# Product Assessment Report

# Visir Oljegrunning Pigmentert

Revised PAR 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 August 2016

Addendum – minor change of the formulation- added February 2018

Replaces PAR November 2011; see addenda for details

| | |
|---|---|
| R4BP3 assett no: | NO-0003172-0000 |
| Authorisation/Registration no: | NO-2011-0003 |
| Granting date/entry into force of authorisation/ registration: | 16 November 2011 |
| Expiry date of authorisation/ registration: | 16 November 2021, provided that the active substance is still included in Annex I. |
| Active ingredient: | Tebuconazole |
| Product type: | PT 8 |

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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 |
| **Fax:** | +47 33 45 77 10 |
| **E-mail address:** | anne.margrete.nes@jotun.no |

### 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 |
| **Telephone:** | +47 33 45 70 00 |
| **Fax:** | +47 33 45 77 10 |
| **E-mail address:** | anne.margrete.nes@jotun.no |

## 1.2 Current authorisation holder

Visir Oljegrunning Pigmentert 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:** | Visir Oljegrunning Pigmentert |
| **Manufacturer's development code number(s), if appropriate:** | n.a |
| **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<br><br>Substances of concern regarding environment: 0.1-0.25 % Cobalt, borate neodecanoate; CAS-No. 68457-13-6<br><br>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);**<br>**If yes: authorisation/registration no. and product name:**<br>**or**<br>**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<br><br>No |

## 1.5.2 Information on the intended use(s)

| | |
|---|---|
| **Overall use pattern (manner and area of use):** | Visir Oljegrunning Pigmentert is an alkyd-oil primer for exterior wooden surfaces like house cladding and fences (use class 3).<br>To be applied outdoors on wooden surfaces by brushing. |
| **Target organisms:** | Wood destroying fungi (Basidiomycetes) |
| **Category of users:** | Professionals and non-professionals (amateur) |
| **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 outdoors on wooden surfaces by brushing.<br>Only one coat (application). On wood endings 3-4 coats (wet-in-wet).<br>One litre of the product covers 4-8 $m^2$ of wood depending on properties of the wooden surface.<br>Sawn wood: 4-7 $m^2$/L<br>Planed wood: 6-8 $m^2$/L<br>To be over coated with a top coat (paint or varnish products) within one month (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 external use only in Use Class 3<br>• Should only be applied by brushing<br>• Maximum application rate: 0.25 L product /$m^2$ wood corresponding to 1.53 g tebuconazole /$m^2$.<br>• Maximum level of the active ingredient tebuconazole in the product: 0.60 % w/w<br>• To comply with the efficacy claim, a topcoat has to be applied. This topcoat should be applied within one month |

### 1.5.3 Information on active substance

| | |
|---|---|
| **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):** | 0.1-0.25 % |
| **Relevant toxicological/ecotoxicological information:** | Xn; R22<br>Xi; R38, R43<br>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.

Visir Oljegrunning Pigmentert 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 0.68 % tebuconazole[1] (0.48 % measured)
- Effectivity: nominal 0.6 % tebuconazole (measured 0.52 %) and nominal 0.3 % IPBC (measured 0.44 %)
- Leaching laboratory study: 0.86 % tebuconazole and 0.3 % IBPC (both nominal)
- Leaching semi-field study: nominal 0.89 % tebuconazole (measured 0.87 %) and nominal 0.3 % IPBC (measured 0.31 %)

### 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 Visir Oljegrunning Pigmentert. 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. Visir Oljegrunning Pigmentert 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.

Visir Oljegrunning Pigmentert is an existing biocidal product (wood preservative) that has been on the Norwegian market for many years. The film preservative contained in the product presently on the Norwegian market is DCOIT. However, during the transitional period and prior to the deadline for application of national product authorisation, the applicant decided to substitute DCOIT with IPBC as film preservative. The main reason for deciding this substitution was to avoid the use of a substance with well known sensitising properties. Another reason was to adjust the composition of Visir Oljegrunning Pigmentert in order to make its composition comparable to Jotun's product for industrial use (Jotun Industri Grunning Visir).

