (steel) or 1,000 litre (PP/PE) containers.

2.3 Physico/chemical properties and analytical methods

2.3.1 Physico-chemical properties

A Letter of Access has been submitted for the active substance. The active substance concentrate is delivered by the producer of the active substance evaluated for Annex I entry.

Table 2.1: **Physico-chemical properties of the biocidal product**

Endpoint	Method	Results	Comments
Physical state and nature	Charles River SOP	Viscous Liquid	*
Colour	ASTM D1535-89	N 8.5 68.4% R (Grey)**	*
Odour	Charles River SOP	Turpentine	*
Explosive properties	-	Not an explosive product	Theoretical assessment, Expert statement. See chapter 2.4
Oxidizing properties	-	Not an oxidising product	Theoretical assessment, Expert statement. See chapter 2.4
Flash point	EC Test A.9	Not detected below 100°C	*
Autoflammability	EC Test A.15	490 ± 10°C	*
Other indications of flammability	n.a.		
Acidity / Alkalinity	CIPAC MT 75	6.43	*
Relative density / bulk density	OECD 109 OJEC A3	1.107	*
Storage stability – stability and shelf life	2 years storage stability in warehouse-condition, dark and ambient temperature	Interim result after one year storage: Tebuconazole concentration: 0.37% w/w initial concentration 0.47% w/w after 12 months storage	* 2 year storage will be submitted in spring 2012 Steel container
Storage stability – Accelerated Storage	Results from Accelerated Storage (CIPAC MT 46.1)	Tebuconazole concentration: 0.37% w/w initial 0.38% w/w after 14 days at 54 ± 2°C.	* Steel container
Storage stability – effects of temperature	Results from low temperature storage (CIPAC MT 39.1)	Storage at 0 ± 1°C for 7 days. *ca* 10% of material separated out at the bottom and *ca* 5% at the top following centrifugation	*
Effects of light	n.a. as container material is not	-	-

Endpoint	Method	Results	Comments
	transparent.		
Reactivity towards container material	Visual inspection	Container was observed to be clean and intact, free of corrosion and dents and showed no other signs of degradation or chemical interaction between the test item and the container material (steel)	Results from accelerated storage stability testing.
Technical characteristics in dependence of the formulation type	n.a.	-	The biocidal product has none of the properties mentioned in the TNsG on Data Requirements. Therefore no tests were performed.
Compatibility with other products	n.a.	-	The product is a stand-alone product and not to be mixed with other products.
Surface tension	n.a.	-	According to Annex IIB to 98/8/EC this is not a data requirement for biocidal products.
Viscosity	OECD 114	Prior to storage: 289mPas (20°C) 208mPas (40°C) Interim result from stability testing (one year storage): 294mPas (20°C) 218mPas (40°C)	* Results from 2 year storage will be submitted in spring 2012
Particle size distribution	n.a.	Only applicable for products that are supplied as powders or granulates.	

*Reference: Balloch, Stephen and Allan, Graham, study initiated in 2009 (see Appendix 1 – reference list)

** Pigment was changed to white in the authorised product (all other formulants are identical)

2.3.2 Analytical methods

	Principle of method
Technical active substance as manufactured:	See Assessment Report for tebuconazole; Letter of Access to Lanxess dossier
Impurities in technical active substance:	See Assessment Report for tebuconazole; Letter of Access to Lanxess dossier
Active substance in the formulation:*	HPLC with UV detection at 225 nm Quantification was done by internal standard Linearity was acceptable; $r^2 = 0.9999$ Overall mean recovery = 101% (96-106%); n = 3 Overall coefficient of variation = 3.1% System precision was determined; coefficient of variation (CV) = 0.1%

** Balloch, Stephen, 2009 and 2010 (see Appendix 1 – reference list)

The analytical method for determination of active substance in the formulation has been validated and accepted with respect to linearity of response, system suitability, assay accuracy and precision, system precision and specificity.

2.3.3 Residue analysis

Analytical methods for the determination of tebuconazole residues in relevant environmental media as well as in animal and human body fluids and tissues have not been submitted for the biocidal product since this point is already covered by the data set for the active substance which can be found in the Assessment Report / dossier for the active substance for which Lanxess Deutschland GmbH has granted Jotun AS a Letter of Access.

2.4 Risk assessment for Physico-chemical properties

The characterisation of the potential risk of the product, which contains the active substance tebuconazole, is based on the physicochemical properties of the product.

Jotun Industri Grunning Visir is considered stable at room temperature. It is not self-igniting (EC Test A.15), and an assessment of the explosive properties was carried out by analysing the chemical structures of the components of the formulation and comparing the bond groupings with those known to be linked with explosive properties. The result of this investigations was that components of the formulation are either known not to be explosive substances or, from consideration of their chemical structures, do not have any bond groupings known to be linked with explosive properties. Therefore, it can be concluded that Jotun Industri Grunning Visir cannot be regarded as explosive in the sense of EC A.14.

The test item was not classified as flammable in terms of its flash point, which was not detected below 100 °C (EC Test A.9).

An expert statement on the oxidizing properties of the test item was conducted in lieu of performing the EC Test A.21. The result of the theoretical assessment was that Jotun Industri Grunning Visir is not an oxidizing formulation. Jotun Industri Grunning Visir contains [redacted]% w/w sodium nitrite, a well-known oxidizing substance, but the other components of

the formulation are either known not to be oxidizing substances or, based on considerations of chemical structure, could not possess oxidizing properties. It is therefore reasonable to assume that the presence of sodium nitrite at such a low level in a formulation, which otherwise comprises only of non-oxidizing materials, would be sufficient to derive the overall conclusion that the product does not have oxidizing properties. Consequently, Jotun Industri Grunning Visir will not give rise to highly exothermic reactions when it comes into contact with other substances, particularly flammable ones, in the way in which recognized oxidizing substances/formulations do.

The investigation on the accelerated storage stability of the formulation was done according to CIPAC MT 46.1. The relevant formulation was stable for 14 days at 54 °C. Results from storage at room temperature after one year shows that the measured concentration after one year increased from 0.37 % w/w initial to 0.47 % w/w after 12 months. No real explanation for this could be provided. It does, however, not seem likely that the concentration really increased by 27 % within one year, especially since no weight loss of the samples was observed during this period. Moreover, the accelerated storage stability study proved stable results (0.37% initial, 0.38 % after 14 days). Therefore, the only possible explanation is that there might have been problems with the quantification of tebuconazole in the samples at the start of the study and also after accelerated storage. This is also in line with the initial nominal concentration of 0.40 % in samples used for the phys-chem. studies (see chapter 1.6.1).

The two-year storage stability study will be finalized in March 2012 and results will be evaluated and reported by the Norwegian CA. This storage stability study was conducted with Jotun Industri Grunning Visir stored in steel containers. No information on storage stability of the product in PP/PE containers is available. Before Jotun Industri Grunning Visir can be marketed in PP/PE containers an accelerated storage stability study has to be submitted.

A low temperature stability test has also been conducted on the product according to CIPAC 39.1. Following storage at 0 ± 1°C for 7 days. *ca* 10% of material separated out at the bottom and *ca* 5% at the top following centrifugation. As a consequence it is required that the product, which is only to be used industrially, should be kept at temperatures above 5 °C during transport and storage.

Therefore no potential risk for users is given due to the physico-chemical properties of this product.

2.5 Effectiveness against target organisms

Jotun Industri Grunning Visir is used for preventive treatment of wooden claddings. It protects wood against wood destroying fungi (Basidiomycetes). Application is by automated airless spray with rotating brushes or flow coating in industrial premises.

2.5.1 Dose / mode of action / known limitations / resistance

The efficacy of tebuconazole as an active substance against wood destroying fungi has been evaluated for Annex I entry. In the Assessment Report, it is concluded that tebuconazole is efficient at use concentrations and application rates which are comparable to those of Jotun Industri Grunning Visir.

The efficacy of Jotun Industri Grunning Visir against wood destroying basidiomycetes has been tested according to conditions described for Use Class 3, superficial application products to be top-coated in EN 599-1:2009. The test method EN 113 has been used after weathering according to EN 73 and EN 84 separately.

BAM has conducted an efficacy study with Jotun Industri Grunning Visir, containing 0.6% tebuconazole nominal, measured 0.41% (BAM, 2010; see Appendix 1 – reference list). Adequate protection was demonstrated for wood after a penetration treatment, with a retention of 68.4 kg/m^3 as tested according to EN113 (after EN73 or EN84 weathering treatment) (corresponding to 0.28 kg/m^3 tebuconazole related to a measured concentration of 0.41%). According to EN 559-1:2009 this corresponds to a surface treatment load of 136.8 g/m^2 (0.56 g/m^2 tebuconazole) of the tested product applied by superficial treatment. The minimum application rate prescribed for Jotun Industri Grunning Visir (with nominal concentration of 0.60% tebuconazole) is 11 m^2/L or 101 g/m^2. This equals 0.61 g/m^2 tebuconazole and is thus higher than the rate shown to be efficient.

In addition to tebuconazole, Jotun Industri Grunning Visir contains IPBC (0.30%) claimed to function only as a film preservative in the product. IPBC is part of the review program under 98/8/EC both as wood preservative (PT 8) and film preservative (PT7). IPBC is already included in Annex I of the BPD as a PT 8 active substance. In the Assessment Report for PT 8, IPBC is shown to be efficient against basidiomycetes at concentrations and application rates comparable to the ones used for Jotun Industri Grunning Visir. On the other hand, efficacy test results presented in the tebuconazole PT 8 Assessment Report show that tebuconazole applied alone, at comparable rates to the ones prescribed for Jotun Industri Grunning Visir, is efficient against basidiomycetes. The efficacy testing of Jotun Industri Grunning Visir, conducted by BAM, has been performed with a formulation containing both tebuconazole and IPBC, and these results can as such not give support to the applicant's argumentation for tebuconazole being the only PT 8 active substance.

The reference MS has nevertheless accepted the argumentation as the need of a film preservative can be foreseen. If Jotun Industri Grunning Visir is re-formulated in the future, using another film preservative, new efficacy data should be provided.

The recommended application rate is 8-11 m^2/L depending on properties of the wooden surface, this corresponds to 0.6-0.83g tebuconazole / m^2, which is equal to or higher than the mean load shown to be efficient.

Information on the mode of action and further information on efficacy of the active substance tebuconazole can be found in the Assessment Report for tebuconazole (European Commission, 2007).

There are no known limitations to the efficacy. Resistance against tebuconazole used for wood preservation is not reported or known at the time being.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

Jotun Industri Grunning Visir is a ready-to-use wood preservative product (PT 8) with tebuconazole being the only wood preservative active substance. It contains also cobalt borate neodecanoate complexes (CAS number 68457-13-6), which is defined as a substance of concern for the environment.

The product is intended to be used in Use Class 3 "wood not covered and not in contact with ground, exposed to the weather or subject to frequent wetting." The product is an alkyd primer for exterior wood. The primer is applied industrially by automated airless spray with rotating brushes or flow coating, in both cases in closed chambers operated by industrial workers.

To comply with the efficacy claim, a topcoat has to be applied. This topcoat should be applied within two months after application of the alkyd primer. For treated wood used outdoor in wintertime with temperatures below freezing point the topcoat should be applied in spring.

2.6.2 Assessment of exposure to humans and the environment

The exposure assessment for human health and the environment has been conducted according to agreed guidance documents. For details on the human health risk assessment please see chapter 2.7. Regarding the environmental risk assessment please see chapter 2.8

2.7 Risk assessment for human health

Jotun Industri Grunning Visir contains 0.6 % tebuconazole as the only PT 8 active substance. The product contains no substances of concern for the human health.

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The active substance, tebuconazole, was evaluated and approved for Annex I inclusion according to the procedures of Directive 98/8/EC for use as a wood preservative by the Danish Competent Authority in 2007. No new data/information on human health has been submitted.

A summary of the human health risk assessment from the Tebuconazole Assessment Report (European Commission, 2007) is presented:

*The **ADME**- studies show that oral administration of tebuconazole is followed by a rapid and extensive absorption in the rat. Thus no correction for incomplete oral absorption is necessary in the risk assessment. The substance is quickly distributed throughout the body tissues with the highest level found in the liver. The majority of the administered dose is excreted in the faeces and enterohepatic circulation is expected. There are no indications of*

accumulation in any tissue. The metabolic study revealed sex differences for example in the excretion of the toxicologically relevant metabolite 1H-1,2,4-triazole amounting 5% in the urine of the male and 1.5% in that of the female.

*In **acute toxicity studies,** tebuconazole was found to be of rather low toxicity by the oral route and of low toxicity by inhalation and dermal application when the rat is used as the test species.*

*Tebuconazole has no potential for **skin or eye irritation** and is not **sensitising** to the skin in the Magnusson-Kligmann maximisation test or in the Buehler Patch test.*

*Several **short-term and long-term tests** were submitted and the dog was again found to be the most sensitive animal tested and the only species showing potential for opacities of the eye lenses. Other effects observed in both rats and dogs were minor effects in the liver in the form of slightly increased weights, enzyme induction and decreased plasma glyceride levels as well as vacuolisation of the zona fasciculata cells of the adrenals.*

*No evidence for **genotoxic** potential, that is, no indication of gene mutations, chromosome anomalies or increases in DNA-repair activity were noted in an adequate battery of in-vitro and in-vivo assays with various endpoints including both prokaryotes and eukaryotes.*

Two 21-months combined chronic toxicity/carcinogenicity studies were conducted in mice. At the highest dose, pronounced liver toxicity and an increased incidence of liver tumours were seen. This tumorigenic potential is not considered relevant to humans as it is only found in a sensitive mouse strain and at very high dose levels above the maximum tolerated dose.

*In a two-year combined **chronic toxicity/carcinogenicity study** in rats there was no evidence for carcinogenicity with relevance to humans.*

*In the **developmental toxicity studies** foetotoxic effects were revealed in all three animal species tested. The developmental toxicity occurred at doses that are associated with some maternal toxicity, however, the toxicity to the dams could not in all cases be categorised in severity to a degree that would influence the development of the offspring via non-specific secondary mechanisms to effects such as malformations (e.g. peromelia in rabbits).*

This conclusion of the DK-CA is in agreement with the decision taken by the Specialised Experts-group at their meeting in December 2001. Here it was resolved that, according to the EU classification criteria, the evidence was not sufficient to place tebuconazole in Category Rep2, but tebuconazole should be regarded as a substance that causes concern for humans owing to possible developmental toxic effects and should therefore be allocated to Category Rep3 for developmental toxicity with the risk phrase R63: Possible risk of harm to the unborn child. The decision appears in Commission Directive 2004/73/EC of 29 April 2004 adapting to the technical progress for the twenty-ninth time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

Impaired spatial cognitive learning was observed during development but no corresponding neuropathology could be found in a developmental neurotoxicity study in rats.

An A(O)EL was derived from the critical endpoint in the toxicological studies, a one-year study in dogs, where unspecific effects like histopathological alterations in the adrenal cortex were found. The NOAEL for this effect was 3 mg/kg b.w./day. An uncertainty factor of 100, a 10-fold factor for interspecies variability and a 10-fold factor for intra-individual variability, is applied to the NOAEL for these non-specific toxicological effects. As absorption by the oral route was found to be close to 100% (> 98% oral absorption based on urinary (7.4%) and

biliary (90.9%) excretion within 48 hours), no correction for absorption from the gastro-intestinal tract is needed for the A(O)EL setting.

Table 2.2. Threshold Limit for Human Health Risk Assessment

	Value	Study	SF
A(O)EL [2]	0.03 mg/kg b.w. day	1 yr dog (oral) – unspecific effects like histopathological alterations in the adrenal cortex were found	100

2.7.1.2 Toxicology of the substance(s) of concern

Jotun Industri Grunning Visir does not contain any substances of concern with regard to human health.

2.7.1.3 Toxicology of the biocidal product

Jotun Industri Grunning Visir was not an example product in the EU-review program for inclusion of tebuconazole in Annex I of Directive 98/8/EC. In order to minimise animal testing, no toxicological studies have been submitted for the product, and the evaluation and classification of the product have been conducted on basis of the ingredients.

The ability of tebuconazole to penetrate the skin was examined *in vitro* with a solvent-based and a water-based wood preservative containing 0.6 % [14C]-tebuconazole. The dermal absorption was studied on dermatomed human skin according to the OECD draft Guideline 428. Exposure was terminated after 8 hours, and absorption was assessed by collecting receptor fluid in hourly fractions from 0-8 h post dose and then in 2-hourly fractions from 8-24 h post dose. Tape stripping was performed (20 strips). A potential absorbable dose (absorbed dose + dose in skin + stratum corneum strips 6-20) of 3.3% for the aqueous formulation and 14.4% for the solvent-based formulation was found. (Toner, F. 2006. Competent Authority Report on tebuconazole, DK. December 2007).

The concentration of tebuconazole (0.6%) is the same in Jotun Industri Grunning Visir and the aqueous formulation tested by Toner, and both products have water as the main solvent. Industri Grunning Visir contains lower concentrations of solvents/co-solvents than the tested formulation.

The most profound difference between these formulations is that Jotun Industri Grunning Visir contains more than 5 times higher concentration of binder and much less solvents (i.e. water and co-solvents) than the aqueous formulation tested. Due to the much lower a.s./binder ratio for Jotun Industri Grunning Visir, tebuconazole (being embedded in the paint matrix) is assumed to be less bioavailable in this product compared to the tested formulation.

[2] A final guidance for setting an acceptable operator exposure level (AOEL)/ acceptable exposure level (AEL) was not agreed upon when the CAR on tebuconazole was made.
A guidance document on AEL setting was developed for the Biocidal area and agreed in September 2009 (TNsG on Annex I inclusion, revision of chapter 4.1, Quantitative Human Health Risk, ex-ECB, 2009). The term AEL replaces the AOEL (Acceptable Operator Exposure Level); the omission of the term operator underlining that the AEL is the reference value for the human population as a whole. Usually three AEL values are derived for acute, medium term and long term exposure respectively. For tebuconazole, only one A(O)EL value was derived. This value will be used in the risk assessment for all exposure scenarios.

Consequently, the skin absorption of tebuconazole from Jotun Industri Grunning Visir is expected to be less than the potentially absorbable dose of 3.3% tebuconazole from the tested aqueous formulation.
A potentially absorbable dose of 5% tebuconazole (a rounded off value due to the fact that product differs somewhat from the tested formulation) is used in the risk assessment of Jotun Industri Grunning Visir based on read across from the tested formulation.

2.7.2 Exposure

The workplace risk for industrial workers formulating Jotun Industri Grunning Visir is controlled through observance of statutory requirements such as formal control measures. The workers have access to Safety Data Sheets (SDS) and personal protective equipment (PPE). They are trained and skilled in the main tasks of their occupation. Exposure during formulation of the product is not assessed, only exposure during use of the product.

In the Competent Authority Report on tebuconazole industrial vacuum pressure impregnation, double-vacuum impregnation and dipping were assessed for human health, whereas the relevant application technique for Jotun Industri Grunning Visir, automated spraying with brushing and flow coating, was not covered.

As no product specific exposure data are available, the assessment of human exposure during use of the product was based on generic exposure data.

The exposure assessment was based on Technical Notes for Guidance (TNsG) on Human Exposure to Biocidal Products (ECB, 2002) as revised by the User Guidance (ECB, 2004) as well as exposure data from the computerised databases, BEAT, which is an integral part of the TNsG on Human Exposure to Biocidal Products (ECB, 2007), and the RISKOFDERM Dermal Model.

No exposure data for the process of automated spraying/flow coating per se is available in any of the exposure guidelines. Hence, data from related processes were used as basis for the exposure assessment, in agreement with guidance given in the User Guidance (ECB, 2004) and recommendations given by the Human exposure Expert Group HEEG (2009).

A tiered approach has been followed, starting out with worst case exposure assumptions which have been further refined, where necessary.

The dermal absorption used in the exposure calculations was 100% in a first tier (default value) and 5 % (primary exposure only) in a second tier based on an *in vitro* penetration study in human skin in related aqueous based wood treatment formulation containing 0.6% of tebuconazole (see 2.7.1.3).

The default value body weights used in the exposure calculations are 60 kg for adults, 15 kg for children and 10 kg for infants (generally agreed default values for the Biocides area).

Identification of possible routes of human exposure
Due to the low vapour pressure of the active ingredient ($1.7x10^{-6}$ Pa at 20°C, Assessment Report on tebuconazole, European Commission, 2007) the application method (enclosed application chamber, reducing the exposure to spray mist) and the assumption of well ventilated working areas, skin exposure is the major source of systemic dose.

Table 2.3. Identification of main paths of human exposure from use of the biocidal product

	Primary exposure,while treating wood	Secondary exposure, via contact with treated wood		Via the environment
Exposure path	**Industrial use**	**Professional use**	**General public**	
Inhalation	Yes (minimal)	Yes (minimal)	Yes (minimal)	Minor importance
Dermal	Yes	Yes	Yes	Minor importance
Oral	Negligible	Negligible	Yes (relevant primarily for infants)	Minor importance

Table 2.4. Applications of wood preservatives, including concentrations of tebuconazole in both the products and on/in wood

Field of use	Relative density	Concentration at which the active substance (a.s.), tebuconazole will be used in % weight/weight	Active substance in surface layer (based on the recommended application rates)
Industrial application	1.107	0.6	0,6 - 0,83 g/m^2

2.7.2.1 Exposure of professional (industrial) users

Jotun Industri Grunning Visir (JIGV) is applied by industrial application in closed application chambers. No in-situ application is relevant.

Mixing/loading

The product is sold as a ready to use product. Mixing is therefore not a relevant task and is not assessed. The product is delivered in 20 and 1000 litres containers. Loading of the supply tank/application chamber with wood preservative is manual (pouring from the small container, tapping and pouring from the large container) or semi-automated through pumping. The former process might be associated with significant potential for exposure.

Two scenarios are assessed:

- One scenario assuming repeated manual loading of liquid (tapping/pouring from the containers as well as recycling of wood treatment solution after use)
- One scenario assuming a semi-automated transfer of the solution (pumping)

Use of exposure models

Manual loading of liquid

The Mixing and loading model 7 from the TNsG on human exposure to biocidal products (2002) provides data for the task pouring and pumping of liquids. The model has been used to assess the exposure while loading products into vessels/systems in industrial scale in several active substance dossiers. However, the model is of low reliability and is consequently not included in the User guidance (ECB, 2004). It was agreed at the Technical meeting in the

Biocides Group (TMV07) to check for alternative models. Such models were presented in an HEEG opinion and agreed at TM I08 (HEEG, 2008b).

For the process of repeated manual loading (pouring) of liquid, three models/data sets are indicated as the most relevant models: *loading DEGBE* (diethylene glycol monobuthyl ether) in BEAT, *Mixing & loading model 7* and *Loading liquid* in RISKOFDERM. There is a big difference (i.e. more than a factor of 100) between the exposure values for the models/data sets. This might, according to HEEG, partly be due to variable operating conditions in the models and poor consistency of the dataset (the width of the distribution of the measurements was very large in some of the models).

The recommended choice of model is *Loading DEGBE* in BEAT. The description of the scenario is:

Loading of DEGBE involved the addition of the pure substance to the production process, or a mixer. DEGBE was usually packaged in cargo containers or drums and was transferred to the process or mixer using a bucket or a pump. Loading measurements took between 1 and 15 minutes (AM 6 minutes). The amount of product handled was between 5 and 560 litres (AM 108 litres) and consisted of pure DEGBE (Gijsbers et al., 2004).

The 95th percentile values for exposure to hands (4610 mg/min) and body (18.1 mg/min) are proposed used in BEAT for the dataset due to the wide distribution of the measurements (even the maximal values are considered representative for the scenario). No measurements for exposure by inhalation are presented. Due to the low vapour pressure of the active ingredient (see identification of possible routes of human exposure in 2.7.2), and the low likelihood of aerosol formation, exposure by inhalation is considered to be negligible, and is not assessed for this process.

Semi automatic transfer (pumping)

Generally, for semi automatic loading, exposure can occur while placing hoses in containers and receiving vessels and cleaning of the equipment. *Mixing & loading model 7* from TNsG on human exposure to Biocidal Products from 2002, and RISKOFDERM dermal model (*Loading liquid, automated or semi-automated*) are proposed as relevant models for semi-automated loading (HEEG, 2008b). No relevant model can be found in the TNsG on human exposure to Biocidal Products from 2007/BEAT.

The recommended choice is the RISKOFDERM dermal model *Loading liquid, automated or semi-automated*. The exposure values are dependent on the product and conditions; use rate being an important parameter. *Mixing & loading model 7* is not recommended by HEEG for assessing the exposure, although it is stated that it might be used with caution.

In the exposure calculation, RISKOFDERM has been used, using the exposure values referred in the HEEG document. These exposure values are estimated 95 percentile values for a use rate of 25 L/min. With 10 minutes cumulative duration of the scenario during a shift, this corresponds to a total amount of 250 liter wood preservative.

Based on a maximum application rate of Jotun Industri Grunning Visir (0.125 L product /m^2 wood), a maximum daily consumption of 250 and 2500 liter product/day is estimated for a small and big plant, respectively (based on the default values for treated wood area per day in the Emission Scenario Document for wood preservatives, i.e. 2,000 and 20,000 m^2/day, OECD 2003). Information obtained from Norwegian wood impregnation plants indicate that the typical value for wood area treated per day in Norway lies somewhere between these two default values.

It is assumed that several workers will be responsible for the loading of product in a big plant.

Application

The product is stored indoor in approved containers. The primer is applied by automated airless spraying with rotating brushes or by flow coating in closed chambers. The excess product will be recycled, automatically or manually. As for the process of flow-coating, the wood treatment solution will be filtered before reuse to avoid clogging of the nozzles. After application of the primer, two possible ways of handling are common. The primed claddings/panels are immediately stacked and subsequently stored in a dry environment (spraying with rotating brushes). The other way is to dry panels by elevated temperatures (IR-light) in a drying chamber before stacking (flow coating).

Manuel handling might occur during stacking.The workers are protected with the adequate safety equipment as stated in the data sheets. The stacks will be wrapped in plastic before entering outdoor facilities.

Use of generic exposure data for assessing the exposure:

According to the User Guidance (ECB, 2004) professional workers typically works 8-10 hours a day, at least five days a week. However, only a fraction of the time is spent using wood preservatives. Two hours continues treatment a day is assumed for deluge/flood spray processes (conveyor line) in the TNsG on human exposure to Biocidal product (ECB, 2002). According to the applicant this estimate is not sufficiently conservative, and in the exposure calculations a more realistic value of 6 hours has been used.

According to the User Guidance, operator exposure should be low during deluge processes (e.g. automated spraying/flow coating) and be predominantly due to residues from handling freshly sprayed timber. No generic exposure data are available for deluge processes, however, exposure during a professional dipping process is considered to be a good approximation of the exposure during such application.

The dipping model 1 included in the TNsG on human exposure to biocidal products from 2002 (ECB, 2002) has been used for assessing exposure for the process of automated spraying/flow coating in some CA-reports on active substances. The model contains data for **manual** dipping of wooden articles in **open** tanks and is also applicable for coating of wood with fluid by pouring and scrubbing. In manual dipping operations the operator gets relatively highly contaminated by the wood preservative as the operator lifts and places by hand the wooden article into the dipping tank before it is either pushed with a post under the wood preservative or is brushed with preservative using a broom. The operator manually lifts the wooden article from the dipping tank and stacks the article to dry.

The exposure of operators automated spraying/flowcoating is likely to be less than by manual dipping, due to the automated nature of the applications and the enclosed application chamber.

The Human Exposure Expert Group (HEEG) has recommended that exposure data from vacuum pressure /double vacuum treatment processes should be used instead of the dipping model for **automated** dipping processes (using a fork lift truck); the dermal exposure in both cases being due to intermittent handling of treated wet timber and associated equipment. For water-based in use formulations there should be negligible inhalation exposure since no aerosol formation is expected (HEEG, 2009).

In accordance with this decision it seems logical also to use dermal exposure data from vacuum pressure /double vacuum treatment processes for assessing automated spraying/deluge processes.

Exposure data from vacuum pressure/double vacuum treatment plants are included in the handling 1 model in the TNsG on human exposure to biocidal products from 2002 (ECB, 2002). The plants are operated on a cyclical basis, with loading of the treatment vessel, impregnation of timber in sealded chambers, unloading the treatment vessel and removal of treated timber to storage. Dermal exposure to wood treatment solution will only take place after the treatment of the timber.

Fresh and treated wood is usually moved using lift trucks. Exposure to the wood preservative takes place as the operators are restraining straps and handling treatment machinery, are maintaining the door seals of treatment vessels and are removing fallen wood and sawdust sludge. The exposure may be described as dermal exposure through intermittent contact with wet objects with a small contribution from exposure to inhalation (ECB 2002/ECB 2004).

The data source behind the Handling 1 model is a publication by Garrod et al. from 1999. Deposition of wood preservative on the external work clothing was estimated using the patch technique; relating the amount of active substance on sampling pads to the relevant exposed area of the body, using appropriate conversion factors. Estimation of contamination of hands and feet were done through measurements of deposits of the wood preservative on cotton gloves and socks beneath protective gloves and inside shoes/boots (actual exposure).

The wood preservatives were not distributed uniformly on the body surface. About 90% was deposited on the legs, and most of the remainder on the arms and chest. The hand exposure (inside gloves; i.e. actual exposure) reported for water-based products were high and represented ca. 45% of total dermal exposure (based on indicative values, assuming a clothing penetration of 10%). Neither the material nor the type of gloves were specified. The publication indicates that contamination inside gloves may at least partly result from contamination from putting on old gloves:

> *"The gloves and gauntlets worn were apparently impermeable and generally in a reasonable condition. It is unlikely that the preservatives permeated the glove material. The mode of entry for the active substance into the glove is a matter of speculation, but operators were seen to remove the gloves to operate equipment (e.g. to drive the lift truck, to complete paper work) and then replace the gloves when hands were potentially contaminated. Contamination inside protective gloves was found to be frequent".*

In the handling 1 model the dermal exposure is given as mg product per cycle at a nominal density of 1.0 g/ml. All data are expressed in terms of distributions (ECB, 2002). Automated spraying/flow coating is a continuoes process, and as such the Handling 1 model can not be used directly. However, the exposure data behind the handling 1 model (Garrod et al. 1999) has been included in BEAT ("timber pre-treatment" data set), and the exposure data has been re-expressed to the unit µl/min.

The inhalation exposure is given in time-weighted average exposures to product measured over one or two treatment cycles (expressed as mg product m^3). However, as it is probable that most of the inhalation exposure occurred through generation of transient aerosols following the opening of the treatment vessel door of the vacuum pressure process (Garrod et al. 1999), the exposure is not readily applicable for the scenario of automated spraying/flow coating. Minimal spray mist should be released due to the enclosed chamber.

Due to the low vapour pressure of tebuconazole the inhalation exposure to vapour will be negligible (6 hours exposure to the saturated vapour concentration of tebuconazole, 2.15 x 10

$^{-4}$ mg tebuconazole/m^3, with an inhalation rate of 1.25 m^3/h results in an exposure of 2.7 x 10^{-5} mg/kg b.w. for a person of 60 kg).

Post-application/Maintenance/Cleaning

Accidental contact with freshly treated, wet wood might occur. However, much lower contamination than during application and/or cleaning is assumed as the contact will be of short duration and to a small skin area only. Hence, exposure through accidental contact with wet wood is not calculated.

Post application exposure constitutes system maintenance, including cleaning of the inner surface of the supply tray/application chamber (by flushing with water). The task is not well described by the available models.

A model that has been used to assess the potential exposure while cleaning of impregnation chambers/dipping tanks for vacuum pressure treatment and dipping processes in the evaluation of active substances in PT 8 has been the handling 1 model (see description above) using the exposure values for one cycle (a typical cycle duration being 180 minutes). However, the real exposure during this task could differ markedly from the one estimated as the model is not really suitable. A quantitative exposure assessment for the process of cleaning the supply tank/application chamber used in the automated spraying/ flow coating process has not been made.

Another relevant task is cleaning the spray equipment (nozzles).The activity is assumed to be of short duration and the potential contamination expected to be limited to hands.
The task is not well described by the available models.

The potential for contamination might be high for the cleaning processes, necessitating a higher degree of protection when performing these tasks (impermeable coverall or apron in addition to chemical protective gloves).

Table 2.5. Exposure models used for assessing exposure to professional (industrial) users.

Exposure path	**Industrial use : Automated spraying/Flowcoating**			
	Mixing/loading	Application	Post application	Maintenance/ Cleaning
Inhalation	Negligible	Negligible		Negligible
Dermal	Exposure when loading only. No mixing • Manual loading (pouring): *BEAT: "loading DEGBE*" • Semi automated transfer (pumping): *RISKOFDERM Dermal model "Loading liquid, automated or semi-automated"*	Significant exposure *BEAT, "timber pre-treatment (water)*"		Cleaning: Significant exposure
Oral	No exposure	No exposure	No exposure	No exposure

A tiered approach has been followed, starting out with worst case exposure assumptions which have been further refined. The recommended indicative values have been used in the calculations (BEAT (ECB, 2007), HEEG, 2008b).

Tier 1 estimations should not take into account exposure reduction measures as personal protective equipment (PPE). However, whereas the potential body exposure is available for the "timber pre-treatment" data set, only the actual hand exposure (i.e. exposure measured underneath protective gloves) is available. It is difficult to assess the exposure reduction factors of the gloves in use. Furthermore, the exposure inside previously used gloves may partly result from pre-existing contamination, thus not reflecting penetration through the gloves (Garrod et al., 1999). In general reduction of exposure with the use of gloves is between 90-99%. According to the Human Exposure Expert Group (HEEG), and as agreed at the Biocides Technical Meeting in March 2008 (HEEG, 2008a), it should generally not be attempted to convert actual hand exposure data to potential hand exposure. The data for actual hand exposure can be used for the exposure assessment with the provision that the users will have to wear gloves.

Personal Protective Equipment

According to the User guidance professionals will wear coveralls, protective footwear and gloves and may use eye and face protection when working with wood preservatives. Respiratory protective equipment is often provided where solvent-based products are used (ECB, 2004).

A default penetration factor of 10% for coated coveralls, 5% for impermeable coverall and 10% for protective gloves was used in the calculations in agreement with recommendations from the Human Exposure Expert Group (Opinion by HEEG endorsed by the Technical Meeting in the Biocides Group in February 2010. HEEG, 2010).

For coated coveralls two default values are given, 80 and 90 %, the protection depending on the nature of the challenge. For wood preservatives, 90% is proposed used. The challenge is from the coverall coming into contact with the wet surface treated with wood preservative. It is assumed that less substance gets under the coverall via the wrists/neck of the coverall as there is no spray mist. The degree of protection given by protective clothing and gloves depends on the behaviour of the operator in correctly fitting, removing and maintaining the protective clothing and gloves.

Table 2.6. Assessment assumptions for primary exposure

	Assumptions		
	Tier I	**Tier IIa**	**Tier IIb**
Penetration of clothing	100 %	10 % for coated coverall *(TNsG on human exposure, part 2 pg. 36, 2002, User Guidance 2004, pg 42, HEEG, 2010)*	5% for impermeable coverall *(TNsG on human exposure, part 2 pg 36, 2002, HEEG, 2010)*
Gloves	Generally: No gloves Application: Gloves **	Gloves	Gloves
Dermal uptake	100 %	5 % water based wood treatment solution	5 % water based wood treatment solution
Inhalation uptake*	100 %	100 %	100 %
Inhalation rate (moderate physical activity) *	1.25 m^3/hour	1.25 m^3/hour	1.25 m^3/hour
Adult bodyweight*	60 kg	60 kg	60 kg

* *Generally agreed default values for the Biocides area*
** *Only actual hand exposure available for the relevant data set ("timber pre-treatment (water)")*

The exposure calculations can be found in appendix 3.

The estimated exposure to professionals (industrial) workers is summarised in the tables below.

Table 2.7. Estimated exposure to tebuconazole for industrial workers manually loading wood preservative

	Inhalation exposure (mg/kg b.w./event)	**Dermal exposure (mg/kg b.w./event)**	**Total exposure (mg/kg b.w./event)**
Tier I	-	**4.6**	**4.6**
Tier II	-	0.023	0.023

Values in bold exceeding the A(O)EL of tebuconazole of 0.03mg/kg b.w./day

Table 2.8. Estimated exposure to tebuconazole for industrial workers semi-automatically loading wood preservative

	Inhalation exposure (mg/kg b.w./event)	**Dermal exposure (mg/kg b.w./event)**	**Total exposure (mg/kg b.w./event)**
Tier I	-	**0.10**	**0.10**
Tier II	-	0.00052	0.00052

Values in bold exceeding the A(O)EL of tebuconazole of 0.03mg/kg b.w./day

Table 2.9. Estimated exposure to tebuconazole for industrial workers applying wood preservative by automated spraying/flowcoating

	Inhalation exposure (mg/kg b.w./event)	Dermal exposure (mg/kg b.w./event)	Total exposure (mg/kg b.w./event)
Tier I	-	**4,2**	**4.2**
Tier IIa	-	**0.035**	**0.035**
Tier IIb	-	0.026	0.026

Values in bold exceeding the A(O)EL of tebuconazole of 0.03mg/kg b.w./day

Table 2.10. Estimated combined exposure to tebuconazole for industrial workers (loading + application)

	Total exposure (mg/kg b.w./event)	
	Application + manual loading	**Application + Semi automatic loading (Riskofderm)**
Tier I	**4.6 + 4.2 = 8.8**	**0.10 +4.2 = 4.3**
Tier IIa	0.023 + **0.035 = 0.058**	0.00052 + **0.035 = 0.036**
Tier IIb	0.023 + 0.026 = **0.049**	0.00052 + 0.026 = 0.027

Values in bold exceeding the A(O)EL of tebuconazole of 0.03mg/kg b.w./day

2.7.2.2 Exposure of non-professional users and the general public

The product is intended for professional use only.

2.7.2.3 Secondary (indirect) exposure to the non-user

Indirect (secondary) exposure is defined as the exposure via the environment of which the exposed person may not be aware of. The exposure occurs after the actual use or application of the biocidal product. Secondary exposure to wood preservatives may result from professional and non-professional handling of treated material. Exposure can occur as a single event (acute phase) or occur during long term (chronic phase).

Preserved wood is not placed on the market until it is dry. Consequently, exposure through touching of treated wet surfaces is considered to be an unlikely exposure scenario for non-user.

Secondary exposure scenarios are discussed in the TNsG on human exposure to biocidal products (ECB, 2002) as revised by the User Guidance to the TNsG on human exposure to biocidal products (ECB, 2004).

Selected reference scenarios are used to estimate a realistic worst-case exposure based on default value calculations and stated assumptions:

Acute exposure:

- Adult cutting and sanding treated wood (non-professional)
- Infant chewing wood off-cut

Chronic exposure:

- Adult cutting and sanding treated wood (professional)
- Adults handling treated wood
- Adult/Infant inhaling volatilised residues indoors
- Child/Infant playing on playground structure outdoors (incl. hand to mouth transfer)

- Infant playing on and mouthing weathered structure
- Home laundry of clothes

Table 2.11. Assessment assumptions for secondary (indirect) exposure

	Assumptions	
	Tier 1	**Tier 2**
Dermal uptake	100 %	-
Inhalation uptake[1]	100 %	-
Inhalation rate[1]	1.25 m^3/hour	-
Adult bodyweight[1]	60 kg	-
Child bodyweight[1]	15 kg	-
Infant bodyweight[1]	10 kg	-
Dislodgeable fractions (wood)	2% transfer coefficient of dried fluid from rough sawn wood[2] 10% extraction when chewing[3]	Leaching (immersion day 1)[4]: 9.83 mg a.s./m^2
Dislodgeable fractions (coverall)	30 % transfer coefficient for contamination (dried fluid) from cotton, knitwear to wet hands [5]	-
Active substance in surface layer of wood:	Worst case based on recommended application rates[6]: 0.083 mg a.s/cm^2	-

1 Generally agreed default values for the Biocides area
2 TNsG on human exposure of biocidal products (ECB, 2002, part 2, pg 204 + ECB, 2007, pg 102)
3 User Guidance for TNsG on human exposure of biocidal products (ECB, 2004, pg. 52)
4 Refinement: Leaching of a.s. from preservative-treated timber, Laboratory study (Lindegaard, 2009).
5 TNsG on human exposure of biocidal products (ECB, 2002, part 2, pg 204 + ECB, 2007, pg 102)
6 Product-specific information from the Applicant: Worst case based on recommended application rates: 8m^2/l for Industri Grunning Visir. Density taken into account

Tier 1 takes into account the maximum amount of treatment solution applied to the wood according to the applicant. Only a small fraction of the absorbed preservative will be assumed to be dislodgeable due to dermal contact. A dislodgeable portion (transfer efficiency) of 2% for handling rough sawn wood is used in the calculations. It is assumed that 10% of the absorbed preservative is extracted when chewing on a piece of wood.

Tier 2 scenarios for the scenario infant chewing wood off-cut are based on actual data on leaching (leaching of tebuconazole from wood specimen treated three times with wood preservatives to water, 2 times 1 hour immersion regime, presented result for the first day of testing. Start of testing 5 days after the last treatment).

A higher level of tebuconazole could be extracted from the wood as a consequence of mechanical stress (chewing) and contact with saliva rather than water. The leakage would also be higher from freshly treated wood. On the other hand, the leaching rate is based on two immersion events lasting for one hour each (and a larger volume) whereas infants are not expected to chew/mouth wood for more than a few minutes.

Description of the scenarios (with some refinements from the scenarios described in the User Guidance to the TNsG on human exposure, 2004):

Model Calculations - Acute Phase

a) Adult - sanding treated wood - inhalation route

Processing activities with preserved wood can be performed by professionals as well as by amateurs. Exposure may occur by dermal contact or by inhalation of wood dust. While non-professionals are assumed to work for relatively short periods and only rarely, professionals are assumed to work for several hours and more frequently. However, professionals are assumed to take appropriate measures to minimise dust development.

The scenario is the same for professionals and non-professionals, except the time frame:

A non professional (acute scenario)/professional (chronic scenario) is sanding the surface of a treated wood post (volume: 4 cm x 4cm x 2.5 m= 4000 cm^3, surface area: 4032 cm^2 including the surface area of the two ends of the post, 2 x 4 x 4 cm) for one and six hours a day respectively.

The amount of treatment solution absorbed by the wood depends on multiple parameters including the wood species, fraction of hard versus sapwood, formulation of the preservative and application process.

For wood preservatives applied by superficial treatments the wood preservative is assumed to penetrate only the outermost layer of the wood (1 mm or less). Only this outermost layer is assumed sanded

> *(Note: In the reference scenarios in the User guidance the wood preservative is assumed to be in the 1 cm outer layer. However, the piece of wood in question has been treated by a penetration technique, i.e. double vacuum treatment and the default value is as such not relevant for wood treated by superficial techniques).*

The volume of the wooden post containing the wood preservative is:
Volume of post – volume of untreated inner core of post:

Superficial techniques: 4 x 4 x 250 – 3.8 x 3.8 x 249.8 = 393cm^3

The concentration of tebuconazole in the outer layer of wood treated by superficial treatment is:
a.s. on timber surface x surface area of wooden post ÷ volume of treated wood in the post

0.083 x 4032/393 = 0.85 mg a.s./cm^3

Inhalation route:

An inhalation exposure equal to the occupational exposure limit for wood dust of 5 mg/m^3 and a wood dust density (average value for soft wood) 0.4 g/cm^3 is assumed. The density for soft wood is used as a worst case and a more realistic value than the density for hardwood (0.8 g/cm^3) which was proposed in the User guidance document. An agreement to use the density for soft wood was made at the Biocides Technical Meeting in October 2008 (MOTA version 4, 2010).

For amateurs a time duration of 60 minutes and an inhalation rate of 1.25 m^3/hour is assumed.

5 mg dust/m³ × 1.25 m³/h = 6.25 mg wood dust/h
6.25 mg wood dust (density 0.4 g/cm^3) are equivalent to 0.0156 cm³ of treated wood
0.0156 cm³ wood contains: 0.85 mg/cm^3 × 0.0156 cm³ = 0.0133 mg tebuconazole
Exposure (inhalation, adult, 60 kg) = 0.00022 mg tebuconazole/kg b.w.

Dermal exposure

The tebuconazole concentration on the surface of timber is 0.083 mg a.s./cm^2.

For the dermal exposure calculation 20% of two hands[3] (20% x 840 cm^2 = 168 cm^2), is assumed contaminated during contact with wood (only 20% of one hand or 20 % of both palms of the hands assumed in the User guidance). The transfer efficiency is 2 % for rough-sawn wood (TNsG (2002), Part 2, p.204). A default dermal penetration value of 100 % is used in the exposure calculation. This is obviously an extreme worst case.

The systemic dose for a 60 kg adult can be calculated as:

0.083 mg/cm^2 x 168 cm^2 x 0.02 = 0.279 mg tebuconaxole on hands
Systemic exposure = 0.279 x 100% = 0.279 mg tebuconazole
Exposure (dermal, adult 60 kg) = 0.0047 mg tebuconazole/kg b.w.

Total Systemic Dose (inhalation + dermal): **0.0049 mg tebuzonazole/kg b.w.** (60 kg adult)

b) Infants chewing wood off-cut - ingestion route

It is assumed that the infant (10 kg b.w.) is chewing a 4 cm × 4 cm × 1 cm chip, extracting 10% of the active substance.

Only the 1 mm outer layer is assumed to contain tebuconazole. The surface area of the wooden block is 48 cm^2, however, it is assumed that wood preservative is not applied at two of the sides of the block (2 x (4 cm x 1 cm) = 8 cm^2). Thus, for the exposure calculations a surface area of 40 cm^2 is assumed. The wood contains 0.083 mg tebuconazole/cm^2.

40 cm^2 x 0.083 mg tebuconazole/cm^2 = 3.3 mg tebuconazole

Exposure (oral, infant, 10 kg) = (3.3 mg tebuconazole x 10%)/ 10 kg = **0.033 mg tebuconazole/kg b.w.**

Only one A(O)EL value is established for tebuconazole; i.e. A(O)EL 0.03 mg/kg b.w. However, it should be kept in mind that this value is based on a one year dog study (NOAEL = 3 mg/kg b.w./day (oral) for adrenal effects in the dog.

Refinement:

As a refinement leaching data might be used[4]:
40 cm^2 x 0.000983 mg a.s./cm^2= 0.0393 mg tebuconazole
Exposure (oral, infant, 10 kg) = 0.0393 mg tebuconazole/10 kg = 0.00393 mg tebuconazole/kg b.w. ≈ **0.0039 mg tebuconazole/kg b.w.**

[3] Surface area hands (fronts and backs): 840 cm^2, for men *(TGD, part I, Chapter 2, Appendix II. ECB 2003)*

[4] It has been accepted at TM (TMII11) that leaching data might be used in a refinement of the infants chewing wood off-cut scenario.

Model Calculations - Chronic Phase

a) Adult - sanding treated wood - inhalation route

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

Inhalation route:

5 mg dust/m³ × 1.25 m³/h × 6 h/day = 37.5 mg wood dust/day
37.5 mg wood dust (density 0.4 g/cm^3) is equivalent to 0.0938cm³ wood
0.0938 cm³ wood contains (0.85 mg/cm^3 × 0.0938 cm³/day) =
0.0797 mg tebuconazole/day

Exposure (inhalation, adult, 60 kg) = 0.0013 mg tebuconazole /kg b.w./day

Dermal exposure

The tebuconazole concentration on the surface of timber is 0.083 mg a.s./cm^2.

For the dermal exposure calculation 20% of two hands (20% x 840 cm^2 = 168 cm^2), is assumed contaminated during contact with wood (only 20% of one hand or 20 % of both palms of the hands assumed in the User guidance). The transfer efficiency is 2 % for rough-sawn wood (TNsG (2002), Part 2, p.204). A default dermal penetration value of 100 % is used in the exposure calculation. This is obviously an extreme worst case.

The systemic dose for a 60 kg adult can be calculated as:

0.083 mg/cm^2 x 168 cm^2 x 0.02 = 0.279 mg tebuconazole on hands
Systemic exposure = 0.279 x 100% (dermal uptake) = 0.279 mg tebuconazole
Exposure (dermal, adult 60 kg) = 0.0047 mg tebuconazole /kg b.w./day

Total Systemic Dose (inhalation + dermal): **0.0060 mg tebuconazole/kg b.w./day** (60 kg adult)

b) Adults – handling treated wood – dermal route

An adult (60 kg body weight) is handling treated wood ("hammering") outdoors. The hand surface area is 840 cm². During prolonged and repeated contact 20% of the hands are contaminated. The concentration of tebuconazole at the wood surface is assumed to be 0.083 mg/cm^2. The transfer efficiency is taken from the TNsG (Human exposure to biocidal products, June 2007, page 102) as 2% for transfer of dried fluid to skin. The dermal absorption is 100% (default).

0.083 mg/cm^2 × 840 cm² × 0.2 × 0.02 = 0.279 mg tebuconazole on hands
Systemic dose = 0.279 mg × 100% (dermal uptake) = 0.279 mg tebuconazole
Exposure (adult, 60 kg b.w.) = **0.0047 mg tebuconazole/kg b.w./day**

c) Adult/Infant inhaling volatilised residues indoors

Window frames and external doors might be treated with the product by professional automated spraying or flowcoating. However, such treated articles will generally be painted/stained before or shortly after installation, and as tebuconazole is of low volatility, it is considered that exposure indoors from volatilised residues will be insignificant. A worst case calculation is nevertheless included.

Scenario: Adult and infant inhale volatilised residues from treated wood installed indoors. Assume a moderately ventilated room and residence time of 18 hours/day with an adult

inhaling 18.5 m^3 air and an infant inhaling 4 m^3 air. As a worst-case inhalation exposure is taken as 100 % of the saturated vapour pressure of the active substance in tier 1, 1% of the saturated vapour pressure in tier 2.