Before submitting an application for national product authorisation, the applicant therefore decided to change the formulation in order to be able to substitute DCOIT with IPBC as film preservative. In fact, all product testing (phys-chem., efficacy and leaching studies) carried out for the current application has been performed with the new formulation containing IPBC as film preservative. However, this is actually not the formulation which presently is on the Norwegian market.

This decision was taken in close contact with the Norwegian Competent Authority. The Norwegian CA agreed that extensive testing of a formulation, which has been decided to be removed from the market, was not sensible. For the applicant it is important that the old formulation, containing DCOIT, can stay on the market until the new formulation is authorised and introduced on the market.

## 2.2 Classification, labelling and packaging

### 2.2.1 Classification of the biocidal product

On the basis of study results on the products and the concentration and properties of the active substance and formulants in the product, classification and labelling of Visir Oljegrunning Pigmentert 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:** | S2 | Keep out of the reach of children<br><br>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 Visir Oljegrunning Pigmentert 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:** | S2 - Keep out of the reach of children<br><br>Contains 3-iodo-2-propynyl-butylcarbamate and cobalt borate neodecanoate complexes. May produce an allergic reaction. |

### 2.2.3 Packaging of the biocidal product

Visir Oljegrunning Pigmentert is packed in containers made of clear coated steel or plastic (PP/PE). The biocidal product is supplied to the end market in 1, 3 and 10 liter 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 | 8/4 10 YR (Beige) | * |
| 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 | 450 ± 10°C | * |
| Other indications of flammability | n.a. | | |
| Acidity / Alkalinity | CIPAC MT 75 | 6.88 | * |
| Relative density / bulk density | OECD 109<br>OJEC A3 | 1.0239 | * |
| Storage stability – stability and shelf life | 2 years storage stability in warehouse-condition, dark and ambient temperature | Interim result after one year storage:<br>Tebuconazole concentration:<br>0.48% w/w initial concentration<br>0.65% w/w after 12 months storage | *<br>2 year storage will be submitted in spring 2012<br>Steel container |
| Storage stability – Accelerated Storage | Results from Accelerated Storage (CIPAC MT 46.1) | Tebuconazole concentration:<br>0.48% w/w initial<br>0.50% w/w after 14 days at 54 ± 2°C. | *<br>Steel container |
| Storage stability – effects of temperature | Results from low temperature storage (CIPAC MT 39.1) | Storage at 0 ± 1°C for 7 days. The test item was found to remain homogenous and no material settled out 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:<br>205 mPas (20°C)<br>181 mPas (40°C)<br><br>Interim result from stability testing (one year storage):<br>222 mPas (20°C)<br>198 mPas (40°C) | *<br>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)

### 2.3.2 Analytical methods

**Table 2.2: Analytical methods for tebuconazole and Visir Oljegrunning Pigmentert**

| | **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<br>Quantification was done by internal standard<br>Linearity was acceptable; $r^2 = 0.9999$<br>Overall mean recovery = 104% (99-107%); n = 3<br>Overall coefficient of variation = 3.1%<br>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 Physicochemical 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.

Visir Oljegrunning Pigmentert 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 Visir Oljegrunning Pigmentert 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 Visir Oljegrunning Pigmentert is not an oxidizing formulation. Visir Oljegrunning Pigmentert 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, Visir Oljegrunning Pigmentert 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 show that the measured concentration increased from 0.48% w/w initial to 0.65% 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 35 % 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 (0.48% initial, 0.50 % after 14 days) and also storage at low temperature showed stability. 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 and during low temperature storage. This is also in line with the initial nominal concentration of 0.68 % in samples used for the phys-chem studies (se 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. These storage stability studies were conducted with Visir Oljegrunning Pigmentert stored in steel containers. No information on storage stability of the product in PP/PE containers is available. Before Visir Oljegrunning Pigmentert 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 a period of 7 days, the test item was found to remain homogenous and no material settled out following centrifugation.