Vp = 1.7 x 10^{-6} Pa at 20º C
R= 8.31 $J.K^{-1}.mol^{-1}$ = 8.31 Pa m^3 K^{-1} mol^{-1}
V= 1 m^3
T= 293 K
Mw= 307.8 g/mol
Inhalation volume: 18.5 m^3/d (adults) – 4 m^3 (infant)

Tier I:
Airborne concentration **(SVC): (Vp / (R x T)) x Mw** =
1.7 x 10^{-6} Pa/ (8.31Pa m^3 K^{-1} mol^{-1} x 293 K) x 307.8 g/mol= 2.15 x 10^{-7}g/m^3 = 2.15 x 10^{-4} mg a.s. /m^3
Exposure adults: (2.15 x 10^{-4} mg/m^3 x 18.5 m^3)/60 kg = **6.63 x 10^{-5} mg a.s./kg b.w./day**
Exposure infant: (2.15 x 10^{-4} mg/m^3 x 4 m^3)/10 kg = **8.6 x 10^{-5} mg a.s./kg b.w./day**

Tier II:
A tier II calculation is not necessary as the calculated exposure in tier I is far below the AEL value for tebuconazole.

d) Child - playing on a playground structure outdoors - dermal route

A proposal for modifications of the scenario was presented at the Technical Meeting in the Biocide Group in March 2008. However, no agreement on the modified scenario was reached. Hence, the scenario as presented in the User Guidance is used.

A child (15 kg body weight) is playing on a playground structure outdoors. The hand surface area is 200 cm². During prolonged and repeated contact 20% of the hands are contaminated. The concentration of tebuconazole at the wood surface is assumed to be 0.083 mg/cm². The transfer efficiency is taken from the TNsG as 2% for transfer of dried fluid to skin. The dermal absorption is 100% (default).

0.083 mg/cm² × 200 cm² × 0.2 × 0.02 = 0.066 mg tebuconazole on hands
Systemic dose = 0.066 mg × 100% (dermal absorption) = 0.066 mg tebuconazole
Exposure (child, 15 kg b.w.) = **0.0044 mg tebuconazole/kg/day**

e) Infants - playing on a weathered (playground) structure and mouthing - dermal and ingestion

The exposure for infants who play on treated wood structures and have hand-to-mouth contact as they play is calculated. The scenario is a somewhat modified scenario from the User Guidance (Licking of hand rather than 100% ingestion of surface deposits on 5 x 10 cm^2 wood (which seems rather unrealistic)

Dermal exposure

An infant (10 kg body weight) is playing on playground structure outdoors. The hand surface area is 200 cm². During prolonged and repeated contact 20% of the hands are contaminated. The concentration of tebuconazole on the wood surface is assumed to be 0.083 mg/cm². The transfer efficiency is taken from the TNsG as 2%.

0.083 mg/cm² × 200 cm² × 0.2 × 0.02 = 0.066 mg tebuconazole on hands
Systemic dose = 0.066 mg × 100% (dermal absorption) = 0.066 mg tebuconazole

Oral exposure:

In addition; licking the hands and assuming an oral uptake of 100%:
0.083 mg/cm² × 200 cm² × 0.2 × 0.02 = 0.066 mg tebuconazole on hands
Systemic dose = 0.066 mg tebuconazole

Exposure (infant, 10 kg b.w.) = 0.0066 mg/kg b.w. tebuconazole per day via skin
+ 0.0066 mg/kg b.w. tebuconazole per day oral uptake

Overall exposure (infant, 10 kg b.w.) = **0.0132 mg tebuconazole/kg b.w./day**

f) Adults - cleaning work wear at home

An additional scenario for home laundry of clothes has been introduced in several CA-reports. The scenario has not been considered as relevant in this report as only industrial use is foreseen and it is not assumed that the contaminated work clothings are washed at home.

Table 2.12. Summary - Secondary exposure to tebuconazole- Surface treated wood

	Scenario	**Systemic dose** mg kg/b.w. (per day)	
		Tier I	**Tier II**
Acute scenarios	Adult cutting and sanding treated wood	0.0049	-
	Infant chewing wood	**0.033**	0.0039
Chronic scenarios	Adult cutting and sanding treated wood	0.0060	-
	Adults handling treated wood	0.0047	-
	Adult inhaling volatilised residues indoors	6.6×10^{-5}	-
	Infant inhaling volatilised residues indoors	8.6×10^{-5}	-
	Child playing on playground structure	0.0044	-
	Infant playing on weathered (playground) structure and mouthing	0.013	-

Values in bold exceed the A(O)EL value of tebuconazole of 0.03 mg kg^{-1} b.w. per day

2.7.2.4 Exposure to residues in food

Jotun Industri Grunning Visir is not to be used on materials which are in direct contact with food or feeding stuff.

2.7.3 Risk Characterisation

2.7.3.1 Risk for Professional (Industrial) Users

Table 2.13. Risk characterisation for Professional (industrial) Users during Mixing and loading

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/LOAEL [mg/kg b.w./day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE$_{ref}$	MOE	Exposure /AEL
		estimated oral uptake [mg/kg b.w./day]	estimated inhalation uptake [mg/kg b.w./day]	estimated dermal uptake [mg/kg b.w./day]	estimated total uptake [mg/kg b.w./day]				
Tier I (100% dermal absoption 100% clothing penetration	Manual loading	-	-	**4.6**	**4.6**	NOAEL: 3 (1yr dog) AOEL: 0.03	100	**0.65**	**153.3**
	Semi auto. loading (Riskofderm)	-	-	**0.10**	**0.10**			**30**	**3.33**
Tier II (5% dermal absorption Coated coverall 10% penetration, gloves)	Manual loading	-	-	0.023	0.023	NOAEL: 3 (1yr dog) AOEL: 0.03	100	130	**0,77**
	Semi auto loading (Riskofderm)	-	-	0.00052	0.00052			5769	0,017

Values in bold: MOE<100, Exposure/AEL > 1

Conclusion: The ration Exposure/AEL is below 1 for all scenarios in tier II.

Table 2.14. Risk characterisation for Professional (industrial) Users for application (automated spraying/flow coating)

Exposure Scenario (indicate duration)	Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w./day] & Reference Value e.g: A(O)EL (acute or medium or chronic)	AF MOE ref	MOE	Exposure /A(O)EL
	estimated oral uptake [mg/kg b.w./day]	estimated inhalation uptake [mg/kg b.w./day]	estimated dermal uptake [mg/kg b.w./day]	estimated total uptake [mg/kg b.w./day]				
Tier I (100% dermal absorption 100% clothing penetration, gloves)	-	-	4,2	**4.2**	NOAEL: 3 (1yr dog) A(O)EL: 0.03	100	**0.71**	**140**
Tier IIa (5% dermal absorption Coated coverall 10% penetration, gloves)	-	-	**0.035**	**0.035**		100	**85.7**	**1.2**
Tier IIb (5% dermal absorption Impermeable coverall 5% penetration, gloves)	-	-	0.026	0.026		100	115	0.87

Values in bold: MOE<100, Exposure/A(O)EL > 1

Conclusion:

Based on the exposure data presented in BEAT (*"timber pre-treatment (water)*" dataset), the estimated exposure to professional is above the A(O)EL value for tebuconazole, assuming use of coated coveralls and protective gloves, but below the the A(O)EL value for tebuconazole, assuming use of impermeable coveralls and protective gloves.

It should be kept in mind that BEAT exposure data for a different application process (vacuum pressure treatment) was used in the exposure calculation for the application phase in lack of exposure data for the actual processes. Hence, considerable uncertainty exist on the exposure to be expected during the process.

Table 2.15. Risk characterisation for Professional (industrial) Users for – combined exposure (M&L and application)

Exposure Scenario (indicate duration)		Estimated Internal Exposure(total uptake, mg/kg b.w./day)	Relevant NOAEL/ LOAEL [mg/kg b.w./day] & Reference Value e.g: A(O)EL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /A(O)EL
Tier I (100% dermal absorption 100% clothing penetration, Gloves (application))	Application + manual loading	**8.8**	NOAEL: 3 (1yr dog) A(O)EL: 0.03	100	**0.34**	**293**
	Application + semi-automated loading	**4.3**			**0.70**	**143**
Tier IIa (5% dermal absorption Coated coverall 10% penetration, gloves)	Application + manual loading	**0.058**		100	**52**	**1.9**
	Application + semi-automated loading	**0.036**			**83**	**1.2**
Tier IIb (5% dermal absorption. Coated coverall 10%penetration (M&L), impermeable coverall 5% penetration (application), gloves)	Application + manual loading	**0.049**		100	**61**	**1.6**
	Application + semi-automated loading	0.027			111	0.9

Values in bold: MOE<100, Exposure/A(O)EL > 1

Conclusion:

Based on the available exposure data, the estimated combined exposure to professional (loading and application) is above the A(O)EL value for tebuconazole, assuming manual loading. The exposure is acceptable if semi automated loading is assumed (using coated coverall and protective gloves) and impermeable coveralls and protective gloves are used during application.

As commented above, it should be kept in mind that generic exposure data for a different application process (vacuum pressure treatment) was used in the exposure calculation for the application phase in lack of exposure data for the actual processes. Hence, considerable uncertainty exists on the exposure to be expected during the process.

2.7.3.2 Risk for non-professional users and the general public

Non professionals do not apply the product.

2.7.3.3 Risk for secondary (indirect exposure)

Table 2.16. Risk characterisation - Secondary (indirect) exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL [mg/kg b.w./day] & Reference Value e.g: A(O)EL (acute or medium or chronic)	AF MOE ref	MOE	Exposure/ A(O)EL
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Acute scenarios									
Adult cutting and sanding treated wood	Tier I		0.00022	0.0047	0.0049	NOAEL: 3 (1yr dog) A(O)EL: 0.03	100	612	0.16
Infant chewing wood	Tier I	0.033			**0.033**		100	**61**	**1.1**
	Tier II	0.0039			0.0039		100	769	0.13
Chronic scenarios									
Adult cutting and sanding treated wood	Tier I		0.0013	0.0047	0.0060	NOAEL: 3 (1yr dog) A(O)EL: 0.03	100	500	0.2
Adults handling treated wood	Tier I			0.0047	0.0047		100	638	0.16
Adult inh. vol. residues indoors	Tier I		6.6×10^{-5}		6.6×10^{-5}		100	45×10^{3}	0.0022
Infant inh. vol. residues indoors	Tier I		8.6×10^{-5}		8.6×10^{-5}		100	35×10^{3}	0.0029
Child playing on playground structure	Tier I			0.0044	0.0044		100	682	0.15
Infant playing on weathered (playground) structure and mouthing	Tier I	0.0066		0.0066	0.013		100	231	0.43

Values in bold: MOE<100, Exposure/A(O)El for tebuconazole > 1

Conclusion: The MOE is more than 100 for all scenarios.

2.7.3.4 Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

2.7.4 Discussion and summary of the Human health Risk Assessment

Based on the available exposure data and assuming use of PPE (protective gloves and coverall) the estimated exposure to professional users loading Jotun Industri GrunningVisir into supply/application chambers is below the established threshold limit (A(O)EL) for tebuconazole.

The estimated exposure to professional users applying the product by automated spraying/flow coating is above the A(O)EL for tebuconazole assuming use of protective gloves and coated coveralls, with a risk ratio (Exposure/A(O)EL) of 1.2, but below the threshold limit if protective gloves and impermeable coveralls are used.

The estimated combined exposure to tebuconazole (loading of the product into application chambers/supply tanks/recycling used wood preservative and applying the wood preservative by automated spraying/flow-coating) is above the A(O)EL for tebuconazole. A risk ratio (Exposure/A(O)EL) of 1.9 is calculated for manual loading/application assuming use of a coated coverall and protective gloves (1.6 if impermeable coveralls is used during application).For semi automated loading/application a risk ratio of 1.2 is estimated assuming use of a coated coverall and protective gloves (0.9 if impermeable coveralls is used during application).

Appropriate use of adequate and suitable personal protective equipment (coveralls and gloves) is needed to protect workers against exposure to the wood preservative and to ensure safe use.

Exposure data for a different application process (vacuum pressure treatment) was used in the exposure calculation for the application phase in lack of exposure data for the actual processes (automated spraying, flow coating). Hence, considerable uncertainty exist on the exposure to be expected during the process. The relevant application process is an automated process supervised by industrial users; nevertheless contact with treated claddings/pannels will occasionally happen.

In the data sets used for estimating exposure during manual loading as well as application, the hand exposure was very high. For manual loading the hand exposure represented more than 99 % of the total dermal exposure (potential exposure). In the data set used to assess the application phase, hand exposure represented approximately half of the total dermal exposure (actual exposure). In the latter data set, the exposure was measured inside gloves; the publication indicating that the hand contamination may at least partly be the result of contamination from putting on used gloves.

Hand exposure depends on a number of parameters. The exposures will be high when inappropriate gloves are used (e.g. leather gloves to protect from abrasions and splinters, giving no protection against chemicals) in an inappropriate way (e.g. taking gloves off and contaminating the hands or the inside of the gloves before putting them back on). Furthermore, a high exposure will result if the barrier has been compromised.

The degree of protection given by PPE depends on the operator correctly fitting, removing and maintaining the equipment. Training in correct use of PPE as well as establishement of

good routines for replacing contaminated or damaged PPE is necassary to reduce exposure to an acceptable level.

As for Jotun Industri Grunning Visir the product is coloured (white) and contamination of clothing and other equipment will be readily spotted. Hence, further exposure should be avoided by removing of contaminated clothing/gloves, washing of hands/skin and equipment etc.

The potential for contamination might be high for post application processes, i.e. the cleaning of vessels/spray equipment (nozzles), necessitating a higher degree of protection when performing these tasks (impermeable coverall or apron, in addition to chemical protective gloves).

Preserved wood is not placed on the market until it is dry. Consequently, exposure through touching of treated wet surfaces is considered to be an unlikely exposure scenario for non-user. An acute secondary exposure to tebuconazole can be anticipated for adults 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). The estimated exposures result in a MOE > 100 for both scenarios (tier II refinement needed for the scenario of infant chewing wood).

Chronic secondary exposure is relevant for adults who cut or sand treated wood as part of their occupation (e.g. carpenters) and handle treated wood. As only industrial use is foreseen it is not assumed that the contaminated work wear is washed at home. Hence, the scenario has not been considered as relevant in this report. Children may have repeated contact to tebuconazole-treated wood, e.g., on playgrounds. For infants, dermal contact and oral absorption after hand-to-mouth contact are possible routes of exposure. The MOE is more than 100 for all scenarios. Hence, it can be concluded that the normal use of tebuconazole-treated material should not pose an acute or chronic health risk for humans.

The overall outcome of the risk assessment for humans is that proper use, i.e. use in compliance with the conditions on the label/SDS of Jotun Industri Grunning Visir and wood treated with it, is considered safe for all subpopulations.

2.8 Risk assessment for the environment

Jotun Industri Grunning Visir contains 0.6 % tebuconazole as the only PT 8 active substance and 0.1-0-5% cobalt borate neodecanoate (CAS number 68457-13-6), which is defined as a substance of concern for the environment. Concerning the environmental exposure and risk assessment these two substances have been taken into account using the mixture toxicity approach (for details please see chapter 2.8.3.3).

2.8.1 Fate and Effects assessment

Tebuconazole

No ecotoxicological studies were performed with the product. For tebuconazole, information on fate and effects from the BPD 98/8/EC Assessment Report is used, to which Jotun AS has a letter of access.

Tebuconazole is stable to hydrolysis and is also assumed to be stable against direct photolysis in water. Regarding biodegradation, the following degradation constants from the active substance Assessment Report were used:

Soil: $k = 9.0E\text{-}03\ d^{-1}$ (DT_{50} = 77 d, normalised to 12 °C)

Surface water: k = 1.6E-02 d^{-1} (DT_{50} = 43 d, referring to the average outdoor temperature between May and November in Europe)

Sediment: k = 1.9E-03 d^{-1} (DT_{50} = 365 d)

In water no major metabolites were found. Regarding metabolites from the soil studies, the highest concentration was found for 1,2,4-Triazole. However, it cannot be regarded as major metabolite as it only was formed in a maximum amount of 9 %. Moreover, the ecotoxicity of this metabolite is significantly lower than that of tebuconazole, both for the aquatic and the terrestrial environment:

Table 2.17: Ecotoxicologial data for 1,2,4-triazole

Endpoint	RESULTS	
	Tebuconazole	**1,2,4-Triazole**
Acute toxicity for fish	LC_{50} = 4.4 mg/L	LC_{50} = 498.0 mg/L
Acute toxicity for invertebrates	EC_{50} = 2.79 mg/L	EC_{50} > 100.0 mg/L
Growth inhibition on algae	E_rC_{50} = 5.3 mg/L	E_rC_{50} > 31.0 mg/L
Acute toxicity to earthworms	LC_{50} = 470 mg/kg dw	LC_{50} > 1000 mg/kg dw

Therefore, the metabolite has not been taken into account in the environmental risk assessment.

Regarding ecotoxicity, the following PNEC values for tebuconazole are directly taken from the active substance Assessment Report:

$PNEC_{surface\ water}$ = 1 µg a.i./L
$PNEC_{sediment}$ = 0.55 mg ^{14}C equiv./kg wwt sediment
$PNEC_{soil}$ = 0.1 mg a.i./kg wwt soil
$PNEC_{STP}$ = 320 µg a.i./L

These PNEC values will be used for the risk assessment.

All the fate and effect values for tebuconazole can be found in the List of Endpoints of the tebuconazole Assessment Report.

Cobalt borate neodecanoate

Various data from the REACH registration of cobalt borate neodecanoate as part of a group registration for cobalt compounds are available, including a summary of PNEC values. The data are publicly available on ECHAs database ECHA CHEM, under Registered Substances. The PNEC values seem to be based on data on both cobalt borate neodecanoate and other cobalt compounds and the effect concentrations are based on dissolved/free cobalt. The PNEC values are based both on short- and long-term data, for various taxonomic groups.

$PNEC_{freshwater}$ = 0.51 µg/L
$PNEC_{sediment}$ = 9.5 mg/kg dwt
$PNEC_{soil}$ = 7.9 mg/kg dwt
$PNEC_{STP}$ = 0.37 mg/L

The $PNEC_{soil}$ based on wet weight is 6.97 mg/kg wwt when using a conversion factor from dry to wet weight of 1.13 (according to EUSES).

$PNEC_{sediment}$ based on wet weight is 2.07 mg/kg wwt using a conversion factor from dry to wet weight of 4.6 (according to EUSES).

The ecotoxicity of cobalt borate neodecanoate can be assumed to be caused by the cobalt ion. Therefore, in the exposure calculations, no biodegradation was assumed. Moreover, 100 % bioavailability of the metal ion was assumed.

2.8.2 Exposure assessment

2.8.2.1 Leaching

A laboratory leaching study has been carried out (Lindegaard, B. and Morsing, E., 2009; see Appendix 1 – reference list) according to OECD guideline; series on Testing and Assessment No. 107 (2009) *"OECD Guidance on the Estimation of Emissions from Wood Preservative-Treated Wood to the Environment: for Wood held in Storage after Treatment and for Wooden Commodities that are not covered and are not in Contact with Ground"*. Samples were immersed 2 x 1 hours over a 19 days period. The curve was extrapolated to 30 days and the estimated cumulative amount leached out during 30 days was 88 mg/m^2. The 30 days average leach rate is therefore 2.93 mg/m^2 day. This value was, however, not used for risk assessment, as a semi-field leaching study has been conducted as well.

This semi-field leaching test (Klamer and Venås, 2011; see Appendix 1 – reference list) has been conducted according to NT Build 509 over one year. During this year five samples were taken; at days 29, 76, 138, 198 and 355, respectively. Samples were analysed for tebuconazole and cobalt borate neodecanoate, which is a substance of concern for the environment in this product. The annual rain was 679 mm. The results of the semi-field leaching study were normalised to a standard precipitation of 700 mm per year.

The evaluation of these two study summaries can be found in Appendix 2.

The product is to be applied industrially by airless spray with rotating brushes or flow coating. One litre of the product covers 8 - 11 m^2 of wood, depending on the properties of the wooden surface. The maximum application rate is therefore 8 m^2/L. The density of the product is 1.107 kg/L and with this the maximum retention of Jotun Industri Grunning Visir can be calculated:

8 m^2 wood / L product = 0.125 L product / m^2 wood = 0.138 kg product / m^2 wood = 0.830 g teb. / m^2

The retention in semi-field leaching study was 0.668 g tebuconazole / m^2. As the maximum retention applied for is 0.830 g teb. / m^2, the results of the leaching study have to be multiplied with a correction factor of 1.243.

To comply with the efficacy claim, a topcoat has to be applied. This topcoat should be applied within two months after set-up of treated wood. For treated wood used outdoor in wintertime with temperatures below freezing point, the topcoat should be applied in spring. However, for the environmental risk assessment, only the results from the uncoated samples have been used for PEC calculations. No long-term risk to soil and surface water/sediment has been identified with this approach apart from a risk in the Bridge over Pond scenario (for details please see chapter 2.8.3). Therefore, results from the coated samples were not taken into account for the environmental risk assessment. As in practice a topcoat will be applied within two months, or in spring in case treated wood was set up in wintertime with temperatures below freezing point, the calculated PEC values for Time 2 are an overestimation of the emissions of tebuconazole and cobalt borate neodecaonate complexes to the environment.

Leaching data for tebuconazole

Table 2.18: Data from semi-field study for tebuconazole for uncoated samples

	Days	Rain (mm)	Volum/L	Tebu. (mg/L)	Period	Periodic release (mg/m^2)	Cumulative Release (mg/m^2)	Normalised Periodic flux (mg/m^2 day)
Replicate 1	29	40.4	2.1	0.90	1	2.32	2.32	0.110
	76	143.3	1.6	0.78	2	1.53	3.85	0.029
	138	266.7	6.8	0.61	3	5.08	8.93	0.079
	198	483.4	17.2	0.41	4	8.64	17.57	0.076
	355	678.7	22.9	0.21	5	5.89	23.5	0.058
Replicate 2	29	40.4	2.2	0.92	1	2.48	2.48	0.118
	76	143.3	1.5	0.78	2	1.43	3.91	0.027
	138	266.7	7.0	0.57	3	4.89	8.80	0.076
	198	483.4	17.6	0.38	4	8.20	17.00	0.073
	355	678.7	23.1	0.19	5	5.38	22.4	0.053
Replicate 3	29	40.4	2.3	0.95	1	2.68	2.68	0.127
	76	143.3	1.8	0.84	2	1.85	4.53	0.035
	138	266.7	6.9	0.64	3	5.41	9.94	0.084
	198	483.4	17.5	0.43	4	9.22	19.16	0.082
	355	678.7	23.2	0.26	5	7.25	26.4	0.071

Interpretation of the tebuconazole data

- Time 1 = 30 days:

  Cumulative amount leached out: 3.55 mg/^{2} (calculated by using the amount leached out during the first period over 29 days (mean of 3 replicates), normalized to 700 mm precipitation. Leaching rate from test was therefore 0.118 mg/m^2 day. Applying the correction factor of 1.243 to account for the maximum retention applied for leads to a leach rate of **0.147 mg/m^2 day**, which will be used Time 1 tebuconazole PEC calculations.

- Time 2 = 15 years = 5475 days:

  The leaching rates after 138 days were only slowly decreasing; from 0.080 mg/m^2 day at day 138/139 to 0.077 mg/m^2 day at 198/252 days and finally to 0.061 mg/m^2 day after one year/354 days. Therefore, extrapolating with the measured values of the 1 year semi-field study to 5 years, has not been carried out according to Appendix 2 of the ESD.

  As a first tier, long-term PECs were calculated using the cumulative leaching over 1 year (mean of three replicates, normalized to standard rainfall) and deriving a one-year leach rate from this value. The 1 year leach rate was therefore 0.068 mg/m^2 day. Applying the correction factor of 1.243 leads to a leach rate of **0.085 mg/m^2 day**, which will be used for Time 2 tebuconazole PEC calculations.

  Details on the calculation of the tebuconazole leach rates for the uncoated samples can be found in Appendix 4a (Excel file), which is part of the Product Assessment Report for mutual recognition.

Leaching data for cobalt

Table 2.19: Data from semi-field study for cobalt borate neodecanoate for uncoated samples

	Days	Rain (mm)	Volum/L	Co (mg/L)	Period	Periodic release (mg/m^2)	Cumulative Release (mg/m^2)	Normalised Periodic flux (mg/m^2 day)
Replicate 1	29	40.4	2.1	0.68	1	1.74	1.7	0.082
	76	143.3	1.6	0.52	2	1.02	2.8	0.019
	138	266.7	6.8	0.49	3	4.04	6.8	0.063
	198	483.4	17.2	0.20	4	4.16	11.0	0.037
	355	678.7	22.9	0.10	5	2.67	13.6	0.026
Replicate 2	29	40.4	2.2	0.59	1	1.58	1.6	0.075
	76	143.3	1.5	0.51	2	0.94	2.5	0.017
	138	266.7	7.0	0.43	3	3.67	6.2	0.057
	198	483.4	17.6	0.16	4	3.40	9.6	0.030
	355	678.7	23.1	0.09	5	2.44	12.0	0.024
Replicate 3	29	40.4	2.3	0.95	1	2.66	2.7	0.126
	76	143.3	1.8	0.59	2	1.29	4.0	0.024
	138	266.7	6.9	0.54	3	4.54	8.5	0.071
	198	483.4	17.5	0.19	4	4.10	12.6	0.036
	355	678.7	23.2	0.09	5	2.69	15.3	0.026

Interpretation of the cobalt data

Cobalt borate neodecanoate dissociates in aqueous solutions and only dissolved / free cobalt was measured. Therefore, leach rates refer to cobalt, not the complex.