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

## 2.5 Effectiveness against target organisms

Visir Oljegrunning Pigmentert is used for preventive treatment of wooden claddings. It protects wood against wood destroying fungi (Basidiomycetes). Application is by brushing only.

### 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 Visir Oljegrunning Pigmentert.

The efficacy of Visir Oljegrunning Pigmentert 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 Visir Oljegrunning Pigmentert, containing 0.6% tebuconazole nominal, measured 0.52% (BAM, 2010; see Appendix 1 – reference list). Adequate protection was demonstrated for wood after a penetration treatment, with a retention of 61.7 kg/$m^3$ as tested according to EN113 (after EN73 or EN84 weathering treatment) (corresponding to 0.32 kg/$m^3$ tebuconazole related to a measured concentration of 0.52%). According to EN 559-1:2009 this corresponds to a surface treatment load of 123.4 g/$m^2$ (0.64 g/$m^2$ tebuconazole) of the tested product applied by superficial treatment. The minimum application rate prescribed for Visir Oljegrunning Pigmentert (with nominal concentration of 0.60% tebuconazole) is 8 $m^2$/L or 128 g/$m^2$ . This equals 0.765 g/$m^2$ tebuconazole and is thus higher than the rate shown to be efficient.

In addition to tebuconazole, Visir Oljegrunning Pigmentert 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 Visir Oljegrunning Pigmentert. 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 Visir Oljgrunning Pigmentert, is efficient against basidiomycetes. The efficacy testing of Visir Oljegrunning Pigmentert, 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 Visir Oljegrunning Pigmentert is re-formulated in the future, using another film preservative, new efficacy data should be provided.

The recommended application rate is 4-8 $m^2$/L depending on properties of the wooden surface, this corresponds to 0.77-1.53 g 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. However, as the product contains water, the applicant prescribes to use other products based on hydrocarbon solvents in winter time when temperatures below freezing point are expected.

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)

Visir Oljegrunning Pigmentert (VOP) 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 and is to be applied by brushing by both professionals and non-professionals.

To comply with the efficacy claim, a topcoat has to be applied. This topcoat should be applied within one month after application of the alkyd primer.

### 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

Visir Oljegrunning Pigmentert 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 studies on toxicology for human health have 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 bw/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 2.7.1. Threshold Limit for Human Health Risk Assessment**

| | Value | Study | SF |
|---|---|---|---|
| A(O)EL [2] | 0.03 mg/kg bw 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

Visir Oljegrunning Pigmentert does not contain any substances of concern with regard to human health.

### 2.7.1.3 Toxicology of the biocidal product

Visir Oljegrunning Pigmentert 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 Visir Oljegrunning Pigmentert and the aqueous formulation tested by Toner, and both products have water as the main solvent.

[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 on 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.

The most profound difference between these formulations is that Visir Oljegrunning Pigmentert contains almost 6 times higher concentration of binder and much less solvents (i.e. water and co-solvents) than the aqueous formulation. Due to the much lower a.i./binder ratio for Visir Oljegrunning Pigmentert, tebuconazole (being embedded in the paint matrix) is assumed to be less bioavailable in this product compared to the tested formulation. Consequently, the skin absorption of tebuconazole from Visir Oljegrunning Pigmentert 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) is used in the risk assessment of Visir Oljegrunning Pigmentert based on read across from the tested formulation.

### 2.7.2 Exposure

The product is a ready-to-use primer which is used for protection of exterior wood surfaces. The product is to be applied by brush by both professionals and non professionals (see chapter 2.6.1 for further information).

**General remark**

The workplace risk for industrial workers formulating Visir Oljegrunning Pigmentert 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.

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 the pattern of use (the frequency and duration of potential exposure) and the generic database exposure models presented in the Technical Notes for Guidance (TNsG) on Human Exposure to Biocidal Products (ECB, 2002) as revised by the User Guidance (ECB, 2004). These guidance documents were used when evaluating the active substance, tebuconazole (using the consumer product painting model 3 for assessing exposure to professionals and non-professionals applying wood preservatives by brushing) as well as other wood preservatives.

These guidance documents were replaced by a new version of TNsG on Human Exposure to Biocidal Products in June 2007 (ECB, 2007), which in addition to a written part includes the computerised databases, BEAT and Cons Expo.

Using the new guidance when evaluating products for authorisation would imply that the efforts made in the active substance evaluation period to harmonise exposure parameters based on the old guidance would not come to use. Discrepancies and questions on equal treatment of the applicants might result. Based on these considerations the Norwegian CA (reference member state) has decided to base the exposure assessment on the old guidance document.

Considerations made by the Human Exposure Expert Group (HEEG) on e.g. default values for penetration through PPE have been taken into account.

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 chapter 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. These are 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, Ref: Assessment Report on tebuconazole, European Commission, 2007) and the application method, skin exposure is the major source of systemic (and local) dose.

**Table 2.7.2 Identification of main paths of human exposure towards active substance from its use in the biocidal product**

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

**Table 2.7.3 Applications of wood preservation including concentrations in both the product and on/in wood**

| Field of use | Relative density | Concentration at which tebuconazole will be used in % weight/weight | Active substance in surface layer (based on application rate) |
|---|---|---|---|
| Painting by brushing | 1.0239 | 0,6 | 0,77 - 1.53 g/m$^2$ |

### 2.7.2.1 Exposure of professional users

***Mixing/loading***

Products are sold as ready to use products. Mixing/loading is therefore not a relevant task and is not assessed.

***Application***

Brushing outdoor may be associated with exposure, mainly by skin contact. Professionals apply wood preservatives occasionally. The average duration of the task when using the product, is estimated as 360 min (adjusted value used in several CA reports for PT 8 substances, as well as in BEAT for the brushing scenario).

The TNsG on Human Exposure to Biocidal Products provides several models to estimate exposure levels during brush painting: one for overhead indoor brush painting (Consumer product painting, Model 1) and two for outdoor painting of sheds and fences (Consumer product painting, Model 2 and 3). Consumer product painting model 1 returns much higher exposure values (especially with respect to hand exposure) than model 2 and 3.

Model 2 gives separate data for water-based and solvent-based products, but contains no data for inhalation. Dermal data are only provided as potential exposure. Model 3 contains data for inhalation exposure and for hand and feet exposure inside gloves and shoes.

Only model 1 and 3 are included in the User Guidance.

Exposure calculations have not been made using the Consumer product painting model 1 as:

- The intended use of the primer is for painting of exterior wood surfaces like house cladding and fences, i.e. the expected exposure will predominately be from painting with a brush directed to the side or downward rather than overhead painting.
- Painting with the primer will take place outdoor, rather than indoor.

The task description for the consumer product painting model 3 is “Brush painting sheds and fences outdoors direct from can using household gloves or no gloves by non-professionals”. The exposure data included in the model (Garrod et al. 2000) is also included in BEAT and is used as a reference source in the worked example for “Brush application of curative wood preservatives”(Reference data source:“Garden timber treatment data set”).

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 (where used) and next to footwear.
The model describes the exposure (potential and actual exposure) in mg in-use product per minute at a nominal density of 1.0 g/ml. Inhalation exposure is expressed as mg product $m^{-3}$ (time-weighted exposures). All data are expressed in terms of distributions.

Although no models are available for professional treatment of timber using a brush, it is proposed in the User guidance that the non-professional model should also be used to estimate exposure of professional operators applying wood preservatives by brush.

In the exposure calculations the indicative values proposed in the User Guidance for the respective simple database model have been used.