For derivation of Time 1 and Time 2 leach rates the same approach was taken as for tebuconazole. For cobalt Time 1 and Time 2 leach rates were 0.095 mg/m^2 day and 0.039 mg/m^2 d, respectively. Applying the correction factor of 1.243 leads to **Time 1 and Time 2 leach rates of 0.118 mg/m^2 day and 0.048 mg/m^2 day**, respectively, which are used for PEC calculations for cobalt. Details on the calculation of the cobalt leach rates for the uncoated samples can be found in Appendix 4b (Excel file), which is part of the Product Assessment Report for mutual recognition.

2.8.2.2 PEC calculations

Due to the use pattern of the product, STP, the aquatic compartment including sediment, and the terrestrial compartment will be exposed.

Formulation of Jotun Industri Grunning Visir

During formulation of Jotun Industri Grunning Visir, water, binder, additives and solid raw materials are added to a mixing tank by automatic and closed process equipment. The tanks are well ventilated and the lid is only opened during sampling and manually adding of small raw material additives. The filling operation is well ventilated and with negligible emission.

Generally, Jotun follows the regulations as given in the Norwegian Pollution Control Act and the restrictions given in the specific discharge permit for the paint manufacturing plant.

Specifically, during formulation of Jotun Industri Grunning Visir, no release of tebuconazole to the environment occurs:

- Formulation takes place in a closed/semi-closed system.
- After production of the formulation, the plant is cleaned with water. The cleaning water, containing traces of the formulation, will be sent as hazardous waste to an external treatment facility.
- No emissions to air are expected for tebuconazole during formulation of Jotun Industri Grunning Visir, as the active substance has a low vapour pressure and no aerosols are generated in the formulation process.

Therefore, no environmental exposure and risk assessment is performed for the life cycle stage ”formulation of the biocidal product”.

Application and storage of Jotun Industri Grunning Visir

Jotun Industri Grunning Visir is applied industrially, in closed facilities. According to the practice in two Norwegian wood impregnation plants, the application method is industrially by automated airless spraying with rotating brushes or flow coating, in both cases in closed chambers. The excess product is recycled, and waste water, containing cleaning water and remains of the product, is collected in flocculation vessels. Aluminium sulphate is used as flocculation agent at both sites. The settled material is handled according to national and local legislation, while the supernatant is released to a municipal STP.

The PECs from the industrial application phase were calculated according to the Emission Scenario Document (ESD) for wood preservatives (OECD, 2003) and the Technical Guidance Document on Risk Assessment (TGD; ECB, 2003). In the ESD for wood preservatives, chapter 4.2.1.3 on calculation of emissions for automated spraying, the default values for treated wood area per day are given as 2,000 and 20,000 m^2/day (for a small and big plant, respectively). Information obtained from the two Norwegian wood impregnation plants indicate that the typical value for wood area treated per day in Norway lies somewhere between these two default values, but not above 20,000 m^2/day. It is therefore considered that the approach outlined in the ESD will cover the situation in Norway.

After application of the primer, two possible ways of handling are common at these two sites. Either, the primed claddings/panels are immediately stacked and subsequently stored in a dry environment. Or panels are dried by elevated temperatures in a drying chamber (IR-light) before stacking. The stacks will be wrapped in plastic before entering outdoor facilities. Therefore, no emission of primer to the environment will occur during storage.

In-use phase of Jotun Industri Grunning Visir

Regarding the use-phase of Jotun Industri Grunning Visir, calculations of predicted environmental concentrations (PECs) for tebuconazole and cobalt for tier 1 PECs (without taking into account degradation/dissipation) have been carried out according to the ESD for wood preservatives and the TGD. Tier 2 PECs (including degradation/dissipation) have been calculated for tebuconazole according to the Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration (FOCUS, 2006). For Tier 2 calculations, FOCUS and not the equations from the ESD on wood preservatives has been used. The reason for this was mainly that when assessing products for which in-situ treatment is foreseen, the ESD equations did not seem to correctly take into account the degradation of the active substance emitted during the in-situ treatment. In order to follow the same approach also for this product, it was considered more appropriate to follow the guidance given in FOCUS also for Jotun Industri Grunning Visir, even if no in-situ treatment is foreseen for this product.

As leach rates, the results from the semi-field leaching study were used. PECs were only calculated using leach rates from the uncoated samples.

Jotun Industri Grunning Visir is intended to be used industrially only, up to Use Class 3. Relevant scenarios for this Use Class are fence, house, noise barrier and bridge over pond. No exposure calculations were conducted for the fence scenario, however, as emissions to soil from the house scenario are worst case and therefore cover emissions from the fence scenario. As the product is to be applied industrially, PECs for in-situ treatment were not applicable.

The receiving soil compartment is a rectangular soil box 50 cm deep and at a horizontal distance of 50 cm from the treated wood.

PECs for tebuconazole

<u>Industrial application (automated spraying)</u>

The PECs for automated spraying were calculated according to the ESD for wood preservatives. Details of the PEC calculations for tebuconazole can be found in Appendix 4c (Excel file), which is part of the Product Assessment Report for mutual recognition.

Table 2.20 Tier 1 PECs for tebuconazole from automated spraying

Scenario	Tier 1 PECwater (µg/L)	Tier 1 PECsediment (mg/kg_{wwt})	Tier 1 PECstp (µg/L)
Small plant	0.20	4.4E-03	1.97
Big plant	1.97	0.04	19.7

In-service use

The following leach rates are used for PEC calculations for service-life:

- Time 1 PECs (30 days) were calculated using the leach rate of 0.147 mg/m^2 day.
- Time 2 PECs (15 years) were calculated using the leach rate of 0.085 mg/m^2 day.

Tier 1 PECs were calculated according to the ESD for wood preservatives. The tier 1 PECs represent the total amount of emitted a.s. during Time 1 and Time 2, not taking into account any degradation/dissipation.

Tier 2 PECs of tebuconazole were calculated in soil and surface water (in bridge scenario), taking into account degradation and dissipation.

However, in the noise barrier scenario, tier 2 PECs were only calculated for the soil compartment – no risks were identified for surface water, sediment or STP at tier 1. Further PEC refinements were therefore not considered necessary for these compartments.

Tier 2 PECs were calculated according to the following description. For service life (continuous release of a.s. from the treated wood), time-weighted average PECs were calculated. As a simplification, it was assumed that the initial concentration is equal to the total amount leached out during Time 1 and Time 2 with no degradation/dissipation, i.e. the tier 1 PEC. From this, a tier 2 PEC was calculated, which represents a time-weighted PEC over the whole period taking into account degradation and dissipation. This approach is in accordance with the FOCUS kinetics guidance for calculating PEC values following multiple applications (chapter 11.4.2, first paragraph):

$$PEC_{twa} = (PEC_{tier\ 1} / kt) \times (1 - e^{-kt})$$

The following degradation constants were used, taken from the tebuconazole Assessment Report:

Soil:	k = 9.0E-03 d^{-1} (DT_{50} = 77 d, 12 °C)
Surface water:	k = 1.6E-02 d^{-1} (DT_{50} = 43 d, ave. outdoor temp. May-Nov, Europe)
Sediment:	k = 1.9E-03 d^{-1} (DT_{50} = 365 d)

No PECs were calculated for the soil metabolite 1,2,4-triazole. This metabolite was detected in a maximum amount of 9 % and it is clearly less toxic than tebuconazole. Therefore, it is not taken into account further.

Details of the PEC calculations for tebuconazole can be found in Appendix 4c (Excel file), which is part of the Product Assessment Report for mutual recognition.

Table 2.21 Tier 1 PECs for tebuconazole from in-service leaching

Scenario	Tier 1 PECsoil (mg/kg_{wwt})		Tier 1 PECwater (µg/L)		Tier 1 PECsediment (mg/kg_{wwt})		Tier 1 PECstp (µg/L)	
	Time 1	Time 2	Time 1	Time 2	Time 1	Time 2	Time 1	Time 2
House	0.03	2.74	-	-	-	-	-	-
Noise barrier	0.01	0.99	0.01	0.01	2.7E-04	1.6E-07	0.12	0.07
Bridge o.p.	-	-	2.21	233	0.05	5.20	-	-

Table 2.22 Tier 2 PECs for tebuconazole from in-service leaching, taking into account biodegradation/dissipation

Scenario	Tier 2 PECsoil (mg/kg_{wwt})		Tier 2 PECwater (µg/L)		Tier 2 PECsediment (mg/kg_{wwt})		Tier 1 PECstp (µg/L)	
	Time 1	Time 2	Time 1	Time 2	Time 1	Time 2	Time 1	Time 2
House	0.02	0.06	-	-	-	-	-	-
Noise barrier	0.01	0.02	-	-	-	-	-	-
Bridge o.p.	-	-	1.75	2.64	0.05	0.27	-	-

The Time 2 PECs in the Bridge over Pond scenario are actually higher than the Tier 1 PECs. The explanation for this is that biodegradation/dissipation in surface water is quite slow.

PECs for cobalt

The ecotoxicity of cobalt borate neodecanoate can be assumed to be caused by the metal ion cobalt and hence, no biodegradation was assumed. Therefore, only tier 1 PECs were calculated, according to the ESD for wood preservatives and as described for tebuconazole. It was further assumed that 100 % cobalt is bioavailable.

For both industrial application (automated airless spraying with rotating brushes or flow coating) and in-service use (Noise Barrier), release to an STP is foreseen. As no adsorption data for cobalt borate neodecanoate is available, as a simplification and worst case, 100 % partitioning to the water phase is assumed.

Industrial application (automated spraying scenario acc. to ESD)

The PECs for automated spraying were calculated according to the ESD for wood preservatives. Details of the PEC calculations for cobalt can be found in Appendix 4d (Excel file), which is part of the Product Assessment Report for mutual recognition.

Table 2.23 Tier 1 PECs for cobalt from automated spraying

Scenario	Tier 1 PECwater (µg/L)	Tier 1 PECsediment (mg/kg_{wwt})	Tier 1 PECstp (µg/L)
Small plant	1.41	1.1E-03	14.1
Big plant	14.1	0.01	141

In-service use

The following leach rates are used for PEC calculations:

- Time 1 PECs (30 days) were calculated using the leach rate of 0.118 mg/m^2 day.
- Time 2 PECs (5 years) were calculated using the leach rate of 0.048 mg/m^2 day.

The Bridge over Pond scenario PECs were not calculated for cobalt, since risks were already identified for tebuconazole alone in this scenario (see chapter 2.8.3.1). Therefore, no mixture toxicity issues have been addressed for this scenario.

Details of the PEC calculations for cobalt can be found in Appendix 4d (Excel file), which is part of the Product Assessment Report for mutual recognition.

Table 2.24 Tier 1 PECs for cobalt from in-service leaching

Scenario	Tier 1 PECsoil (mg/kg$_{wwt}$)		Tier 1 PECwater (µg/L)		Tier 1 PECsediment (mg/kg$_{wwt}$)		Tier 1 PECstp (µg/L)	
	Time 1	Time 2	Time 1	Time 2	Time 1	Time 2	Time 1	Time 2
House	0.02	1.55	-	-	-	-	-	-
Noise barrier	0.01	0.58	0.01	0.01	1.1E-05	4.1E-09	0.13	0.05

2.8.3 Risk characterisation

2.8.3.1 Risk Characterisation of Tebuconazole in JIGV

Industrial application (automated spraying)

Table 2.25 PEC/PNEC ratios for tebuconazole from automated spraying (tier 1)

Scenario	PEC/PNEC Surface water	PEC/PNEC Sediment	PEC/PNEC STP
Small plant	0.20	< 0.01	< 0.01
Big plant	**1.97**	0.08	0.06

Based on the content of tebuconazole in Jotun Industri Grunning Visir, a risk to surface water was identified from application in big plants at Tier 1 (without taking into account biodegradation/adsorption). However, no treatment of the waste water before releasing it to a STP was taken into account.

No risk to surface water from the application in small plants was identified. No risks for STP or sediment were identified.

In-service use

Table 2.26 PEC/PNEC ratios for tebuconazole from in-service leaching, based on tier 2 PECs (see footnote for exception)

Scenario	PEC/PNEC Soil		PEC/PNEC Surface water		PEC/PNEC Sediment		PEC/PNEC STP	
	Time 1	Time 2	Time 1	Time 2	Time 1	Time 2	Time 1	Time 2
House	0.23	0.56	-	-	-	-	-	-
Noise barrier*	0.08	0.20	0.01	0.01	< 0.01	< 0.01	< 0.01	< 0.01
Bridge	-	-	**1.75**	**2.64**	0.09	0.49	-	-

* The PEC/PNEC ratios for the noise barrier scenario are based on tier 1 PECs for surface water, sediment and STP, and tier 2 PECs for soil.

The Time 2 PEC/PNEC ratios in the Bridge over Pond scenario are actually higher than the Tier 1 PEC/PNEC ratios. The explanation for this is that biodegradation/dissipation in surface water is quite slow.

Summary tebuconazole for Time 1:

- STP, surface water and sediment: No risk was identified for the Noise Barrier scenario in STP, surface water and sediment, even if PEC/PNEC ratios are based on Tier 1 concentrations (without biodegradation/dissipation). For Bridge over Pond (Tier 2) a risk to surface water was identified for Time 1, while for sediment, no risk was identified.
- Soil: No risk was identified for the Noise Barrier scenario in soil, even if PEC/PNEC ratios are based on Tier 1 concentrations. No risk was identified in soil for the House scenario based on Tier 2 results.

Summary tebuconazole for Time 2:

- STP, surface water and sediment: No risk was identified for the Noise Barrier scenario in STP, surface water and sediment, even if PEC/PNEC ratios are based on Tier 1 concentrations (without biodegradation/dissipation). For Bridge over Pond (Tier 2) a risk to surface water at Time 2 was identified, while for sediment, no risk was identified.
- Soil: At Time 2, no risk was identified for the Noise Barrier scenario in soil, even if PEC/PNEC ratios are based on Tier 1 concentrations. No risk was identified in soil for the House scenario based on Tier 2 results.

2.8.3.2 Risk characterisation of cobalt in JIGV

Industrial application (automated spraying)

Table 2.27 PEC/PNEC ratios for cobalt from automated spraying, based on tier 1 PECs

Scenario	PEC/PNEC Surface water	PEC/PNEC Sediment	PEC/PNEC STP
Small plant	**2.77**	5.3E-04	0.04
Big plant	**27.7**	0.01	0.38

Based on the content of cobalt in Jotun Industri Grunning Visir, risks to surface water were identified from application both in small and big plants. However, no treatment of the waste water before releasing it to a STP was taken into account. No risks for STP or sediment were identified.

In-service use

Table 2.28 PEC/PNEC ratios for cobalt from in-service leaching, based on tier 1 PECs

Scenario	PEC/PNEC Soil		PEC/PNEC Surface water		PEC/PNEC Sediment		PEC/PNEC STP	
	Time 1	Time 2	Time 1	Time 2	Time 1	Time 2	Time 1	Time 2
House	< 0.01	0.22	-	-	-	-	-	-
Noise barrier	< 0.01	0.08	0.03	0.01	< 0.01	< 0.01	< 0.01	< 0.01

Both at Time 1 and Time 2, no risks for STP, surface water, sediment and soil were identified for the Noise Barrier and House scenarios.

No risk characterisation for the Bridge over Pond scenario has been carried out for cobalt, since a risk to surface water for Time 1 and Time 2 was already identified for tebuconazole alone in this scenario.

2.8.3.3 Combined risk assessment of tebuconazole and cobalt

Industrial application (automated spraying)

As a risk was already identified for both tebuconazole (only big plant) and cobalt (big and small plant) alone, no combined risk assessment was performed.

In-service use

As a first tier PEC/PNEC ratios for tebuconazole and cobalt were summarized:

$$PEC/PNEC_{mixture} = PEC/PNEC_{tebuconazole} + PEC/PNEC_{cobalt}$$

For the Noise Barrier scenario the following PEC/PNEC ratios based on the combined risk assessment were calculated for STP, surface water, sediment and soil:

STP:	Time 1: < 0.01 Time 2: < 0.01
Surface water:	Time 1: 0.04 Time 2: 0.02
Sediment:	Time 1: < 0.01 Time 2: < 0.01
Soil:	Time 1: 0.08 Time 2: 0.28

No combined risk characterisation for the Bridge over Pond scenario has been carried out since a risk to surface water was already identified for tebuconazole alone.

For the House scenario the following combined PEC/PNEC ratios were calculated for soil:

- Time 1: 0.23
- Time 2: 0.79

2.8.3.4 Groundwater assessment

In the PT 8 Assessment Report for tebuconazole, it is explained that since tebuconazole has been shown to have a low mobility in soil, it is not expected to reach groundwater. The groundwater leaching potential was nevertheless evaluated for the service life of the wood, using the leaching model PEARL 3.3.3. The results show that tebuconazole is not expected to leach to groundwater in unacceptable amounts.

2.8.4 Summary of the Environmental Risk Assessment

The environmental risk assessment has been carried out for industrial application by automated airless spraying with rotating brushes or flow coating as well as for the Use Class 3 scenarios Noise Barrier, House and Bridge over Pond. For calculation of environmental concentrations for Time 1 = 30 days and Time 2 = 15 years, leaching rates for samples without a topcoat have been used. A risk assessment has been carried out for tebuconazole and cobalt (cobalt borate neodecaonate is a substance of concern with respect to environment).

Regarding the industrial application (automated airless spray with rotating brushes or flow coating), risks to surface water were identified both for tebuconazole (big plant) and cobalt (both for small and big plants). No treatment of the waste / washing water before release to a STP has been taken into account in the calculations. To reduce this risk, waste water, including cleaning water, has to be treated before releasing it to a municipal STP. Regarding tebuconazole the daily load from a big treatment plant to facility drain has to be reduced by about 50 % by using suitable treatment methods (e.g. flocculation) in order to reduce the PEC/PNEC ratio to below 1. For cobalt, the daily loads from big and small treatment plants has to be reduced by approximately 66 % and 96 %, respectively, in order to reduce the PEC/PNEC ratio to below 1.

For the service life phase, safe use has been identified with respect to PEC/PNEC ratios based on mixture toxicity:

- In STP, surface water and sediment from Noise Barrier use (Time 1 and 2)
- In soil from the House scenario and the Noise Barrier scenario (Time 1 and 2)

No combined risk characterisation for the Bridge over Pond scenario has been carried out since a risk to surface water for Time 1 and Time 2 was already identified for tebuconazole alone.

Regarding groundwater, no risk is anticipated.

The following risk mitigation measures have to be in place to remove the identified risks to surface water and soil:

(i) Waste water, including cleaning water from the industrial application sites must be treated appropriately in order to prevent unacceptable amounts of tebuconazole and cobalt from entering a facility drain.
(ii) It has to be ensured that during storage of treated wood, no emissions to the environment occur.
(iii) Not to be used on materials intended to be used near surface water or in direct contact with water and/or soil.

2.9 Measures to Protect Man, Animals and the Environment

Handling and storage:

Store in accordance with local regulations.

Notes on joint storage: Keep away from: oxidising agents, strong alkalis, strong acids.

Additional information on storage conditions: Observe label precautions. Store in a dry, cool and well-ventilated area. Keep container tightly closed.

Prevent unauthorised access. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

Avoid contact with skin and eyes.

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Use appropriate personal protective equipment. Never use pressure to empty container. Container is not a pressure vessel. Always keep in containers made from the same material as the original one.

Comply with laws and regulations regulating health and safety at work.

Do not allow the product to enter drains or watercourses.

Transport:

Transport within user's premises: 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.

This preparation is not classified as dangerous according to international transport regulations (ADR/RID, IMDG or ICAO/IATA).

Fire:

Extinguishing media: Recommended: alcohol-resistant foam, CO_2, powders, water spray.

Extinguishing media not to be used: Do not use water jet.

Recommendations: 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.

Emergency measures in case of an accident:

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. Seek immediate medical attention.

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

Environmental precautions:

The product is classified as dangerous according to Directive 1999/45/EC and its amendments. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Do not allow to enter drains or watercourses.

Methods of cleaning up:

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. Preferably clean with a detergent. Avoid using solvents.

Disposal:

Do not allow to enter drains or watercourses. Material and/or container must be disposed of as hazardous waste. European waste catalogue (EWC) code: 08 01 11.

If this product is mixed with other wastes, the appropriate code should be assigned. For further information contact your local waste authority.

3 Proposal for decision

The evaluation has shown that sufficient data have been provided concerning the evaluation of the application for product authorisation for the product Jotun Industri Grunning Visir. The authorisation of the product Jotun Industri Grunning Visir as wood preservative is therefore granted with the use conditions and restrictions outlined in chapter 3.1.The registration number is NO-2011-0005.

Jotun Industri Grunning Visir contains cobalt borate neodecaonate complexes as a substance of concern for the environment. The applicant has committed to replacing this substance by another siccative having more favourable environmental properties (and at the same time no detrimental human health properties) as soon as the technical challenges related to this substitution are solved. A proposal for changes to the existing authorisation for Jotun Industri Grunning Visir will then be sent to the Norwegian Competent Authority.

3.1 Summary of Use Conditions and Restrictions for Jotun Industri Grunning Visir

Jotun Industri Grunning Visir shall be authorised with the following use conditions and restrictions. These will be indicated on the product label/technical datasheet/safety data sheet:

(i) Authorised for industrial use only.

(ii) Application method: Industrially by automated airless spray with rotating brushes or flow coating, in both cases in closed chambers.

(iii) Waste water, including cleaning water from the industrial application sites, must be treated appropriately in order to prevent unacceptable amounts of tebuconazole and cobalt from entering a facility drain.

(iv) It has to be ensured that during storage of treated wood no emissions to the environment occur.

(v) Product should be kept at temperatures above 5°C during transport and storage.

(vi) For treatment of materials intended to be used outdoor in Use Class 3

(vii) The maximum level of the active ingredient tebuconazole in the product is 0.60 % w/w

(viii) The maximum application rate is 8 m^2/L (0.83 g tebuconazole /m^2 corresponding to 0.125 L or 0.138 kg product /m^2)

(ix) To comply with the efficacy claim, a topcoat has to be applied. The topcoat should be applied within two months after set-up of treated wood. For treated wood used outdoor in wintertime with temperatures below freezing point the topcoat should be applied in spring.

(x) Appropriate and suitable PPE (coverall and gloves) has to be used by operators.

(xi) When performing tasks where an elevated risk of contamination of hands/clothes is likely (manual loading, washing of equipment) extra protective clothing should be used (impermeable coverall/apron and chemically resistant gloves).

(xii) Contaminated and damaged gloves should be replaced and spillage on hands should be washed off.

(xiii) Treated materials should not be placed on market until it is dry.

(xiv) Not to be used on materials intended to come in direct contact with food or feeding stuff.

(xv) Not to be used on materials intended to be used near surface water or in direct contact with water and/or soil.

(xvi) Do not allow to enter drains or watercourses. Material and/or container must be disposed of as hazardous waste.

3.2 Necessary Issues Accounted for in the Product Label

In addition to the use conditions and restrictions outlined in chapter 3.1 the product will be labelled according to 1999/45/EC:

(i) R52/53 Harmful to aquatic organisms, may cause long term adverse effects in the aquatic environment

(ii) S23 Do not breathe vapour/spray

(iii) Contains 3-iodo-2-propynyl-butylcarbamate and cobalt borate neodecanoate complexes. May produce an allergic reaction

3.3 Requirement for Further Information

Results of the two-year storage stability of Jotun Industri Grunning Visir in steel containers will be submitted in spring 2012. Before the product can be marketed in PP/PE containers an accelerated storage stability study of Jotun Industri Grunning Visir in PP/PPE has to be submitted. Moreover, new efficacy testing of Jotun Industri Grunning Visir will have to be required in case of a re-formulation involving changes in use of film preservative.