***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.

The only other relevant post-application task which may lead to some degree of exposure is the cleaning of the brush. Cleaning of brushes is not covered by any of the models in the

TNsG on human exposure to Biocidal Products. A worst case scenario was described in an HEEG opinion of August 2010 which was endorsed by the Technical Meeting in the Biocides Group in TMIII 2010 (HEEG, 2010b). The scenario was to be used for application of non water-based paints, primarily. For water based paints the brush are often cleaned under a running tap. The running water washes both the paint from the brush and any contamination from the hands, reducing exposure considerably.

Visir oljegrunning pigmentert is an oil based primer with water as main solvent. The brush should be cleaned according to the instruction given by the Applicant, avoiding cleaning under a running tap.

Description of the model in the endorsed HEEG document:

*"Cleaning the brush used for applying paint may be done by repeated dipping and swilling it in a vessel containing an appropriate solvent. A large brush might have a size of 10 x 10 x 2 cm, corresponding to a volume of 200 ml. It is assumed that after painting one eighth ($^1/_8$) of the brush volume is paint. Cleaning is assumed to be done in three steps, each time using fresh solvent. The volume at each step should be large enough to allow a sufficient dilution of the residues in the brush. For a brush having a volume of 200 ml the volume of the cleaning solvent would be at least 400 ml per step. Each washing step is assumed to result in an approximately 10-fold dilution of the residues in the brush (i.e. 10 % of the paint originally on the brush remains after one washing). After each step the brush is assumed to be squeezed by the hand to get rid of as much solvent as possible. It is assumed that with this step 50% of the solution in the washed brush is released and may potentially contaminate the hand. However, it is further assumed that the squeezing is not done by the bare hand but rather by wrapping it first with a cleaning rag, which absorbs 90% of the released liquid. It is assumed the brush is washed and squeezed for a maximum of 3 times.*

*It is emphasised, the described exposure scenario for washing out a brush reflects a worst-case situation which assumes <u>all</u> contamination remains on the hands at the end of the activity and is available for dermal absorption".*

**Table 2.7.4 Exposure models used for assessing exposure to professional users.**

| Exposure path | **Professional use : Brushing outdoor** | | | |
|---|---|---|---|---|
| | Mixing/loading | Application | Post application | Maintenance/ Cleaning |
| Inhalation | No exposure | Low exposure (TNsG on human exposure, consumer product painting model 3) | No exposure | No exposure |
| Dermal | No exposure | Significant exposure (TNsG on human exposure, consumer product painting, model 3) | Very limited exposure compared to application<br>No exposure calculation | Exposure when cleaning brush (HEEG opinion) |

| | | | | |
|---|---|---|---|---|
| Oral | No exposure | No exposure | No exposure | No exposure |

### 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.

A default penetration factor of 10% for coated coveralls, 25% for cotton coverall, and 10% for protective gloves was used in the calculations (Opinion by HEEG endorsed by the Technical Meeting in the Biocides Group in February 2010. HEEG, 2010a).

The default penetration value for cotton coveralls is according to the guidelines only applicable for dry substances. Cotton coveralls may offer little or no protection from wet substances and may lead to increased rather than reduced dermal exposure if the challenge is from a wet substance, by absorbing the liquid challenge and holding it next to the skin.

For coated coveralls two default values were 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.

A 90 % protection factor has been generally used for wood preservatives where the main challenge is from contact with preservative wet wood.

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 2.7.5. Assessment assumptions for primary exposure of professionals**

| | **Assumptions** | |
|---|---|---|
| | **Tier I** | **Tier II** |
| **Penetration of clothing** | 100 % | Tier IIa: 25% for cotton coverall<br>Tier IIb: 10 % for coated coverall<br><br>*(TNsG on human exposure, part 2 pg.36, 2002, User Guidance 2004, pg 42, HEEG, 2010a)* |
| **Gloves** | No gloves | Gloves |
| **Dermal uptake** | 100 % | 5 % |
| **Inhalation uptake*** | 100 % | 100 % |
| **Inhalation rate** (moderate physical activity) * | 1.25 $m^3$/hour | 1.25 $m^3$/hour |
| **Adult bodyweight*** | 60 kg | 60 kg |

** Generally agreed default values for the Biocides area*

The exposure calculations can be found in Appendix 3.