Norwegian Competent Authority

December 2011

Appendix 1 – Reference list

Author(s)	Year	Title	Data protection claimed	Owner
Allan, G. and Balloch, S.	Initiated in 2009	Two Year Storage Stability, Accelerated Storage Stability and Physical Chemistry Testing on Jotun Industri Grunning Visir. Charles River Tranent Edinburgh EH33 2NE UK. Test Facility Study No. 215361 Report No. 30708. Sponsor's Ref. No. BIO1308	Yes	Jotun A/S
Balloch, S.	2009	Validation of Methodology for Tebuconazole, Propiconazole, Thiachloprid and Iodocarb Determination in Paint Formulations. Charles River Final Report, Test Facility Study No 215335, Report No 30381, Sponsors Ref No BIO 1308	Yes	Jotun A/S
Balloch, S.	2010	Validation of Methodology for Tebuconazole, Propiconazole, Thiachloprid and Iodocoarb Determination in Paint Formulations. Charles River Tranent Edinburgh EH33 2NE UK. Test Facility Study No. 215335-F2 Report No. 30381 Sponsor's Ref. No. BIO1308 Report Amendment 1	Yes	Jotun A/S
European Chemicals Agency (ECHA)	2011	ECHA CHEM, Information on Registered Substances: http://apps.echa.europa.eu/registered/registered-sub.aspx	No	Public
European Chemicals Bureau (ECB)	2002	Technical Notes for Guidance. Human Exposure to biocidal products. Guidance on exposure estimation. Published.	No	Public
European Chemicals Bureau (ECB)	2003	TGD: Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market", Part II, EUR 20418 EN/2.	No	Public
European Chemicals Bureau (ECB)	2004	Technical Notes for Guidance on human exposure to Biocidal products (June 2002), User Guidance version 1. Guidance on exposure estimation. Published.	No	Public
European Chemicals Bureau (ECB)	2007	Technical Notes for Guidance. Human Exposure to biocidal products. (Version 2, June 2007). Guidance on exposure estimation. Published.	No	Public
European	2009	TNsG on Annex I inclusion, revision of chapter	No	Public

Author(s)	Year	Title	Data protection claimed	Owner
Chemicals Bureau (Ex-ECB)		4.1, Quantitative Human Health Risk		
Ex-European Chemicals Bureau (Ex-ECB)	2011	Manual of Technical Agreements (MOTA) Biocides Technical Meeting Version 4; 2011. Published (available on the JRC-IHCP web site: http://ihcp.jrc.ec.europa.eu/)	No	Public
European Commission	2000	Technical Notes for Guidance on Data Requirements for active substances and biocidal products in: Technical Notes for guidance in support of Directive 98/8/EC concerning the placing of biocidal products on the market	No	Public
European Commission	2007	Assessment Report for Tebuconazole (published 2008), available from the CIRCA database (Communication & Information Resource Centre Administrator), Group "Biocides Public - Directive 98/8/EC on the placing of biocidal products on the market": http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/assessement_directive&vm=detailed&sb=Title	No	Public
European Commission	2008	Assessment Report IPBC, available from the CIRCA database (Communication & Information Resource Centre Administrator), Group "Biocides Public - Directive 98/8/EC on the placing of biocidal products on the market": http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/assessement_directive&vm=detailed&sb=Title	No	Public
FOCUS	2006	Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0.	No	Public
Garrod A.N.I., Martinez M., Pearson J., Proud A., Rimmer D.A.	1999	Exposure to preservatives used in the industrial pre-treatment of timber. Annals of Occupational Hygiene 43(8) 543-555.Proposal for decision	No	Public
Gijsbers J.H.J., Tielemans E., Brouwer D.H., Van Hemmen J.J.	2004	Dermal Exposure During Filling, loading and Brushing with Products containing 2-(2-Butoxyethoxy)ethanol Annals of Occupational Hygiene (48) 219-228	No	Public
Human Exposure Expert	2008a	HEEG Opinion on the assessment of Potential & Actual Hand Exposure, 07/04/2008,	No	Public

Author(s)	Year	Title	Data protection claimed	Owner
Group (HEEG)		Agreed at the Biocides Technical Meeting in March 2008		
Human Exposure Expert Group (HEEG)	2008b	HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale. 06/04/2008 Agreed at the Biocides Technical Meeting in March 2008	No	Public
HEEG Human Exposure Expert Group	2009	HEEG opinion on defaults and appropriate models to assess human exposure for dipping processes (PT8). 02/09/2009 HEEG proposal for TMIII09.	No	Public
HEEG Human Exposure Expert Group	2010	HEEG opinion on default protection factors for protective clothing and gloves, Agreed at TMI2010. Published	No	Public
Klamer, M. and Venås, T. M.	2011	Leaching of IPBC, Tebuconazole and Propiconazole from wood treated with Jotun Industri Grunning Visir (Waterborne) SF 2202-6 - One year of Exposure. Danish Technological Institute, Project no 1900026, order no. 354846-4	Yes	Jotun A/S
Klamer, M. and Venås, T. M.	2011	Leaching of Cobalt from wood treated with Jotun Industri Grunning Visir (Waterborne) SF 2202-6 – One year of Exposure. Danish Technological Institute, Project no 1900026, Order no 345846-4A	Yes	Jotun A/S
Lindegaard, B. and Morsing, E.	2009	Test Report Jotun Industri Grunning Visir DTI Danish Technological Institute, Lab. report no: Proj. No 1006657-17, Order No. 319962-D	Yes	Jotun A/S
Nordic Innovation Centre	2005	Nordtest Method NT Build 509, ISSN: 1459—2762, Project 04202 (1582-02)	No	Public
Organisation for Economic Co-operation and Development (OECD)	2003	OECD Series on Emission Scenario Documents, Number 2 – Emission Scenario Document for Wood Preservatives, Part 1-4.	No	Public
Organisation for Economic Co-operation and Development (OECD)	2009	OECD guideline; series on Testing and Assessment No. 107 (2009), “OECD Guidance on the Estimation of Emissions from Wood Preservative-Treated Wood to the Environment: for Wood held in Storage after Treatment and for Wooden Commodities that are not covered and are not in Contact with Ground”, ENV/JM/MONO(2009)12	No	Public
Plarre, R.	2010	Test report Jotun Industri Grunning Visir	Yes	Jotun

Author(s)	Year	Title	Data protection claimed	Owner
		SF2202-7 DIN EN 113:1996 Wood preservativs. Test method for determining the protective effectiveness against wood destroying basidiomycetes. Determination of Toxic values in combination with DIN EN 84: 1997 Wood preservatives. Accelerated ageing of treated wood prior to biological testing. Leaching procedure. BAM Bundesanstalt für Materialforschung und –prüfung, Lab. report no.: IV.1/8318 Ba A.		A/S
Toner, F.	2006	The In vitro Percutaneous Absorption of Radiolabelled Tebuconazole in Two Wood Protection Formulations through Human Skin. Included in the Competent Autority Report on Tebuzonazole from December 2007, Document IIIB, section B6.4	Yes	Lanxess

Appendix 2 – Documents III-B

Section B4 Analytical methods for detection and identification

Annex Point IIB IV.4.1

B4.1-01	**1 REFERENCE**	**Official use only**
1.1 Reference	**Charles River Final Report, Test Facility Study No 215335, Report No 30381, Sponsors Ref No BIO 1308 and Amendment 1** **Validation of Methodology for Tebuconazole, Propiconazole, Thiachloprid and Iodocarb Determination in Paint Formulations**	
1.2 Data Protection	Yes	
1.2.1 Data owner	Jotun AS	
1.2.2 Companies with letter of access	Scanox AS	
1.2.3. Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	There are no specific guidelines for studies of this nature, however the method validation will be used to support an registration under the Biocidal Product Directive 98/8/EC. The method was validated to meet the acceptance criteria of the EEC working document SANCO/3029/99 rev.4 (11/07/00), Doc IVB 2,3	
2.2 GLP	Yes	
2.3 Deviations	None	
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment	Aliquots of the biocidal products were accurately weighed in triplicate (*ca* 1 g) into plastic centrifuge tubes. A measured amount of internal standard was added and the sample was then diluted using the mobile phase. Sample tubes were shaken manually for *ca* 10 seconds, vortex mixed for *ca* 30 seconds, then sonicated for 10 minutes followed by centrifugation for 5 minutes at 4500 rpm. An aliquot of supernatant of each sample was taken for analysis. Routine samples were supported with double and single blank samples of the same formulation in addition to quality control samples prepared in triplicate. The following reagents were used during the study. Chemicals were of analytical grade unless otherwise stated: MilliQ Water In House Charles River Acetonitrile HPLC Grade Rathburn Chemicals Glacial Acetic Acid Analytical Grade Fisher The following equipment was used throughout the study: Balance: Mettler Toledo AE100	

Section B4 Analytical methods for detection and identification

Annex Point IIB IV.4.1

	Pipettes: Gilson Microman Vortex mixer: IKA MS3 Basic Centrifuge: Jouan GR422 Sonic Bath: Decon F5400b Filters: Acrodisc CR 25mm syringe filter with 0.2 µm PTFE membrane.	
3.2 Detection	The following conditions have been established using a Waters Alliance 2695 chromatograph with a Waters 486 Tunable detector. Chromatographic conditions may be changed to obtain satisfactory performance with other instruments provided adequate resolution and sensitivity are achieved. HPLC: Waters Alliance 2695 with Waters 486 Tunable detector Column: Zorbax RX-C8, 250 x 4.6 mm, 5 µm Injection Volume: 5 µL Mobile Phase: 50:50 (v/v) 0.5% Acetic Acid (aq.) / Acetonitrile Flow Rate: 1.0 mL/min Temperature: Ambient Detection: u.v. at 225 nm Run Time: 30 min Retention Times: Tebuconazole at ca 12.6 min Penconazole at ca 15.5 min Data Handling: Thermo LabSystems Atlas 2002, Release 1 Quantification: Penconazole supplied by Dr. Ehrenstorfer was used as internal standard (purity 99.2%) to quantify the active ingredient.	x
3.3 Linearity	The system responses for tebuconazole (peak area ratio with internal standard) were evaluated and found to fit a linear model over the range 100 to 300 µg/mL (0.1 to 0.3 % w/w equivalent). Calibration curves were constructed by plotting the analyte peak area ratio (analyte peak area divided by internal standard peak area) against the analyte concentration. Determined concentrations of standard solutions were obtained from the curve using least squares linear regression analysis with no weighting factor. Linearity was deemed to be acceptable as correlation coefficients were found to be 0.9999 for tebuconazole. As the concentration of tebuconazole was expected to be outwith the linear range, the sample was diluted appropriately in mobile phase.	
3.4.Specifity interfering substances	No substances interfering with analyses of tebuconazole	

3.5 Recovery rates at different levels

Table 5 Assay Accuracy and Precision: Tebuconazole in Jotun Industri Grunning Visir 2 – Method No. 1533A

Nominal Concentration (µg/mL)	Equivalent Concentration (% w/w)	Determined Concentration (µg/mL)	Recovery (%)	Mean Recovery (%)	Coefficient of Variation (%)
149	0.15	143 151 148	96.0 101.3 99.3	98.9	2.7
250	0.25	264 251 252	105.6 100.4 100.8	102.3	2.8

Overall mean recovery = 100.6%
Overall coefficient of variation = 3.1%

3.6 Limit of determination

LOD is not relevant for the determination of the active component(s) in the formulations.

3.7 Precision

Assay Accuracy and Precision

The assay accuracy and precision, as measured by the coefficient of variation (CV) was performed at approximately 0.15 % w/w equivalent (n=3) and 0.25 % w/w equivalent (n=3) tebuconazole in blank (fungicide free) paint formulation.

System Precision

System precision was determined by analysing a standard containing tebuconazole at a fixed concentration 10 times according to the conditions described in Charles River Method No. 1533A.
The coefficient of variation (CV) value was 0.1% for tebuconazole.

Table 11 System Precision: Tebuconazole – Method No. 1533A

Nominal Concentration (µg/mL)	Equivalent Concentration (% w/w)	Measured Peak Area Ratio	Mean Measured Peak Area Ratio	Coefficient of Variation (%)
197	0.200	1.3752 1.3734 1.3731 1.3747 1.3764 1.3722 1.3701 1.3748 1.3744 1.3715	1.3736	0.1

4 APPLICANT'S SUMMARY AND CONCLUSION

The test was performed by a GLP facility, the studies fulfil the aim of the guideline and no flaws which may have affected the quality or integrity of the study have been noted.

4.1 Materials and methods

Samples of Jotun Industri Grunning Visir were assayed for active ingredient content by addition of internal standard solution and mobile phase followed by HPLC with u.v. detection.

A validated analytical method for the analysis of tebuconazole in Jotun Industri Grunning Visir was required. The method was validated with respect to linearity of response, system suitability, assay accuracy and precision, system precision and specificity.

Fungicide free Jotun Industri Grunning Visir 2 formulation was received from the sponsor on 20 May 2009. It had a various appearance and was stored in a sealed container under ambient and dark conditions for the duration of the study.

4.2 Conclusion	As there are no specific guidelines for studies of this nature the method validation will be used to support a registration under the Biocidal Product Directive 98/8/EC. The method was validated to meet the acceptance criteria of the EEC working document SANCO/3029/99 rev.4 (11/07/00), Doc IVB 2,3. The chromatographic system employed was suitable in terms of column efficiency, tailing factor, resolution ratio, linearity of response, system precision, assay accuracy and precision and specificity of assay for tebuconazole in the formulation. Linearity was established for tebuconazole at 0.1 to 0.3 % w/w equivalents in the formulation. The analytical methods were acceptable in terms of column efficiency, calculated tailing factor and resolution ratio. Variability in the system was assessed by calculating the coefficient of variance between repeat injections. CV values were sufficiently low to meet the specification set out in the study protocol. The accuracy and precision (coefficient of variance, CV) of each method was assessed and found to be acceptable for the analyte in the formulation. An assessment was made of the specificity of the analyte in the formulation. This was confirmed by the absence of interfering peaks at the identified retention time of the analyte in blank formulations.
4.2.1 Reliability	1, reliable without restrictions.
4.2.2. Deficiencies	None

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	26 August 2011
Material and methods	**Comment (3.2):** Generally, the use of UV detection with low wavelength is not ideal for the identification of the active substance due to interferences. However, for tebuconazole, interferences were low and quantification was acceptable.
Conclusion	Agree with applicant's version.
Reliability	1, reliable without restrictions
Acceptability	Acceptable
Remarks	-

Section B5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)			Official use only
5.1	**Product type(s) and field(s) of use envisaged (IIB5.1)**	Jotun Industri Grunning Visir is a water repellent primer for wood protection (PT8). Jotun Industri Grunning Visir is used for protection of exterior wood surfaces like house cladding and fences (use class 3). Industrial application in closed system by spraying or dipping.	x
5.1.1	**Product type(s)**	Preservatives Product type PT08	
5.1.2	**Overall use pattern**	Industrial application in closed system by spraying or dipping once in a claddings life time.	
5.2	**Method of application including description of system used (IIB5.2)**	Ready to use. Industrial application in closed system by spraying and dipping. Assembled cladding should be treated with preferred paint system within 3 months.	x
5.3	**Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used.**	One litre of the product covers 8-11 m^2 of wood depending on properties of the wooden surface. The concentration of the active substance tebuconazole is 0,6% corresponding to 0,6-0,83g/m^2.	x
5.4	**Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals (IIB5.4)**	Only one coat (application). Assembled cladding should be treated with preferred paint system as soon as possible and within 3 months.	x
5.5	**Function (IIB5.5)**	Wood preservative, PT 8 for use class 3. The product is a water repellent primer against wood rot. It binds loose wooden fibres and insures good adhesion for further surface treatment. The product is also containing chemicals or pigments to protect the wood from the adverse effects of UV-light. The product is a necessity to provide long life time of the paint system.	
5.6	**Pest organism(s) to be controlled and products, organisms or objects to be protected**		

Section B5		**Effectiveness against target organisms and intended uses**	
	(IIB5.6)		
5.6.1	**Pest organism(s) to be controlled**	Protection of wood against wood destroying fungi (Basidiomycetes).	
5.6.2	**Products, organisms or objects to be protected**	Jotun Industri Grunning Visir is used for protection of exterior wood surfaces like house cladding and fences (use class 3). Protects wood from wood-destroying fungi.	
5.7	**Effects on target organisms (IIB5.7)**	Inhibits fungal growth by interfering with the ergosterol biosynthesis in the fungal cell membrane.	
5.8	**Mode of action (including time delay) in so far as not covered by section A5.4 (IIB5.8)**	Ref: LoA tebuconazole, Lanxess in Confidential folder. Ref. dossier of tebuconazole.	
5.9	**User: industrial, professsional, general public (non-professional) (IIB5.9)**		
	1. Industrial	Industrial application in closed system by spraying or dipping.	x
	2. Professional	n.a.	
	3. General public	n.a.	
5.10	**Efficacy data: The proposed label claims for the product and efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate (IIB5.10)**		
5.10.1	**Proposed label claims for the product**	Primer for wood protection	
5.10.2	**Efficacy data**	Protective effectiveness against wood destroying basidiomycetes: From the efficacy studies performed the mean toxic value for Jotun Industri Grunning Visir is 136,8 g/m^2. This corresponds to 0,56g/m^2 tebuconazole as the concentration of a.i tebuconazole was analysed to be 0,41% in the formulation tested. The efficacy studies show that 0,56g/m^2 tebuconazole is needed to give adequate protection against wood destroying basidiomycetes. **This corresponds to 93,3 g/m^2 of Jotun Industri Grunning Visir containing 0,6% a.i tebuconazole.**	x
5.11	**Any other known limitations on efficacy including resistance (IIB5.10)**	Resistance against tebuconazole for wood preservation is not reported or known up to the time being. More detailed information regarding the active ingredient can be found in the active ingredient dossier.	
5.11.1	**Use-related restrictions**	None	
5.11.2	**Prevention of the development of resistance**	None	
5.11.3	**Concomittant use with other (biocidal)**	Stand alone product. No data available on mixtures with other substances or biocidal products.	

Section B5 Effectiveness against target organisms and intended uses

products

Table A5-1: Summary table of data on the method of application including description of system used

Serial number	Product type	Substance(s) used for dilution	Concentration of dilutant(s)	Other substance(s) added	Application technique	Remarks
	PT 8	Not applicable	Not applicable	Not applicable	Industrial application in closed system by spraying or dipping	-

Table A5-2: Summary table of data on the number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals

Serial number	Product type	Application type	Number and timing of application	Waiting periods	Information on recommended variations of the application rate in different locations	Remarks
	PT 8	Industrial	Only one coat.	Not applicable	Not applicable	-

Evaluation by Competent Authority	
Date	7 Mars 2011
Comments	**Comment (5.1, 5.2 and 5.9):** The application mode is airless spray with rotating brushes or flow coating not dipping. **Comment (5.3):** The nominal concentration in the product is 0.6 %, However, the tested product was analysed to contain only 0.41 % tebuconazole. **Comment (5.2 and 5.4):** According to the label and technical data sheet a topcoat has to be applied within two months. For treated wood used outdoor in wintertime with temperatures below freezing point the topcoat should be applied in spring. **Comment (5.10.2):** The EN113 tests were run only with one retention (g/m^3) corresponding to an application rate of 136.8 g/m^2 and this retention passes the criteria for all three fungi tested. This concentration cannot be regarded as an indication for a mean toxic value as only one retention was tested. However, the corresponding uptake of tebuconazole is comparable to the mean toxic values found in efficacy tests submitted with the active substances dossier for tebuconazole. The mean toxic value is thus below the tested uptake of 136.8 g/m^2 corresponding to 0.56 g/m^2 tebuconazole based on the measured concentration (0.41 %).
Summary and conclusion	The submitted data are based on studies were the product was applied by penetration treatment (EN 113), while the products in practice is to be applied by surface treatment (brushing) together with a topcoat. However, the standard EN 599-1:2009 prescribe in § 5.2.15 that for products to be applied by surface treatment with a topcoat a factor could be used to find toxic values for the corresponding surface application rate. This has been done in this case. The studies submitted for Jotun Industri Grunning Visir indicate that the product will have sufficient efficacy to be used as a Use Class 3 wood preservative if treated with a topcoat as prescribed on the instruction for use (label).

Section B5.10 **Annex Point IIB5.10** **TNsG: Pt. I-B5.10,** **Pt. III-Ch. 6**	**Efficacy Data** **Wood rotting fungi, laboratory study EN 113 in combination with EN 84.**	**Official use only**
	1 REFERENCE	
1.1 Reference	**Author:** Dr. R. Plarre **Year:** 2010 **Title:** Test report Jotun Industri Grunning Visir SF2202-7 DIN EN 113:1996 Wood preservativs. Test method for determining the protective effectiveness against wood destroying basidiomycetes. Determination of Toxic values in combination with DIN EN 84: 1997 Wood preservatives. Accelerated ageing of treated wood prior to biological testing. Leaching procedure. **Lab. name:** BAM Bundesanstalt für Materialforschung und -prüfung **Lab. report no**:IV.1/8318 Ba A **Report date:** 2010-11-03	X
1.2 Data protection	Yes	
1.2.1 Data owner	Jotun AS	
1.2.2 Companies with letter of access	Scanox	
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation	
1.3 Guideline study	EN 113 Wood preservatives. Test method for determining the protective effectiveness against wood destroying basidiomycetes. Determination of Toxic values.	
1.4 Deviations	No	
	2 METHOD	
2.1 Test Substance (Biocidal Product)		
2.1.1 Trade name/ proposed trade name	Jotun Industri Grunning Visir	
2.1.2 Composition of Product tested	Ref formulation in Confidential Folder. A.i. tebuconazole 0,6 %. The formulation also contained 0,3% of Film preservative IPBC (PT7).	
2.1.3 Physical state and nature	Liquid	
2.1.4 Monitoring of active substance concentration	Yes, Analysis report IV.1/8318 Ch. The concentration of a.i tebuconazole was analysed to be 0,41%.	

Section B5.10 **Annex Point IIB5.10** **TNsG: Pt. I-B5.10,** **Pt. III-Ch. 6**	**Efficacy Data** **Wood rotting fungi, laboratory study EN 113 in combination with EN 84.**	
2.1.5 Method of analysis	Quantitative determination of tebuconazole according to BAM- test procedures (LC/MS).	
2.2 Reference substance	No	
2.2.1 Method of analysis for reference substance	Not applicable	
2.3 Testing procedure		
2.3.1 Test population / inoculum / test organism	Test organisms, according to EN 113: *Coniophora puteana* BAM Eb.w.. 15, *Poria placenta* FPRL 280, *Gloeophyllum trabeum* BAM Eb.w.. 109. See table 1.2 below.	
2.3.2 Test system	See Table 1.3 below	X
2.3.3 Application of TS	See Table 1.4 below	
2.3.4 Test conditions	See Table 1.5 below	
2.3.5 Duration of the test / Exposure time	According to EN 113 and EN 84. 16 weeks exposure to fungi	
2.3.6 Number of replicates performed	5 replicates for each concentration of biocidal product per fungus	X
2.3.7 Controls	Yes; Untreated control specimens equal in number to the treated test specimens (5 for each concentration of biocidal product per fungus) 6 untreated virulence control specimens for each fungus. 4 treated controls for each concentration of biocidal product, treated in the same way as the test specimens but not exposed to fungi.	X
2.4 Examination		
2.4.1 Effect investigated	As specified in EN 113: Effectiveness of wood preservative against wood destroying basidiomycetes is determined by difference in mass loss for treated and untreated specimens after attack by fungi.	
2.4.2 Method for recording / scoring of the effect	As specified in EN 113: Initial dry mass (m0) is recorded before the samples are subjected to attack by fungi. After 16 weeks of exposure to fungal attack the test specimens are weighed (m2) before the samples are owen dried and final dry mass (m3) is measured. Mass loss is calculated by expressing the loss in mass (m0 – m3) as a percentage of initial dry mass.	
2.4.3 Intervals of examination	As specified in EN 113: 1 examination after 16 weeks of exposure.	
2.4.4 Statistics	Calculations according to EN 113.	

Section B5.10 **Annex Point IIB5.10** **TNsG: Pt. I-B5.10,** **Pt. III-Ch. 6**	**Efficacy Data** **Wood rotting fungi, laboratory study EN 113 in combination with EN 84.**	
2.4.5 Post monitoring of the test organism	None	
	3 RESULTS	
3.1 Efficacy	Pass/fail criteria: The protection provided for the wood by the test preservative at a given concentration is deemed to be adequate if the corrected mean mass loss of the specimens is less than 3,0% (m/m) of initial dry mass and not more than one specimen has suffered a loss in mass greater than 3,0% but less than 5,0% independent on the number of valid replicates.	
3.1.1 Dose/Efficacy curve	N.a.	
3.1.2 Begin and duration of effects	N.a.	
3.1.3 Observed effects in the post monitoring phase	No post monitoring phase.	
3.2 Effects against organisms or objects to be protected	No adverse effects observed.	
3.3 Other effects	No other effects observed	
3.4 Efficacy of the reference substance	N.a.	
3.5 Tabular and/or graphical presentation of the summarised results	The formulation containing 0,41% tebuconazole provides adequate protection for wood at a mean load of 136,6 g/m^2 (*Ref §5.2.15 in EN 599-1:2009)	X
3.6 Efficacy limiting factors		
3.6.1 Occurrences of resistances	Resistance against the active used in Jotun Industri Grunning Visir for wood preservation is not reported or known up to the time being. More detailed information regarding the active ingredient can be found in the active ingredient dossier.	
3.6.2 Other limiting factors	No other limiting factors.	