The estimated exposure to professionals is summarised in the tables below.

**Table 2.7.6. Estimated exposure to tebuconazole for professionals applying wood preservative by brushing**

| | Inhalation exposure (mg/kg bw/event) | Dermal exposure (mg/kg bw/event) | Total exposure (mg/kg bw/event) |
|---|---|---|---|
| **Tier I** | 0.00122 | **0.821** | **0.822** |
| **Tier IIa** | 0.00122 | 0.00867 | 0.00989 |
| **Tier IIb** | 0.00122 | 0.00411 | 0.00533 |

*Values in bold exceeding the A(O)EL of tebuconazole of 0.03mg/kg bw/day*

**Table 2.7.7. Estimated exposure to tebuconazole for professionals washing out of a brush**

| | Inhalation exposure (mg/kg bw/event) | Dermal exposure (mg/kg bw/event) | Total exposure (mg/kg bw/event) |
|---|---|---|---|
| **Tier I** | - | 0.000658 | 0.000658 |
| **Tier II** | - | 0.0000658 | 0.0000658 |

*Values in bold exceeding the A(O)EL of tebuconazole of 0.03mg/kg bw/day*

**Table 2.7.8. Estimated combined exposure of tebuconazole (brushing + washing out of brush) for professionals**

| | Inhalation exposure (mg/kg bw/event) | Dermal exposure (mg/kg bw/event) | Total exposure (mg/kg bw/event) |
|---|---|---|---|
| **Tier I** | 0.00122 | **0.822** | **0.823** |
| **Tier IIa** | 0.00122 | 0.00874 | 0.00996 |
| **Tier IIb** | 0.00122 | 0.00418 | 0.0054 |

*Values in bold exceeding the A(O)EL of tebuconazole of 0.03mg/kg bw/day*

### 2.7.2.2 Exposure of non-professional users and the general public

***Mixing/loading***

Products are sold as ready to use products. Mixing/loading is therefore not a relevant task and is not assessed.

***Application***

Brushing outdoor may be associated with exposure, mainly by skin contact. Non professionals (amateurs) apply wood preservatives very rarely, not more than once or twice a year. The average duration of the task when using the product, is 155 min a day according to the TNsG on human exposure to biocidal products (ECB, 2002).

In the exposure calculations for non professionals, the consumer product painting model 3, from the TNsG on human exposure to biocidal products (2002) has been used (see chapter 2.7.2.1 for further information on the model). The indicative values proposed in the User Guidance for the model have been used.

***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.

The only other relevant post-application task which may lead to some degree of exposure is the cleaning of the brush. Cleaning of brushes is not covered by any of the models in the TNsG on human exposure to Biocidal Products. A worst case scenario was described in an HEEG opinion of August 2010 which was endorsed by the Technical Meeting in the Biocides Group in TMIII 2010 (HEEG, 2010b). For further information on the scenario: see chapter 2.7.2.1.

**Table 2.7.9. Exposure models used for assessing exposure to non-professional users.**

| Exposure path | **Non-professional use : Brushing outdoor** | | | |
|---|---|---|---|---|
| | Mixing/loading | Application | Post application | Maintenance/ Cleaning |
| Inhalation | No exposure | Low exposure (TNsG on human exposure, consumer product painting model 3) | No exposure | No exposure |
| Dermal | No exposure | Significant exposure (TNsG on human exposure, consumer product painting, model 3) | Very limited exposure compared to application<br>No exposure calculation | Exposure when cleaning brush (HEEG opinion) |
| Oral | No exposure | No exposure | No exposure | No exposure |

## Personal Protective Equipment

Non-professionals may wear coveralls and gloves; however such usage cannot be assured and must not be assumed in exposure estimation. At the most, a non-professional may be expected to wear a long shirt, long trousers and footwear, irrespective of any label stipulation.