Test fungus	Mean retention of product	Mean mass loss	Critical value surface treatment*
C.puteana	67,5 kg/m^3	- 0,3%	135g/m^2
P.placenta	68,3 kg/m^3	- 0,7%	136,6 g/m^2
G.trabeum	67,7 kg/m^3	- 0,4%	135,4 g/m^2

		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	**Reasons for laboratory testing**	EN 113 is a validated standard laboratory test giving results within 16 weeks of exposure. A comparable field trial in Scandinavian climate would take 5-10 yrs including ageing. Conditions in the laboratory test are controlled while results from a field trial would differ from one exposure station to another depending on temperature, humidity and load of fungi. EN 113 has been in use for more than 30 yrs and the data produced is regarded relevant for its field of use. It is the recommended method for testing efficacy of preventive wood preservatives in the overlying standard EN 599-1.	
4.2	**Intended actual scale of biocide application**	One litre of Jotun Industri Grunning Visir covers 8-11 m^2 of wood depending on properties of the wooden surface. This corresponds to 100- 137 g/m^2 of the biocidal product and 0,60 – 0,82g/m^2 tebuconazole. The mean toxic value for Jotun Industri Grunning Visir from this study is 136,6 g/m^2. This corresponds to 0,56g/m^2 tebuconazole as the concentration of a.i tebuconazole was analysed to be 0,41% in the formulation tested.	
4.3	**Relevance compared to field conditions**		
4.3.1	Application method	The laboratory test is performed according to conditions described for superficial application products for use class 3 in EN 599-1 The application method in the laboratory test is by vacuum impregnation, while Jotun Industri Grunning Visir should be applied industrial by spraying or dipping.	
4.3.2	Test organism	Yes, the three fungal species used in EN 113 are representatives for the wood destroying basidiomycetes group.	
4.3.3	Observed effect	Yes, the observed effect in the laboratory test is comparable to the desired effects in field applications.	
4.4	**Relevance for read-across**	Yes, the test demonstrates efficacy which is applicable to both laboratory and field situations.	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Methods for testing of efficacy were chosen according to EN 599-1. Test specimens of Scots pine softwood was impregnated with test product. The samples was aged according to EN 84 leaching method and exposed to fungal attack for 16 weeks according to EN 113. After the fungal exposure the mass loss of each sample was calculated. The protection provided for the wood at a given concentration is deemed to be adequate if the mass loss of the specimens is less than 3,0% (m/m) of initial dry mass and not more than one specimen has suffered a loss in mass greater than 3,0% but less than 5,0% independent of the number of valid replicates. From this a toxic value of preservative, the lowest concentration in kg/m^3 deemed to be adequate for protection against wood destroying fungi, is expressed.	X

5.2	**Reliability**	The methods used are reliable and relevant for efficacy assessment.
5.3	**Assessment of efficacy, data analysis and interpretation**	A mean critical value below 136,6 g/m^2 for Jotun Industri Grunning Visir (containing 0,41% tebuconazole) corresponding to 0,56 g/m^2 tebuconazole corresponds well with expected efficacy as stated by the producers of the a.i.
5.4	**Conclusion**	The laboratory test is regarded valid and well suited to show efficacy of Jotun Industri Grunning Visir.
5.5	**Proposed efficacy specification**	The Critical value for Jotun Industri Grunning Visir containing 0,41% tebuconazole is below 136,6 g/m^2. This corresponds to 0,56 g/m^2 tebuconazole.

Evaluation by Competent Authority

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	7 Mars 2011
Comments	**Comment (1.1):** The title used here is not correct. In the test report (Doc IV) the description of the test is: "*Determination of toxic effect of one concentration."* This indicates that the toxic value is not determined, but the toxic effect of only one concentration. This title is thus not correct. **Comment (2.3.2):** See Tab 3.1 and comments on 2.3.6 and 2.3.7 regarding replicates **Comment (2.3.6):** Number of replicates performed: There are 6 replicates for the one concentration tested of the biocidal product per fungus **Comment (2.3.7):** Controls: 6 virulent replica and 6 control replica **Comments (3.5):** Tabular and/or graphical presentation of the summarised results: The reference to § 5.2.15 of the EN599-1 to calculate from uptake in kg/m3 in a penetration treatment to a corresponding application rate in g/m^2 for surface treatment with topcoat is correct. The factor to be used for calculation is: kg/m^3 equals 2 times g/m^2. **Comment (5.1)** Materials and methods**:** Only one concentration was tested.
Summary and conclusion	The results show that the product applied by penetrating treatment after aging according to EN 73 pass criteria for efficacy according to the criteria in EN599-1 The retention rate is comparable to the application rate to be used for surface treatment of Jotun Industri Grunning Visir according to the calculation method prescribed in EN599-1.

Section B5.10 **Annex Point IIB5.10** **TNsG: Pt. I-B5.10,** **Pt. III-Ch. 6**	**Efficacy Data** **Wood rotting fungi, laboratory study EN 113 in combination with EN 73.**

			Official use only
		1 REFERENCE	
1.1	**Reference**	**Author:** Dr. R. Plarre **Year:** 2010 **Title:** Test report Jotun Industri Grunning Visir DIN EN 113:1996 Wood preservatives. Test method for determining the protective effectiveness against wood destroying basidiomycetes. Determination of Toxic values in combination with DIN EN 73: 1990 Wood preservatives. Accelerated ageing tests of treated wood prior to biological testing – evaporative ageing procedure. **Lab. name:** BAM Bundesanstalt für Materialforschung und -prüfung **Lab. report no**:IV.1/8318 Ba B **Report date:** 2010-11-03	X
1.2	**Data protection**	Yes	
1.2.1	Data owner	Jotun AS	
1.2.2	Companies with letter of access	Scanox	
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation	
1.3	**Guideline study**	EN 113 Wood preservatives. Test method for determining the protective effectiveness against wood destroying basidiomycetes. Determination of Toxic values.	
1.4	**Deviations**	No	
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**		
2.1.1	Trade name/ proposed trade name	Jotun Industri Grunning Visir	
2.1.2	Composition of Product tested	Ref formulation in Confidential Folder. A.i. tebuconazole 0,6 %. The formulation also contained 0,3% of Film preservative IPBC (PT7).	
2.1.3	Physical state and nature	Liquid	
2.1.4	Monitoring of active substance concentration	Yes, Analysis report IV.1/8318 Ch. The concentration of a.i tebuconazole was analysed to be 0,41%.	

Section B5.10 **Annex Point IIB5.10** **TNsG: Pt. I-B5.10,** **Pt. III-Ch. 6**	**Efficacy Data** **Wood rotting fungi, laboratory study EN 113 in combination with EN 73.**	
2.1.5 Method of analysis	Quantitative determination of tebuconazol according to BAM- test procedures (LC/MS).	
2.2 Reference substance	No	
2.2.1 Method of analysis for reference substance	Not applicable	
2.3 Testing procedure		
2.3.1 Test population / inoculum / test organism	Test organisms, according to EN 113: *Coniophora puteana* BAM Eb.w.. 15, *Poria placenta* FPRL 280, *Gloeophyllum trabeum* BAM Eb.w.. 109. See table 1.2 below.	
2.3.2 Test system	See Table 1.3 below	X
2.3.3 Application of TS	See Table 1.4 below	
2.3.4 Test conditions	See Table 1.5 below	
2.3.5 Duration of the test / Exposure time	16 weeks exposure to fungi	
2.3.6 Number of replicates performed	5 replicates for each concentration of biocidal product per fungus	X
2.3.7 Controls	Yes; Untreated control specimens equal in number to the treated test specimens (5 for each concentration of biocidal product per fungus) 6 untreated virulence control specimens for each fungus. 4 treated controls for each concentration of biocidal product, treated in the same way as the test specimens but not exposed to fungi.	X
2.4 Examination		
2.4.1 Effect investigated	Effectiveness of wood preservative against wood destroying basidiomycetes is determined by difference in mass loss for treated and untreated specimens after attack by fungi.	
2.4.2 Method for recording / scoring of the effect	As specified in EN 113: Initial dry mass (m0) is recorded before the samples are subjected to attack by fungi. After 16 weeks of exposure to fungal attack the test specimens are weighed (m2) before the samples are owen dried and final dry mass (m3) is measured. Mass loss is calculated by expressing the loss in mass (m0 – m3) as a percentage of initial dry mass.	
2.4.3 Intervals of examination	As specified in EN 113: The test specimens are examined and weighed at the beginning of the test and after 16 weeks of exposure to fungi.	
2.4.4 Statistics	Calculations according to EN 113.	

Section B5.10 **Annex Point IIB5.10** **TNsG: Pt. I-B5.10,** **Pt. III-Ch. 6**	**Efficacy Data** **Wood rotting fungi, laboratory study EN 113 in combination with EN 73.**	
2.4.5 Post monitoring of the test organism	None	
	3 RESULTS	
3.1 Efficacy	Pass/fail criteria: The protection provided for the wood by the test preservative at a given concentration is deemed to be adequate if the corrected mean mass loss of the specimens is less than 3,0% (m/m) of initial dry mass and not more than one specimen has suffered a loss in mass greater than 3,0% but less than 5,0% independent on the number of valid replicates.	
3.1.1 Dose/Efficacy curve	N.a.	
3.1.2 Begin and duration of effects	N.a.	
3.1.3 Observed effects in the post monitoring phase	No post monitoring phase.	
3.2 Effects against organisms or objects to be protected	No adverse effects observed.	
3.3 Other effects	No other effects observed	
3.4 Efficacy of the reference substance	N.a.	
3.5 Tabular and/or graphical presentation of the summarised results	See table below	X
3.6 Efficacy limiting factors	*Non-entry field*	
3.6.1 Occurrences of resistances	Resistance against the active used in Jotun Industri Grunning Visir for wood preservation is not reported or known up to the time being. More detailed information regarding the active ingredient can be found in the active ingredient dossier.	
3.6.2 Other limiting factors	No other limiting factors.	

Test fungus	Mean retention of product	Mean mass loss	Critical value surface treatment*
C.puteana	68,4 kg/m^3	0,4 %	136,8g/m^2
P.placenta	67,8 kg/m^3	1,9 %	135,6 g/m^2
G.trabeum	67,7 kg/m^3	0,5 %	135,4 kg/m^3

The formulation containing 0,41% tebuconazole provides adequate protection for wood at a mean load of 136,8 g/m^2 (*Ref §5.2.15 in EN 599-1:2009).

		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	**Reasons for laboratory testing**	EN 113 is a validated standard laboratory test giving results within 16 weeks of exposure. A comparable field trial in Scandinavian climate would take 5-10 yrs including ageing. Conditions in the laboratory test are controlled while results from a field trial would differ from one exposure station to another depending on temperature, humidity and load of fungi. EN 113 has been in use for more than 30 yrs and the data produced is regarded relevant for its field of use. It is the recommended method for testing efficacy of preventive wood preservatives in the overlying standard EN 599-1.	
4.2	**Intended actual scale of biocide application**	One litre of Jotun Industri Grunning Visir covers 8-11 m^2 of wood depending on properties of the wooden surface. This corresponds to 100- 137 g/m^2 of the biocidal product and 0,60 – 0,83 g/m^2 tebuconazole. The mean toxic value for Jotun Industri Grunning Visir from this study is 136,8 g/m^2. This corresponds to 0,56g/m^2 tebuconazole as the concentration of a.i tebuconazole was analysed to be 0,41% in the formulation tested.	
4.3	**Relevance compared to field conditions**	*non-entry field*	
4.3.1	Application method	The laboratory test is performed according to conditions described for superficial application products for use class 3 in EN 599-1. The application method in the laboratory test is by vacuum impregnation, while Jotun Industri Grunning Visir should be applied by brushing or dipping.	
4.3.2	Test organism	Yes, the three fungal species used in EN 113 are representatives for the wood destroying basidiomycetes group.	
4.3.3	Observed effect	Yes, the observed effect in the laboratory test is comparable to the desired effects in field applications.	
4.4	**Relevance for read-across**	Yes, the test demonstrates efficacy which is applicable to both laboratory and field situations.	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Methods for testing of efficacy were chosen according to EN 599-1. The samples was aged according to EN 73 evaporative method and exposed to fungal attack for 16 weeks according to EN 113. After the fungal exposure the mass loss of each sample was calculated. The protection provided for the wood at a given concentration is deemed to be adequate if the mass loss of the specimens is less than 3,0% (m/m) of initial dry mass and not more than one specimen has suffered a loss in mass greater than 3,0% but less than 5,0% independent of the number of valid replicates. From this a toxic value of preservative, the lowest concentration in kg/m^3 deemed to be adequate for protection against wood destroying fungi, is expressed.	X
5.2	**Reliability**	The methods used are reliable and relevant for efficacy assessment.	

5.3 Assessment of efficacy, data analysis and interpretation	A mean critical value below 136,8 g/m^2 for Jotun Industri Grunning Visir (containing 0,41% tebuconazole) corresponding to 0,56 g/m^2 tebuconazole fits well with expected efficacy as stated by the producers of the a.i.
5.4 Conclusion	The laboratory test is regarded valid and well suited to show efficacy of Jotun Industri Grunning Visir.
5.5 Proposed efficacy specification	The Critical value for Jotun Industri Grunning Visir containing 0,41% tebuconazole is below 136,8 g/m^2. This corresponds to 0,56 g/m^2 tebuconazole.

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	7 Mars 2011
Comments	**Comment (1.1):** The title used here is not correct. In the test report (doc IV) the description of the test is: "*Determination of toxic effect of one concentration."* This indicates that the toxic value is not determined, but the toxic effect of only one concentration. This title is thus not correct **Comment (2.3.2):** See Tab 3.1 and comments on 2.3.6 and 2.3.7 regarding replicates **Comment (2.3.6):** Number of replicates performed: There are 6 replicates for the one concentration tested of the biocidal product per fungus **Comment (2.3.7):** Controls: 6 virulent replica and 6 control replica **Comments (3.5):** Tabular and/or graphical presentation of the summarised results: The reference to § 5.2.15 of the EN599-1 to calculate from uptake in kg/m^3 in a penetration treatment to a corresponding application rate in g/m^2 for surface treatment with topcoat is correct. The factor to be used for calculation is: kg/m^3 equals 2 times g/m^2. **Comment (5.1)** Materials and methods**:** Only one concentration was tested.
Summary and conclusion	The results show that the product applied by penetrating treatment after aging according to EN 73 pass criteria for efficacy according to the criteria in EN599-1 The retention rate is comparable to the application rate to be used for surface treatment of Jotun Industri Grunning Visir according to the calculation method prescribed in EN599-1.

Tables for Method

Table 1.2:Test organism

Criteria	**Details**
Species	*Coniophora puteana*
Strain	BAM Eb.w.. 15
Source	Unknown
Laboratory culture	yes
Stage of life cycle and stage of stadia	Cultures less than four weeks old and still actively growing across the medium. Fungi in active phase of development.
Mixed age population	No, see above
Other specification	Minimum 20% (m/m) loss in mass (%) in 16 weeks of Scots pine sapwood specimens
Number of organisms tested	Exposure takes place as soon as the mycelium completely covers the surface of the culture medium
Method of cultivation	Malt agar medium as specified in EN 113
Pretreatment of test organisms befor exposure	No
Initial density/number of test organisms in the test	n.a.
Criteria	**Details**
Species	*Poria placenta*
Strain	FPRL 280
Source	Unknown
Laboratory culture	yes
Stage of life cycle and stage of stadia	Cultures less than four weeks old and still actively growing across the medium. Fungi in active phase of development.
Mixed age population	No, see above
Other specification	Minimum 20% (m/m) loss in mass (%) in 16 weeks of Scots pine sapwood specimens
Number of organisms tested	Exposure takes place as soon as the mycelium completely covers the surface of the culture medium
Method of cultivation	Malt agar medium as specified in EN 113
Pretreatment of test organisms befor exposure	No
Initial density/number of test organisms in the test	n.a.

Criteria	**Details**
Species	*Gloeophyllum trabeum*
Strain	BAM Eb.w..109
Source	Unknown
Laboratory culture	yes
Stage of life cycle and stage of stadia	Cultures less than four weeks old and still actively growing across the medium. Fungi in active phase of development.
Mixed age population	No, see above
Other specification	Minimum 20% (m/m) loss in mass (%) in 16 weeks of Scots pine sapwood specimens
Number of organisms tested	Exposure takes place as soon as the mycelium completely covers the surface of the culture medium
Method of cultivation	Malt agar medium as specified in EN 113
Pretreatment of test organisms before exposure	No
Initial density/number of test organisms in the test system	n.a.

Table 1.3:Test system

Criteria	**Details**
Culturing apparatus / test chamber	Culture chamber, dark maintained at 22 +/- 2ºC and 70+/-5% relative humidity. Kolle flasks with capacity of between 400 ml and 650 ml providing a flat surface area of 85 -120 cm^2 for the medium and allowing air exchange.
Number of vessels / concentration	5 treated test specimens for each concentration of biocidal product for each fungus 6 untreated specimens for virulence control for each fungus Control specimens, equal in number to the treated specimens.
Test culture media and/or carrier material	Malt extract agar in Kolle flasks.
Nutrient supply	Malt extract agar
Measuring equipment	Laboratory scales with accuracy to the nearest 0,01g

Table 1.4:Application of test substance

Criteria	**Details**
Application procedure	The product is diluted to appropriate concentrations with water. The product is applied by vacuum impregnation according to EN 113.
Delivery method	The product is applied by vacuum impregnation according to EN 113.
Dosage rate	Concentration of product in test % (m/m): 9,03%
Carrier	N.a.
Concentration of liquid carrier	N.a.
Liquid carrier control	N.a.
Other procedures	Samples sterilized by ionizing radiation 60 Co-Quelle before exposure to fungi.

Table 1.5:Test conditions

Criteria	**Details**
Substrate	Scots pine sapwood
Incubation temperature	22 +/- 2ºC
Moisture	70+/-5% relative humidity
Aeration	No
Method of exposure	Individual samples
Aging of samples	Leaching according to EN 84 or EN 73.
Other conditions	None

Section B6 TOXICOLOGICAL STUDIES

			Official use only
Acute toxicity			
1.1.1	Oral	In order to minimise animal testing no toxicological studies have been performed on the product. The product is not hazardous according to Dir 1999/45/EC.	
1.1.2	Dermal	In order to minimise animal testing no toxicological studies have been performed on the product. The product is not hazardous according to Dir 1999/45/EC.	
1.1.3	Inhalation	In order to minimise animal testing no toxicological studies have been performed on the product. The product is not hazardous according to Dir 1999/45/EC.	
1.1.4	For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate	n.a.	
1.2	**Skin and eye irritation**	In order to minimise animal testing no toxicological studies have been performed on the product. The product is not hazardous according to Dir 1999/45/EC.	
1.3	**Skin sensitisation**	In order to minimise animal testing no toxicological studies have been performed on the product. The product is not hazardous according to Dir 1999/45/EC.	
1.4	**Information on dermal absorption**	Using a potentially absorbable dose of 3.3% tebuconazole in the risk assessment of Industri Grunning Visir as a worst case is justified based on *read-across* with Guide recipe JJT 3583. Ref waiving document on percutanous absorption in Confidential Folder in summary dossier.	
1.5	**Available toxicological relevant non-active substances (i.e. substance of concerne)**	There are no substances of concern regarding health in the product.	
1.6	**Information related to the exposure of the biocidal product**	Most relevant route of exposure is by dermal contact during brush application.	
1.7	**Further human health-related studies**		
1.7.1	Food and feedstuffs studies	n.a	

1.7.2	Other tests related to the exposure to humans	n.a

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13 September 2011
Comments on applicant's data	-
Conclusion	In order to minimise animal testing it is acceptable that no toxicological studies have been performed on the product. A dermal absorption of 100 % and 5 % tebuconazole (rounded off value due to the fact that Industri Grunning Visir differs somewhat from the tested guide recipe) have been used in the risk assessment of Industri Grunning Visir in tier I and II respectively.
Acceptability	Acceptable
Remarks	-

Section B7.1/01

Annex Point IIB7.1

OECD Guidance on the estimation of emissions from wood preservative. Laboratory study.

		Official use only
	1 REFERENCE	
1.1 Reference	**Author:** Berit Lindegaard and Elisabeth Morsing **Year:** 2009 **Title:** Test Report Jotun Industri Grunning Visir **Lab. name:** DTI Danish Technological Institute, **Lab. report no**: Proj. No 1006657-17, Order No. 319962-D **Report date:** 09-03-2010	
1.2 Data protection	Yes	
1.2.1 Data owner	Jotun AS	
1.2.2 Companies with Letters of Access	Scanox	
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	OECD Guidance on the estimation of emissions from wood preservative- Treated wood to the environment: for wood held in storage after treatment and for wooden commodities that are not covered and are not in contact with ground: November 2008. The 2x1 hour immersion regime.	
2.2 GLP	No	x
2.3 Deviations	No	
	3 MATERIALS AND METHODS	
3.1 Test material	Jotun Industri Grunning Visir	
3.1.1 Lot/Batch number	n.a.	
3.1.2 Specification	Concentration of active ingredient: 0,6% w/w tebuconazole Concentration of film preservative (PT7): 0,3% IPBC	x
3.1.3 Purity	n.a.	
3.1.4 Further relevant properties	n.a.	
3.2 Testing procedure	According to the guideline study. The test has been performed according to the reat side conditions which are according to the guidelines laid down by DANAK (The Danish accreditation).	x
3.3 Analytical methods	Chemical analysis of active ingredient confirmed concentration of tebuconazole to be 0,6% (reg. no. 34861, Chemistry and Water Technology, Danish Technological Institute). Limit of quantification of tebuconazole: 0,002 µg/ml.	x
	4 RESULTS	
4.1 Determination of treatment solution uptake	Retention of product 250g/m^2	

Section B7.1/01

Annex Point IIB7.1

OECD Guidance on the estimation of emissions from wood preservative. Laboratory study.

4.2 Concentration in treated material

Retention of a.i tebuconazole 1,5 g/m^2

4.3 Concentration in leachatesleaching rate

Immersion days	Leaching (mg/m^2/immersion day)	
	Tebuconazole	IPBC
1	9.83	27.98
3	9.41	25.64
5	8.49	21.32
8	n.a.	n.a.
10	n.a.	n.a.
12	7.74	17.07
15	n.a.	n.a.
17	n.a.	n.a.
19	5.48	9.99

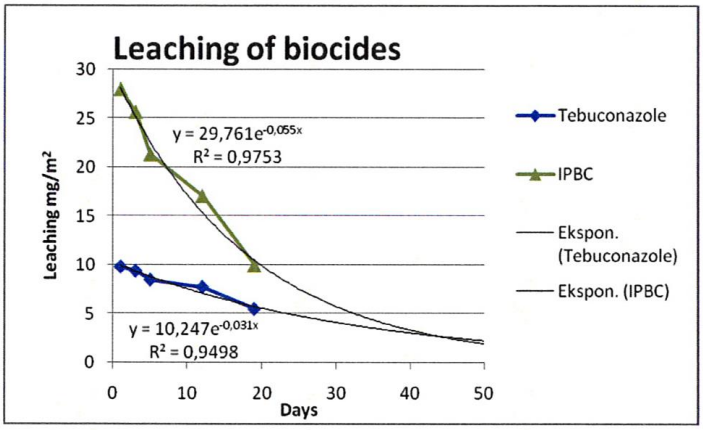
n.a.: Not analysed.

The best mathematical curve which fits the leaching of tebuconazole is an exponential function:

$y = 10.247e^{-0,031x}$; $R^2 = 0.95$

The best mathematical curve which fits the leaching of IPBC is an exponential function:

$y = 29.761e^{-0,055x}$; $R^2 = 0.98$



x

Section B7.1/01 **OECD Guidance on the estimation of emissions from wood preservative. Laboratory study.**

Annex Point IIB7.1

Estimated Leaching of tebuconazole $y = 10.247e^{-0,031x}$ and $R^2 = 0.95$		
Dipping day	Leaching pr. day mg/m^2	Accumulated leaching mg/m^2
1	9.9	9.9
3	9.3	19.3
5	8.8	28.0
8	8.0	36.0
10	7.5	43.6
12	7.1	50.6
15	6.4	57.1
17	6.0	63.1
19	5.7	68.8
22	5.2	74.0
24	4.9	78.8
26	4.6	83.4
29	4.2	87.6
31	3.9	91.5

The 30 days leaching for tebuconazole is estimated to 88 mg/m^2.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

According to the guideline study and DANAK guidelines.

5.2 Results and discussion

The 30 days leaching of Tebuconazole is estimated to be 88 mg/m^2

5.3 Conclusion

5.3.1 Reliability

1, reliable without restrictions

x

5.3.2 Deficiencies

None

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26 August 2011
Guideline	**Comment (2.2**): The influence of not following GLP is not commented.
Material and methods	**Comment (3.1.2):** Generic description of the co-formulants not given.
	Comment (3.2): pH of the test water was not reported. Drying of samples and storage duration before immersion insufficiently reported. Estimated moisture content of the specimens before treatment and amount of water absorbed by the wood during immersion not reported.
	Comment (3.3): No information on the analytical methods is given. Information regarding accuracy and precision missing.
Results and discussion	**Comment (4.3**): Leachates collected at the immersion days 8, 10, 15 and 17 have not been analysed and the influence of this on the reliability of the data has not been evaluated.
	Comment (4.3): The curve fitting applied to the data set is not sufficiently explained. Moreover, the curve fitting used is only valid to the immersion regime applied in the test. Estimation of 30 days accumulated leaching is unclear.
Acceptability	Acceptable
Reliability	**Comment (5.3.1):** Due to the restrictions described, reliability is changed from 1 to 2; reliable with restrictions.
Remarks	A semi-field leaching study has been provided as well and results of this higher tier study will be used for the environmental risk assessment (see study summary III-B7.1/02 below).

Section B7.1/02 Leaching of active ingredients from preservative-treated timber. Semi-field test

Annex Point IIB7.1

Official use only

1 Reference

1.1 Reference	Author: Morten Klamer Year: 2011 Lab. name: DTI Danish Technological Institute Title: Leaching of IPBC, Tebuconazole and Propiconazole from Wood Treated with Jotun Industri Grunning Visir (Waterborne) SF 2202-6 – One Year of Exposure Lab. Report No.: Proj. No. 1900026, Order No. 345846-4 Report date: 14-09-2011 and Title: Leaching of Cobalt from wood treated with Jotun Industri Grunning Visir (Waterborne) SF 2202-6 - One year of Exposure Lab. report no: Proj. No 1900026, Order No. 345846-4A Report date: 12-09-2011
1.2 Data protection	Yes
1.2.1 Data owner	Jotun AS
1.2.2 Companies with Letters of Access	Scanox
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation

2 Guidelines and Quality Assurance

2.1 Guideline study	NT Build 509 Leaching of active components from preservative treated timber – semi-field testing.
2.2 GLP	No. Accredited testing. Danak accr. reg. No.: 358
2.3 Deviations	No

3 Materials and Methods

3.1 Test material	Jotun Industri Grunning Visir
3.1.1 Lot/Batch number	SF2202-6

Section B7.1/02 Leaching of active ingredients from preservative-treated timber. Semi-field test

Annex Point IIB7.1

3.1.2	Specification	Jotun Industri Grunning Visir, brushing application, average uptake 111,3 g/m^2 Concentration of active ingredients: 0,6% tebuconazole Average retention of active ingredient: 0,67 g/m^2 Concentration of film preservative (PT7): 0,3% IPBC Jotun Industri Grunning Visir was tested with and without a topcoat. The topcoat did not contain any a.i. and was applied to assess the effect of a top coat on the leaching profile. Topcoat: Drygolin Oljemaling, Brushing application, 2 coats 120um total film thickness. Drygolin Oljemaling is the most commonly used top coat on the Norwegian market. A wide range of other topcoats can be used.	
3.1.3	Purity	n.a.	
3.1.4	Further relevant properties	n.a.	
3.2	**Testing procedure**	According to the guideline study. The testing contains three test-setups for each combination of products. 159-161: Jotun Industri Grunning Visir with topcoat 171-173: Jotun Industri Grunning Visir without topcoat. Each set-up included 7 specimens, 760x25x100mm. The total exposed area of each set-up was 0,816m^2	x
3.3	**Analytical methods**	The concentration of active ingredient tebuconazole in Jotun Industri Grunning Visir was confirmed by analysis at DTI (Reg.no 35211-4). The concentration of the film preservative IPBC (PT7) was also confirmed by analysis. The degradation product of IPBC, PBC was included in the chemical analyses. Limit of quantification 0,002 ug/ml for Tebuconazole and 0,005ug/ml for IPBC.	x

4 Results

4.1 Determination of treatment solution uptake

4.2 Concentration in treated material

Test set-up no.	Average liquid uptake	Average retention of active ingredient	
		IPBC	Tebuconazole
	g/m^2	g/m^2	g/m^2
159	109	0.32	0.66
160	110	0.32	0.66
161	113	0.33	0.68
171	114	0.34	0.68
172	110	0.32	0.66
173	112	0.33	0.67

Section B7.1/02 Leaching of active ingredients from preservative-treated timber. Semi-field test

Annex Point IIB7.1

4.3 leaching per area

Table 9. Chemical analysis of leachates from test set-up no 159 treated with primer and top coat.

Sampling date	Days since start	Accumulated amount of rain	Collected leachate at each sampling date	Leached amount of active ingredient (mg/m²)		
		mm	L	IPBC	Propiconazole	Tebuconazole
22-04-2010	29	40.4	1.5	0.59	0.14	0.08
08-06-2010	76	143.3	1.1	0.36	0.09	0.05
09-08-2010	138	266.7	5.4	1.32	0.66	0.40
08-10-2010	198	483.4	15.6	2.57	1.59	1.02
14-03-2011	355	678.7	25.0	1.08	0.87	0.43

Table 10. Chemical analysis of leachates from test set-up no 160 treated with primer and top coat.

Sampling date	Days since start	Accumulated amount of rain	Collected leachate at each sampling date	Leached amount of active ingredient (mg/m²)		
		mm	L	IPBC	Propiconazole	Tebuconazole
22-04-2010	29	40.4	1.6	0.61	0.13	0.09
08-06-2010	76	143.3	1.1	0.32	0.09	0.05
09-08-2010	138	266.7	5.8	1.41	0.71	0.42
08-10-2010	198	483.4	16.0	2.69	1.66	1.04
14-03-2011	355	678.7	25.0	0.89	0.74	0.32

Table 11. Chemical analysis of leachates from test set-up no 161 treated with primer and top coat.

Sampling date	Days since start	Accumulated amount of rain	Collected leachate at each sampling date	Leached amount of active ingredient (mg/m²)		
		mm	L	IPBC	Propiconazole	Tebuconazole
22-04-2010	29	40.4	1.7	0.80	0.27	0.22
08-06-2010	76	143.3	1.6	0.44	0.11	0.06
09-08-2010	138	266.7	5.9	1.45	0.77	0.44
08-10-2010	198	483.4	16.7	2.59	1.74	1.09
14-03-2011	355	678.7	26.1	0.93	0.67	0.28

Table 12. Chemical analysis of leachates from test set-up no 171 treated with primer.

Sampling date	Days since start	Accumulated amount of rain	Collected leachate at each sampling date	Leached amount of active ingredient (mg/m²)		
		mm	L	IPBC	Propiconazole	Tebuconazole
22-04-2010	29	40.4	2.1	3.70	2.62	2.36
08-06-2010	76	143.3	1.6	0.96	1.32	1.52
09-08-2010	138	266.7	6.8	1.95	4.76	5.05
08-10-2010	198	483.4	17.2	3.36	9.71	8.55
14-03-2011	355	678.7	22.9	2.28	8.98	5.89

Table 13. Chemical analysis of leachates from test set-up no 172 treated with primer.

Sampling date	Days since start	Accumulated amount of rain	Collected leachate at each sampling date	Leached amount of active ingredient (mg/m²)		
		mm	L	IPBC	Propiconazole	Tebuconazole
22-04-2010	29	40.4	2.2	4.02	2.91	2.42
08-06-2010	76	143.3	1.5	0.81	1.60	1.42
09-08-2010	138	266.7	7.0	1.78	4.72	4.84
08-10-2010	198	483.4	17.6	2.87	9.18	8.10
14-03-2011	355	678.7	23.1	1.82	8.36	5.38

Table 14. Chemical analysis of leachates from test set-up no 173 treated with primer.

Sampling date	Days since start	Accumulated amount of rain	Collected leachate at each sampling date	Leached amount of active ingredient (mg/m²)		
		mm	L	IPBC	Propiconazole	Tebuconazole
22-04-2010	29	40.4	2.3	4.31	3.05	2.63
08-06-2010	76	143.3	1.8	1.16	2.03	1.83
09-08-2010	138	266.7	6.9	1.98	5.22	5.35
08-10-2010	198	483.4	17.5	3.64	10.32	9.25
14-03-2011	355	678.7	23.2	2.14	9.12	7.27

x

Quantity of leached a.i. pr m^2 as a function of accumulated rainfall:

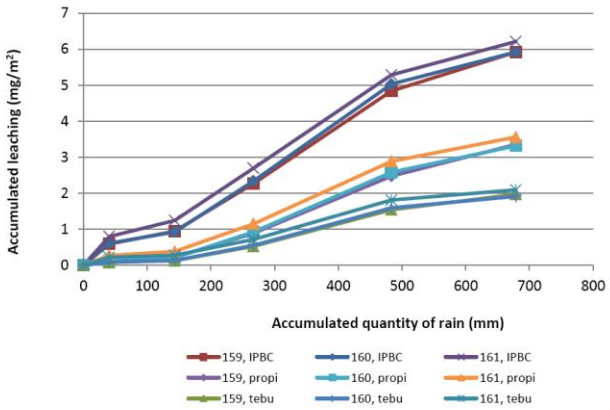


Figure 3. Accumulated amount of active ingredients leached in mg/m^2 as a function of accumulated rainfall for the test set-ups treated with primer and top coat.

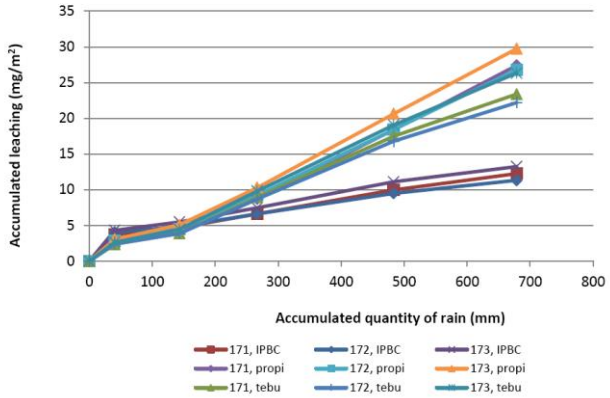


Figure 4. Accumulated amount of active ingredients leached in mg/m^2 as a function of accumulated rainfall for the test set-ups treated with primer only.

Jotun Industri Grunning contains 0.1-0-5% cobalt, borate neodecanoate; CAS-No. 68457-13-6, as a substance of concern for environment. Therefore, leaching of the cobalt ion was also measured:

Table 3. Chemical analysis of leachates from test set-up no 159 treated with primer and top coat.

Sampling date	Days since start	Accu-mulated amount of rain	Collected leachate at each sampling date	Concentration of cobalt in leachate	
		mm	L	mg/L	mg/m^2
22-04-2010	29	40.4	1.5	0.09	0.16
08-06-2010	76	143.3	1.1	0.19	0.25
09-08-2010	138	266.7	5.4	0.15	1.00
08-10-2010	198	483.4	15.6	0.07	1.29
14-03-2011	355	678.7	25.0	0.04	1.22

Table 4. Chemical analysis of leachates from test set-up no 160 treated with primer and top coat

Sampling date	Days since start	Accu-mulated amount of rain	Collected leachate at each sampling date	Concentration of cobalt in leachate	
		mm	L	mg/L	mg/m^2
22-04-2010	29	40.4	1.6	0.10	0.18
08-06-2010	76	143.3	1.1	0.13	0.18
09-08-2010	138	266.7	5.8	0.14	0.98
08-10-2010	198	483.4	16.0	0.08	1.53
14-03-2011	355	678.7	25.0	0.04	1.26

Table 5. Chemical analysis of leachates from test set-up no 161 treated with primer and top coat.

Sampling date	Days since start	Accu-mulated amount of rain	Collected leachate at each sampling date	Concentration of cobalt in leachate	
		mm	L	mg/L	mg/m^2
22-04-2010	29	40.4	1.7	0.08	0.17
08-06-2010	76	143.3	1.6	0.13	0.26
09-08-2010	138	266.7	5.9	0.16	1.18
08-10-2010	198	483.4	16.7	0.08	1.61
14-03-2011	355	678.7	26.1	0.05	1.47

Table 6. Chemical analysis of leachates from test set-up no 171 treated with primer.

Sampling date	Days since start	Accu-mulated amount of rain	Collected leachate at each sampling date	Concentration of cobalt in leachate	
		mm	L	mg/L	mg/m^2
22-04-2010	29	40.4	2.1	0.68	1.77
08-06-2010	76	143.3	1.6	0.52	1.02
09-08-2010	138	266.7	6.8	0.48	4.01
08-10-2010	198	483.4	17.2	0.20	4.17
14-03-2011	355	678.7	22.9	0.10	2.67

Table 7. Chemical analysis of leachates from test set-up no 172 treated with primer

Sampling date	Days since start	Accu-mulated amount of rain	Collected leachate at each sampling date	Concentration of cobalt in leachate	
		mm	L	mg/L	mg/m^2
22-04-2010	29	40.4	2.2	0.59	1.55
08-06-2010	76	143.3	1.5	0.51	0.93
09-08-2010	138	266.7	7.0	0.43	3.67
08-10-2010	198	483.4	17.6	0.16	3.40
14-03-2011	355	678.7	23.1	0.09	2.44

Table 8. Chemical analysis of leachates from test set-up no 173 treated with primer.

Sampling date	Days since start	Accu-mulated amount of rain	Collected leachate at each sampling date	Concentration of cobalt in leachate	
		mm	L	mg/L	mg/m^2
22-04-2010	29	40.4	2.3	0.95	2.62
08-06-2010	76	143.3	1.8	0.59	1.27
09-08-2010	138	266.7	6.9	0.54	4.52
08-10-2010	198	483.4	17.5	0.19	4.11
14-03-2011	355	678.7	23.2	0.09	2.70

Quantity of leached Cobalt pr m^2 as a function of accumulated rainfall:

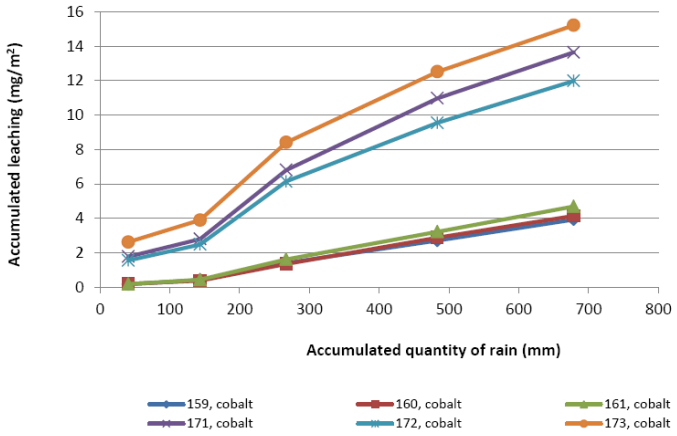


Figure 3. Accumulated amount of cobalt leached in mg/m^2 as a function of accumulated rainfall for the test set-ups treated with primer and top coat.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

According to the guideline study and DANAK guidelines.

5.2 Results and discussion

From the test set-ups treated with primer and top coat the total average leaching of tebuconazole was 1,99 mg/m^2, the relative average leaching was 0,50%. x
The total average leaching of tebuconazole from test set-ups treated with primer only was: 23,96 mg/m^2, the relative average leaching was 7,23%.
The application of a top coat reduced the leaching of tebuconazole by a factor of about 12.

This study is planned to continue at least until 2 years of exposure or 1440 mm of rain is reached.
From the results above long time leaching can be calculated (see dossier doc IIB).

5.3 Conclusion

Danak accredited testing reg. no.:358. Validity criteria can be considered as fulfilled

5.3.1 Reliability

1, reliable without restrictions

5.3.2 Deficiencies

None

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	1 October 2011
Material and methods	**Comment (3.2)**: Temperature and relative humidity are not reported during the drying period after treatment with wood preservative and application of the topcoat. **Comment (3.2)**: Temperature at the exposure sites was not reported. **Comment (3.3):** Regarding the analytical method, information on accuracy and precision is missing.
Results and discussion	**Comment (4.3):** The calculated figures for "leached amount of active ingredient in mg/m^2" are slightly different from the figures calculated in Appendix 4a (leaching calculation for tebuconazole) and 4b (leaching calculation for cobalt) to the Product Assessment Report. This is probably due to different use of decimal digits regarding the input values and is not assumed to have any influence on the outcome of the risk assessment. **Comment (5.2):** Using the figures in Appendix 4a, the total average leaching of tebuconazole from test set-ups treated with primer only was: 24.1 mg/m^2, the total average relative leaching was 3.6 %. The figure mentioned in the study of 7.23% leaching has therefore to be a calculation error. From the test set-ups treated with primer and top coat the total average leaching of tebuconazole was 1.92 mg/m^2, the relative average leaching was 0.29%. Thereby, leaching of tebuconazole was reduced by a factor of about 13 when applying a top coat. Regarding cobalt, from test set-ups treated with primer only the total average leaching was 13.6 mg/m^2 (appendix 4b to the Product Assessment Report). From the test set-ups treated with primer and top coat the total average leaching of cobalt was 4.3 mg/m^2. The application of a top coat reduced the leaching of cobalt by a factor of about 3. **Comment (5.2)**: Flux values have not been calculated. However, the data from this study has been used to calculate Time 1 and Time 2 fluxes in the Product Assessment Report.
Acceptability	Acceptable
Reliability	1, reliable without restrictions
Remarks	-

Appendix 3 – Exposure calculations for Human Health

Mixing and loading

Manual loading (pouring)

Manual loading of wood preservative (pouring) - Tier I BEAT: Loading DEGBE –dataset* Product	
Active substance % (w/v)	0.60 %
Potential body exposure Indicative value µl/min Duration min Potential dermal deposit µl Clothing type Clothing penetration % Actual dermal deposit [*product*] µl	 18.1 10 181 100% penetration 100 % 181
Hand exposure Indicative value µl/min (potential) Duration min Hand deposit µl Mitigation by gloves Actual hand deposit [*product*] µl	 4610 10 46100 1 46100
Total dermal exposure Total dermal deposit [*product]* µl Active substance mg Dermal absorption % Systemic exposure via dermal route mg	 46281 277.686 100.00 % 277.6860
Exposure by inhalation	Negligible
Systemic exposure Total systemic exposure a.s. mg Body weight kg	 277.6860 60
Systemic exposure mg kg^{-1} day^{-1}	**4.63**

*using 95 th percentile values

Manual loading of wood preservative (pouring) - Tier II BEAT: Loading DEGBE – dataset *	
Product	
Active substance % (w/v)	0.60 %
Potential body exposure	
Indicative value µl/min	18.1
Duration min	10
Potential dermal deposit µl	181
Clothing type	Coated coveralls, 10% penetration
Clothing penetration %	10 %
Actual dermal deposit [*product*] µl	18.1
Hand exposure	
Indicative value µl/min (potential)	4610
Duration min	10
Hand deposit µl	46100
Mitigation by gloves	0.1
Actual hand deposit [*product*] µl	4610
Total dermal exposure	
Total dermal deposit [*product]* µl	4628.1
Active substance mg	27.7686
Dermal absorption %	5.00 %
Systemic exposure via dermal route mg	1.3884
Exposure by inhalation	Negligible
Systemic exposure	
Total systemic exposure a.s. mg	1.3884
Body weight kg	60
Systemic exposure mg kg^{-1} day^{-1}	**0.023**

*using 95 th percentile values

Semi-automatic transfer/pumping

Semi – automatic transfer (pumping) – Tier I RISKOFDERM Dermal model - Loading liquid, automated or semi-automated Product		
Length of exposure period	10	minutes
Product on clothing	2.02	mg/min
Product on clothing (total)	20.2	mg
Penetration	100	%
Product on skin (clothing)	**20.2**	**mg**
Product on hands on gloves	101	mg/min
Penetration	100	%
Product on hands in gloves	101	mg
Product on hands in gloves (total)	**1010**	**mg**
Total product on skin	**1030.2**	**mg**
AI in product	0.6	%
Dermal exposure to AI	6.18	mg
Dermal uptake	100	%
Dose via skin	**6.18**	**mg**
Dose via inhalation	Negligible	
Total dose	6.18	mg
Bodyweight	60	kg
Systemic dose	**0.103**	**mg/kg b.w./day**

95th. percentile values from the model

Semi – automatic transfer (pumping) – Tier II **RISKOFDERM Dermal model - Loading liquid, automated or semi-automated** **Product**		
Length of exposure period	10	minutes
Product on clothing	2.02	mg/min
Product on clothing (total)	20.2	mg
Penetration	10	%
Product on skin (clothing)	**2.02**	**mg**
Product on hands on gloves	101	mg/min
Penetration	10	%
Product on hands in gloves	10.1	mg
Product on hands in gloves (total)	**101**	**mg**
Total product on skin	**103.02**	**mg**
AI in product	0.6	%
Dermal exposure to AI	0.62	mg
Dermal uptake	5	%
Dose via skin	**0.0309**	**mg**
Dose via inhalation	Negligible	
Total dose	0.0309	mg
Bodyweight	60	kg
Systemic dose	**0.000515**	**mg/kg b.w./day**

95th. percentile values from the model

Application

Automated spraying/flow coating - Tier I BEAT: "timber pre-treatment (water)" data set* Product	
Active substance % (w/v)	0.60 %
Potential body exposure	
Indicative value µl/min	109
Duration min	360
Potential dermal deposit µl	39240
Clothing type	100% penetration
Clothing penetration %	100 %
Actual dermal deposit [*product*] µl	39240
Hand exposure	
Indicative value µl/min (actual)	8.7
Duration min	360
Hand deposit µl	3132
Mitigation by gloves	Not applicable
Actual hand deposit [*product*] µl	3132
Total dermal exposure	
Total dermal deposit [*product]* µl	42372
Active substance mg	254.232
Dermal absorption %	100.00 %
Systemic exposure via dermal route mg	254.2320
Exposure by inhalation	Negligible
Systemic exposure	
Total systemic exposure a.s. mg	254.2320
Body weight kg	60
Systemic exposure mg kg^{-1} day^{-1}	**4.24**

*Dermal exposure: 75th percentiles of fitted log normal distributions to water-based timber pre-treatment data set. Actual hand exposures used

Automated spraying/flow coating - Tier IIa BEAT: "timber pre-treatment (water)" data set* Product	
Active substance % (w/v)	0.60 %
Potential body exposure	
Indicative value µl/min	109
Duration min	360
Potential dermal deposit µl	39240
Clothing type	Coated coveralls, 10% penetration
Clothing penetration %	10 %
Actual dermal deposit [*product*] µl	3924
Hand exposure	
Indicative value µl/min (actual)	8.7
Duration min	360
Hand deposit µl	3132
Mitigation by gloves	Not applicable
Actual hand deposit [*product*] µl	3132
Total dermal exposure	
Total dermal deposit [*product]* µl	7056
Active substance mg	42.336
Dermal absorption %	5.00 %
Systemic exposure via dermal route mg	2.1168
Exposure by inhalation	Negligible
Systemic exposure	
Total systemic exposure a.s. mg	2.1168
Body weight kg	60
Systemic exposure mg kg^{-1} day^{-1}	**0.0353**

* Dermal exposure: 75th percentiles of fitted log normal distributions to water-based timber pre-treatment data set. Actual hand exposures used.

Automated spraying/flow coating - Tier IIb BEAT: "timber pre-treatment (water)" data set* Product	
Active substance % (w/v)	0.60 %
Potential body exposure	
Indicative value µl/min	109
Duration min	360
Potential dermal deposit µl	39240
Clothing type	Impermeable coverall, 5% penetration
Clothing penetration %	5 %
Actual dermal deposit [*product*] µl	1962
Hand exposure	
Indicative value µl/min (actual)	8.7
Duration min	360
Hand deposit µl	3132
Mitigation by gloves	Not applicable
Actual hand deposit [*product*] µl	3132
Total dermal exposure	
Total dermal deposit [*product]* µl	5094
Active substance mg	30.564
Dermal absorption %	5.00 %
Systemic exposure via dermal route mg	1.5282
Exposure by inhalation	Negligible
Systemic exposure	
Total systemic exposure a.s. mg	1.5282
Body weight kg	60
Systemic exposure mg kg^{-1} day^{-1}	**0.0255**

BEAT: Dermal exposure: 75th percentiles of fitted log normal distributions to water-based timber pre-treatment data set. Actual hand exposures used.

Appendix 4 – Addendum to PAR June 2012; Final storage stability data

Addendum to Product Assessment Report

Jotun Industri Grunning Visir

19 September 2012

R4BP ref no:	2010/2093/6146/NO/AA/7439
Authorisation/Registration no:	NO-2011-0005
Granting date/entry into force of authorisation/ registration:	21 December 2011
Expiry date of authorisation/ registration:	21 December 2021, provided that the active substance is still included in Annex I
Active ingredient:	Tebuconazole
Product type:	PT 8

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

1. Introduction

When granting authorisation for Jotun Industri Grunning Visir in December 2011, results from the 2 years stability study were still outstanding. Authorisation was granted based on interim results over 1 year.

Moreover, authorisation was granted with the requirement for further storage stability testing of the product in PP/PE containers. A provision was added to chapter 3.3 (Requirement for further Information) that before the product can be marketed in PP/PE containers an accelerated storage stability study of Jotun Industri Grunning Visir in PP/PPE has to be submitted.

Both studies have become available now, have been evaluated and accepted by the Norwegian Competent Authority and the results are presented in this addendum to the Product Assessment Report of Jotun Industri Grunning Visir.

In this addendum, only chapters 2.3.1, 2.4 and 3.3 as well as the reference list (Appendix I) of the PAR are presented as the submission of these two studies have implications on these sections only. Changes with respect to the text in the PAR are highlighted in green.

All other chapters, as well as the decision regarding granting of authorisation of Jotun Industri Grunning Visir, are unchanged.

2.3 Physico/chemical properties and analytical methods

2.3.1 Physico-chemical properties

A Letter of Access has been submitted for the active substance. The active substance concentrate is delivered by the producer of the active substance evaluated for Annex I entry.

Table 2.1: **Physico-chemical properties of the biocidal product**

Endpoint	Method	Results	Comments
Physical state and nature	Charles River SOP	Viscous Liquid	*
Colour	ASTM D1535-89	N 8.5 68.4% R (Grey)***	*
Odour	Charles River SOP	Turpentine	*
Explosive properties	-	Not an explosive product	Theoretical assessment, Expert statement. See chapter 2.4
Oxidizing properties	-	Not an oxidising product	Theoretical assessment, Expert statement. See chapter 2.4
Flash point	EC Test A.9	Not detected below 100°C	*
Autoflammability	EC Test A.15	490 ± 10°C	*
Other indications of flammability	n.a.		
Acidity / Alkalinity	CIPAC MT 75	6.43	*
Relative density / bulk density	OECD 109 OJEC A3	1.107	*
Storage stability – stability and shelf life	2 years storage stability in warehouse-condition, dark and ambient temperature	Result after two years storage: Tebuconazole concentration: 0.37% w/w initial concentration 0.47% w/w after 12 months storage 0.44% w/w after 24 months storage.	* Steel container
Storage stability – Accelerated Storage	Results from Accelerated Storage (CIPAC MT 46.1)	Tebuconazole concentration: 0.37% w/w initial 0.38% w/w after 14 days at 54 ± 2°C.	* Steel container
Storage stability – Accelerated Storage	Results from Accelerated Storage (CIPAC MT 46.1)	Tebuconazole concentration: 0.440 % w/w initial 0.429 % w/w after 8 weeks storage at 40 °C.	** Plastic container
Storage stability – effects of temperature	Results from low temperature storage (CIPAC MT 39.1)	Storage at 0 ± 1°C for 7 days. *ca* 10% of material separated out at the bottom and *ca* 5% at the top following centrifugation	*

Endpoint	Method	Results	Comments
Effects of light	n.a. as container material is not transparent.	-	-
Reactivity towards container material	Visual inspection	Container was observed to be clean and intact, free of corrosion and dents and showed no other signs of degradation or chemical interaction between the test item and the container material (steel)	Results from accelerated storage stability testing.
Technical characteristics in dependence of the formulation type	n.a.	-	The biocidal product has none of the properties mentioned in the TNsG on Data Requirements. Therefore no tests were performed.
Compatibility with other products	n.a.	-	The product is a stand-alone product and not to be mixed with other products.
Surface tension	n.a.	-	According to Annex IIB to 98/8/EC this is not a data requirement for biocidal products.
Viscosity	OECD 114	Prior to storage: 289mPas (20°C) 208mPas (40°C) After 12 months storage: 294mPas (20°C) 218mPas (40°C) After 24 months storage: 278 mPas (20°C) 207 mPas (40°C)	*
Particle size distribution	n.a.	Only applicable for products that are supplied as powders or granulates.	

* Balloch, Stephen and Allan, Graham 2012 (see Appendix 1 – reference list)
**Jotun AS 2012 (see Appendix 1 – reference list)
*** Pigment was changed to white in the authorised product (all other formulants are identical)

Risk assessment for Physico-chemical properties

The characterisation of the potential risk of the product, which contains the active substance tebuconazole, is based on the physicochemical properties of the product.

Jotun Industri Grunning Visir is considered stable at room temperature. It is not self-igniting (EC Test A.15), and an assessment of the explosive properties was carried out by analysing the chemical structures of the components of the formulation and comparing the bond groupings with those known to be linked with explosive properties. The result of this investigations was that components of the formulation are either known not to be explosive substances or, from consideration of their chemical structures, do not have any bond groupings known to be linked with explosive properties. Therefore, it can be concluded that Jotun Industri Grunning Visir cannot be regarded as explosive in the sense of EC A.14.

The test item was not classified as flammable in terms of its flash point, which was not detected below 100 °C (EC Test A.9).

An expert statement on the oxidizing properties of the test item was conducted in lieu of performing the EC Test A.21. The result of the theoretical assessment was that Jotun Industri Grunning Visir is not an oxidizing formulation. Jotun Industri Grunning Visir contains 0.04% w/w sodium nitrite, a well-known oxidizing substance, but the other components of the formulation are either known not to be oxidizing substances or, based on considerations of chemical structure, could not possess oxidizing properties. It is therefore reasonable to assume that the presence of sodium nitrite at such a low level in a formulation, which otherwise comprises only of non-oxidizing materials, would be sufficient to derive the overall conclusion that the product does not have oxidizing properties. Consequently, Jotun Industri Grunning Visir will not give rise to highly exothermic reactions when it comes into contact with other substances, particularly flammable ones, in the way in which recognized oxidizing substances/formulations do.

The investigation on the accelerated storage stability of the formulation was done according to CIPAC MT 46.1. The relevant formulation was stable for 14 days at 54 °C. Results from storage at room temperature after two years shows that the measured concentrations increased from 0.37 % w/w initial to 0.47 % and 0.44 w/w after 12 and 24 months, respectively. No real explanation for these findings could be provided. It does, however, not seem likely that the concentration really increased by 27 % and 19 % within one and two years, respectively, especially since no weight loss of the samples was observed during this period. Moreover, the accelerated storage stability study proved stable results (0.37 % w/w initial, 0.38 % w/w after 14 days). Therefore, the only possible explanation is that there might have been problems with the quantification of tebuconazole in the samples at the start of the study and also after accelerated storage. This is also in line with the initial nominal concentration of 0.40 % w/w in samples used for the phys-chem. Studies. All values are mean values of three measurements.

The two-years storage stability study was conducted with Jotun Industri Grunning Visir stored in steel containers. No information on storage stability of the product in PP/PE containers was available. Before Jotun Industri Grunning Visir can be marketed in PP/PE containers an accelerated storage stability study was therefore required. The study is now available and results show that tebuconazole can be considered stable in PP/PE containers during accelerated storage (8 weeks, 40°C). Mean concentrations (3 parallels of 4 samples, respectively) show a content of 0.440 % w/w tebuconazole initial and 0.429 % w/w after accelerated storage. In addition, a positive control in steel was also run in parallel. The initial concentration of tebuconazole in steel was 0.440 % w/w (mean) and after 8 weeks at 40°C

0.432 % w/w (mean). As tebuconazole has been shown to be stable in steel containers over 2 years at room temperature, it can also be assumed that the active substance should also be stable in PP/PE containers over a 2 years period at room temperature.

A low temperature stability test has also been conducted on the product according to CIPAC 39.1. Following storage at 0 ± 1°C for 7 days. *ca* 10% of material separated out at the bottom and *ca* 5% at the top following centrifugation. As a consequence it is required that the product, which is only to be used industrially, should be kept at temperatures above 5 °C during transport and storage.

Therefore no potential risk for users is given due to the physico-chemical properties of this product.

3.3 Requirement for Further Information

New efficacy testing of Jotun Industri Grunning Visir will have to be required in case of a re-formulation involving changes in use of film preservative.

Norwegian Competent Authority

September 2012

Appendix 1 – Reference list

Author(s)	Year	Title	Data protection claimed	Owner
Allan, G. and Balloch, S.	2012	Two Year Storage Stability, Accelerated Storage Stability and Physical Chemistry Testing on Jotun's Industri Grunning Visir. Charles River Tranent Edinburgh EH33 2NE UK. Test Facility Study No. 215361 Report No. 30708. Sponsor's Ref. No. BIO1308	Yes	Jotun A/S
Balloch, S.	2009	Validation of Methodology for Tebuconazole, Propiconazole, Thiachloprid and Iodocarb Determination in Paint Formulations. Charles River Final Report, Test Facility Study No 215335, Report No 30381, Sponsors Ref No BIO 1308	Yes	Jotun A/S
Balloch, S.	2010	Validation of Methodology for Tebuconazole, Propiconazole, Thiachloprid and Iodocoarb Determination in Paint Formulations. Charles River Tranent Edinburgh EH33 2NE UK. Test Facility Study No. 215335-F2 Report No. 30381 Sponsor's Ref. No. BIO1308 Report Amendment 1	Yes	Jotun A/S
European Chemicals Agency (ECHA)	2011	ECHA CHEM, Information on Registered Substances: http://apps.echa.europa.eu/registered/registered-sub.aspx	No	Public
European Chemicals Bureau (ECB)	2002	Technical Notes for Guidance. Human Exposure to biocidal products. Guidance on exposure estimation. Published.	No	Public
European Chemicals Bureau (ECB)	2003	TGD: Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market", Part II, EUR 20418 EN/2.	No	Public
European Chemicals Bureau (ECB)	2004	Technical Notes for Guidance on human exposure to Biocidal products (June 2002), User Guidance version 1. Guidance on exposure estimation. Published.	No	Public
European Chemicals Bureau (ECB)	2007	Technical Notes for Guidance. Human Exposure to biocidal products. (Version 2, June 2007). Guidance on exposure estimation. Published.	No	Public
European	2009	TNsG on Annex I inclusion, revision of chapter	No	Public

Author(s)	Year	Title	Data protection claimed	Owner
Chemicals Bureau (Ex-ECB)		4.1, Quantitative Human Health Risk		
Ex-European Chemicals Bureau (Ex-ECB)	2011	Manual of Technical Agreements (MOTA) Biocides Technical Meeting Version 4; 2011. Published (available on the JRC-IHCP web site: http://ihcp.jrc.ec.europa.eu/)	No	Public
European Commission	2000	Technical Notes for Guidance on Data Requirements for active substances and biocidal products in: Technical Notes for guidance in support of Directive 98/8/EC concerning the placing of biocidal products on the market	No	Public
European Commission	2007	Assessment Report for Tebuconazole (published 2008), available from the CIRCA database (Communication & Information Resource Centre Administrator), Group "Biocides Public - Directive 98/8/EC on the placing of biocidal products on the market": http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/assessement_directive&vm=detailed&sb=Title	No	Public
European Commission	2008	Assessment Report IPBC, available from the CIRCA database (Communication & Information Resource Centre Administrator), Group "Biocides Public - Directive 98/8/EC on the placing of biocidal products on the market": http://circa.europa.eu/Public/irc/env/bio_reports/library?l=/assessement_directive&vm=detailed&sb=Title	No	Public
FOCUS	2006	Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0.	No	Public
Garrod A.N.I., Martinez M., Pearson J., Proud A., Rimmer D.A.	1999	Exposure to preservatives used in the industrial pre-treatment of timber. Annals of Occupational Hygiene 43(8) 543-555.Proposal for decision	No	Public
Gijsbers J.H.J., Tielemans E., Brouwer D.H., Van Hemmen J.J.	2004	Dermal Exposure During Filling, loading and Brushing with Products containing 2-(2-Butoxyethoxy)ethanol Annals of Occupational Hygiene (48) 219-228	No	Public
Human Exposure Expert	2008a	HEEG Opinion on the assessment of Potential & Actual Hand Exposure, 07/04/2008,	No	Public

Author(s)	Year	Title	Data protection claimed	Owner
Group (HEEG)		Agreed at the Biocides Technical Meeting in March 2008		
Human Exposure Expert Group (HEEG)	2008b	HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale. 06/04/2008 Agreed at the Biocides Technical Meeting in March 2008	No	Public
HEEG Human Exposure Expert Group	2009	HEEG opinion on defaults and appropriate models to assess human exposure for dipping processes (PT8). 02/09/2009 HEEG proposal for TMIII09.	No	Public
HEEG Human Exposure Expert Group	2010	HEEG opinion on default protection factors for protective clothing and gloves, Agreed at TMI2010. Published	No	Public
Jotun AS	2012	Accelerated Storage Stability Test of "Jotun Industri Grunning Visir" in Plastic (PP) and Metal Containers	Yes	Jotun A/S
Klamer, M. and Venås, T. M.	2011	Leaching of IPBC, Tebuconazole and Propiconazole from wood treated with Jotun Industri Grunning Visir (Waterborne) SF 2202-6 - One year of Exposure. Danish Technological Institute, Project no 1900026, order no. 354846-4	Yes	Jotun A/S
Klamer, M. and Venås, T. M.	2011	Leaching of Cobalt from wood treated with Jotun Industri Grunning Visir (Waterborne) SF 2202-6 – One year of Exposure. Danish Technological Institute, Project no 1900026, Order no 345846-4A	Yes	Jotun A/S
Lindegaard, B. and Morsing, E.	2009	Test Report Jotun Industri Grunning Visir DTI Danish Technological Institute, Lab. report no: Proj. No 1006657-17, Order No. 319962-D	Yes	Jotun A/S
Nordic Innovation Centre	2005	Nordtest Method NT Build 509, ISSN: 1459—2762, Project 04202 (1582-02)	No	Public
Organisation for Economic Co-operation and Development (OECD)	2003	OECD Series on Emission Scenario Documents, Number 2 – Emission Scenario Document for Wood Preservatives, Part 1-4.	No	Public
Organisation for Economic Co-operation and Development (OECD)	2009	OECD guideline; series on Testing and Assessment No. 107 (2009), “OECD Guidance on the Estimation of Emissions from Wood Preservative-Treated Wood to the Environment: for Wood held in Storage after Treatment and for Wooden Commodities that are not covered and are not in Contact with	No	Public

Author(s)	Year	Title	Data protection claimed	Owner
		Ground", ENV/JM/MONO(2009)12		
Plarre, R.	2010	Test report Jotun Industri Grunning Visir SF2202-7 DIN EN 113:1996 Wood preservativs. Test method for determining the protective effectiveness against wood destroying basidiomycetes. Determination of Toxic values in combination with DIN EN 84: 1997 Wood preservatives. Accelerated ageing of treated wood prior to biological testing. Leaching procedure. BAM Bundesanstalt für Materialforschung und –prüfung, Lab. report no.: IV.1/8318 Ba A.	Yes	Jotun A/S
Toner, F.	2006	The In vitro Percutaneous Absorption of Radiolabelled Tebuconazole in Two Wood Protection Formulations through Human Skin. Included in the Competent Autority Report on Tebuzonazole from December 2007, Document IIIB, section B6.4	Yes	Lanxess

Appendix 5 – Addendum to PAR June 2014: Minor change

Addendum to

Product Assessment Report

Industri Grunning Visir Hvit

June 2014

Minor change of the product formulation

R4BP3 asset no:	NO-0003197-0000
Authorisation no	NO-2011-0005
Date of authorisation	21 December 2011
Expiry date of Authorisation	21 December 2021, provided that the active substance is still included in the Union list of approved substances
Active ingredient:	Tebuconazole
Product type:	PT 8

1.Background

A minor change according to Regulation No 354/2013 of the approved product Jotun Industri Grunning Visir (JIGV) has been applied for by the manufacturer JOTUN AS.

The change comprises a change of name into Jotun Industri Impregnering Visir Hvit (JIGV Hvit) as well as a minor change in the formulation. The change in the formulation of JIGV Hvit is related to the substitution of a non-active ingredient containing cobalt with an alternative ingredient. There will also be an insignificant change in the content of white spirit, titanium dioxide and alkyd resin. The concentration of the active substance Tebuconazole will remain unchanged (0.6%). The new ingredient does not contain any substance of concern, and since cobalt is a substance of concern for the environment, the substitution will result in a change in the environmental classification of the product. All other ingredients will remain unaltered. An accelerated storage stability study of the new formulation has been performed in steel containers (Sander, P. & Lindstrøm, H., 2014) and the efficacy has been evaluated by Danish Technological Institute (Lindegaard, B., 2013).

2. Assessment of some important points

2.1. Classification

Cobalt is a substance of concern in the existing formulation and is classified according to Directive 67/548/EC and Directive 1999/45/EC:

N: R50/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Xn: R22 - Harmful if swallowed

Xi: R38 - Irritating to skin

Xi: R43 - May cause sensitisation by skin contact

The new substance is not a substance of concern and is classified according to Directive 67/548/EC and Directive 1999/45/EC:

Xi: R43 - May cause sensitisation by skin contact

Classification of the authorized formulation of JIGV Hvit according to Directive 67/548/EC and Directive 1999/45/EC:

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Additional warning phrase: Contains 3-iodo-2-propynyl butylcarbamate (IPBC) and Cobalt, borate neodecanoate complexes. May produce an allergic reaction.

Classification of the new formulation of JIGV Hvit according to Directive 67/548/EC and Directive 1999/45/EC:

Not classified.

Additional warning phrase:
Contains 3-iodo-2-propynyl butylcarbamate (IPBC). May produce an allergic reaction.

Classification according to (EC) 1272/2008 [CLP/GHS]:

Not classified.

EUH 208: Contains 3-iodo-2-propynyl butylcarbamate (IPBC), 1,2-benzisotiazol-3(2H)-on (BIT) and 5-chloro-2-methyl-4-isothiazolin-3-one/2-methyl-4-isothiazol (CIT/MIT). May produce an allergic reaction.

1,2-benzisotiazol-3(2H)-on (BIT) and 5-chloro-2-methyl-4-isothiazolin-3-one/2-methyl-4-isothiazol (CIT/MIT) is included in the additional warning phrase due to the 2nd ATP to the CLP regulation. Substances classified as skin sensitisers or respiratory sensitisers with a specific concentration limit lower than 0,1 % shall bear the statement EUH 208 when the concentration is ≥ one tenth of the specific concentration limit for the substance.

There is no change in the concentration of in-can preservatives in the proposed new formulation compared to the authorised formulation.

EUROPEAN WASTE CATALOGUE (EWC)

The product is following the substitution not classified as hazardous and it is suggested to change the waste code from “08 01 11* Waste paint and varnish containing organic solvents or other dangerous substances” to waste code “08 01 12 waste paint and varnish other than those mentioned in 08 01 11”.

2.2. Evaluation of the risk for human health

The substance to be substituted, cobalt, borat neodecanoate is not a substance of concern for human health, but the final concentration in the product triggers the additional warning phrase "Contains Cobalt, borate neodecanoate complexes. May produce an allergic reaction". The new substance is also classified Xi; R43, but is present in a lower final concentration in the product which does not trigger this warning sentence.
Further, it is not expected that the substitution will affect the dermal absorption of the product. The substitution will thus result in a product with less detrimental properties for human health.

2.3. Evaluation of cobalt as a factor in the assessment of the environmental risk

In the PAR for the authorised formulation of JIGV Hvit the risk was calculated for three scenarios (Noise Barrier, House and Bridge over Pond) for tebuconazole alone, for cobalt complexes alone and also for a combination of these two.

Noise Barrier

For cobalt alone no risks for STP, surface water, sediment and soil were identified for amateur and professional use. PEC/PNEC ratios were also calculated based on the combined risk assessment for tebuconazole and cobalt for STP, surface water, sediment and soil: No risks were identified.

House

For cobalt alone no risks for STP, surface water, sediment and soil were identified for amateur and professional use. PEC/PNEC ratios were also calculated based on the combined risk assessment for tebuconazole and cobalt for STP, surface water, sediment and soil: A risk to soil was identified for 30 days leaching, amateur and professional use; however, this risk is due to losses from application. PEC/PNEC ratios based only on 30 days in-service (continuous) leaching show safe use (PEC/PNEC is 0.56 (PEC/PNEC tebuconazole = 0.5 and PEC/PNEC cobalt = 0.06).

Bridge over Pond No risk characterisation for Bridge over Pond was performed for cobalt alone or combined, since a risk to surface water was identified for tebuconazole alone in this scenario.

Groundwater

Cobalt is not specifically mentioned in the PAR under this compartment. However, theoretically, cobalt can be defined as a compound which can be leaching through soil. The use of a leaching rate of 0.282 mg/m^2/day used in PAR confirms this.

Conclusion
The substitution of the cobalt complexes will reduce the environmental risk from use of the product with regards to both toxicity and leaching behaviour of substances in soil.

2.4. Storage Stability Study

A new accelerated storage stability test of the active substance tebuconazole and the film preservative Iodoproponyl butylcarbamate (IPBC) in steel containers was performed for the new formulation. The levels of the active substances were measured prior to and after storage of samples for 4 weeks at 40 °C. The study was conducted according to internal standard methods for the two active substances (AWPA A 28-2005 and an internal standard method for IPBC). The analytical results indicated that the concentration of active substances in the samples were stable following the storage period.
In connection with the authorisation of Jotun Industri Grunning Visir the final results of the 2-year stability test, as well as an accelerated stability test in plastic containers was submitted in 2012 (See addendum to PAR June 2012 for details). The accelerated study in plastic containers showed no difference in the storage stability between steel and plastic containers. The change in the formulation is considered to be minor and is not expected to influence the stability of the active substance in neither of the two packaging types. (Christiansen, R., 2014).

2.5. Efficacy

The Danish Technological Institute (DTI) has evaluated whether the change in the formulation has an effect on the efficacy of JIGV Hvit. Some changes of a preservative formulation are considered minor and no new biological testing is required. Guidance

document EN 599-1 gives guidance to which changes are considered minor. However, as some minor changes, nevertheless, may influence the efficacy of the product, DTI has conducted an individual assessment and concluded that there was no need for a new biological test for efficacy. The product has earlier been tested for efficacy for wood destroying fungi and the substitution of the cobalt compound in the product is assessed not to influence the efficacy.

2.6. Conclusion

The applied minor change of the formulation of JIGV Hvit is considered acceptable and desirable from an environmental and human health point of view and is not expected to influence neither the efficacy, nor the storage stability of the product.

2 Reference list

Author(s)	Year	Title	Data protection claimed	Owner
Sander, P. and Lindstrøm, H.	2014	Testing the storage stability of the biocides tebuconazole and Iodopropynyl butylcarbamate (IPBC).	Yes	Jotun A/S
Lindegaard, B.	2013	Change of product formulation of the BPD approved product. Jotun Industri Grunning Visir.	Yes	Jotun A/S
Christiansen, Rune	2014	Statement Stability test	Yes	Jotun A/S

Addendum to Product Assessment Report

Jotun Industri Grunning Visir

February 2018

Minor change of the product formulation

R4BP3 case no :	BC-XT027875-95
Authorisation/Registration no:	NO-2011-0005
Date:	February 2018
Active ingredient:	Tebuconazole
Product type:	PT 8

1.Background

The manufacturer JOTUN AS has applied for a minor change in accordance with Regulation (EU) No 354/2013 to the authorised product Jotun Industri Grunning Visir / Jotun Industri Grunning Visir Hvit (JIGV Hvit). The change concerns minor changes in constituents of the formulation. In addition, the classification of the product is changed due to a change in the classification of the active substance tebuconazole

2. Description of the changes

2.1. Change in the concentration of the film preservative (PT7) IPBC

The change in the product formulation regards a substitution of the raw material containing the film preservative (PT7) IPBC, as well as its final concentration in the product. The substitution results in the removal or reduction of some of the co-formulats in the product. The difference in the added volume of raw material is substituted with water. The details are described in the confidential annex to this addendum.

The change in raw material and in the concentration of IPBC will not influence the classification of the product, or the final concentration of the active substance. IPBC has the function as a film preservative in JIGV Hvit, thus, the efficacy of the product is not expected to be affected. The applicant has submitted an assessment performed by the Danish Technological Institute (DTI) of the same change for a very similar product for the non-professional market, Visir Oljegrunning Pigmentert (R4BP3 asset no. NO-0003172-0000) (Klamer and Lindegaard 2017). Visir Oljegrunning Pigmentert has a similar composition to JIGV, and the content of both the active substance and of IPBC is identical. It is therefore regarded as reasonable to assume that the assessment of the identical change in Visir Oljegrunning Pigmentert, also is valid for JIGV (hvit). The DTI assessment concludes that the efficacy test submitted for the initial authorisation should be regarded as still valid for the re-formulated product, as the application rate for IPBC still is within the initially accepted application range. Further, the assessment concludes that the reduction is withing the allowed variation given in EN-599 for changes that does not require re-testing for efficacy (Klamer and Lindegaard 2017).
A reduction in the content of IPBC in the formulation is regarded as advantageous for both the environment and human health.

2.2. Change in classification of the product

The product changes classification due to a change in the classification of the active substance tebuconazole (CAS no. 107534-96-3) with the 7th. ATP to Regulation (EC) 1272/2008 (CLP) (Commission regulation (EU) 2015/1221). The new classification of tebuconazole is Aquatic

acute 1; H400 and Aquatic chronic 1; H410, resulting in the classification of JIGV Hvit as Aquatic chronic 2; H411.

Existing classification and labelling of JIGV Hvit according to CLP:

Aquatic chronic 3; H412 Harmful to aquatic life with long lasting effects

Labelling:
Pictogram: None
Signal word: None
H412 Harmful to aquatic life with long lasting effects
P260 Do not breathe spray
P273 Avoid release to the environment
P501 Dispose of content/container in accordance with local/regional/international regulations (to be specified)

EUH208 Contains 1,2-benzisothiazol-3(2H)-on (BIT) and 3-iodo-2-propynyl-butyl-carbamate (IPBC). May produce an allergic reaction.

New classification and labelling of JIGV Hvit:

Aquatic chronic 2; H411 Toxic to aquatic life with long-lasting effects

Labelling:
Pictogram: GSH 09
Signal word: None
H411 Toxic to aquatic life with long lasting effects
P260 Do not breathe spray
P273 Avoid release to the environment
P501 Dispose of content/container in accordance with local/regional/international regulations (to be specified)

EUH208 Contains 1,2-benzisothiazol-3(2H)-on (BIT) and 3-iodo-2-propynyl-butyl-carbamate (IPBC). May produce an allergic reaction.

2.5. Conclusion

The applied change to the formulation of JIGV Hvit is regarded as acceptable.

The change in classification due to the change in classification of tebuconazole, results in an altered environmental classification of the product from *Aquatic chronic 3; H412 Harmful to aquatic life with long lasting effects* to *Aquatic chronic 2; H411 Toxic to aquatic life with long-lasting effects.* The change will not alter the existing conditions for use or restrictions and is therefore regarded as acceptable.