A default penetration factor of 50 % for long sleeved shirt and trousers with shoes (no gloves) was used in the calculations (Opinion by HEEG endorsed by the Technical Meeting in the Biocides Group in February 2010. HEEG, 2010a).

**Table 2.7.10. Assessment assumptions for primary exposure of non professionals**

| | Assumptions | |
|---|---|---|
| | **Tier I** | **Tier II** |
| **Penetration of clothing** | 100 % | 50% (long sleeved shirts and trousers, with shoes)<br><br>*(TNsG on human exposure, part 2 pg.34, 2002, HEEG, 2010a)* |
| **Gloves** | No gloves | No gloves |
| **Dermal uptake** | 100 % | 5 % |
| **Inhalation uptake*** | 100 % | 100 % |
| **Inhalation rate** (moderate physical activity) * | 1.25 $m^3$/hour | 1.25 $m^3$/hour |
| **Adult bodyweight*** | 60 kg | 60 kg |

** Generally agreed default values for the Biocides area*

The exposure calculations can be found in Appendix 3.

The estimated exposure to non-professionals is summarised in the tables below.

**Table 2.7.11. Estimated exposure to tebuconazole for non-professionals applying wood preservative by brushing**

| | Inhalation exposure (mg/kg bw/event) | Dermal exposure (mg/kg bw/event) | Total exposure (mg/kg bw/event) |
|---|---|---|---|
| **Tier I** | 0.000527 | **0.354** | **0.354** |
| **Tier II** | 0.000527 | 0.0111 | 0.0117 |

*Values in bold exceeding the A(O)EL of tebuconazole of 0.03mg/kg bw/day*

**Table 2.7.12. Estimated exposure to tebuconazole for non-professionals washing out of a brush**

| | Inhalation exposure (mg/kg bw/event) | Dermal exposure (mg/kg bw/event) | Total exposure (mg/kg bw/event) |
|---|---|---|---|
| **Tier I** | - | 0.000658 | 0.000658 |

*Values in bold exceeding the A(O)EL of tebuconazole of 0.03mg/kg bw/day*

**Table 2.7.13. Estimated combined exposure to tebuconazole (brushing + washing out of brush) for non-professionals**

| | Inhalation exposure (mg/kg bw/event) | Dermal exposure (mg/kg bw/event) | Total exposure (mg/kg bw/event) |
|---|---|---|---|
| **Tier I** | 0.000527 | **0.355** | **0.356** |
| **Tier II** | 0.000527 | 0.0118 | 0.0123 |

*Values in bold exceeding the A(O)EL of tebuconazole of 0.03mg/kg bw/day*

#### 2.7.2.3 Secondary (indirect) exposure

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. Exposure can occur as a single event (acute phase) or occur during long term (chronic phase).

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 2.7.14. 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]<br><br>10% extraction when chewing[3] | Leaching (immersion day 1)[4]: 13.41 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[6]:** | Worst case based on recommended application rates: 0.15 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: Retention measured in leaching studies in lab (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: 4 $m^2$/l. Density is taken into account

Tier 1 takes into account the recommended application rate for the product (worst case value). 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.

As for the scenario of cleaning of work wear at home, a transfer coefficient of 30 % is used for transfer of contamination from the coverall to wet hands.

The tier 2 scenario for infant chewing wood off-cut is based on actual data on leaching (leaching of tebuconazole to water from wood specimen treated three times with wood preservatives, 2 times 1 hour immersion regime, presented result for the first day of testing. Start of testing 25 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, ECB, 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 techniques, 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 $cm^3$ – (3.8 x 3.8 x 249.8) $cm^3$ = 393$cm^3$

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

0.15 x 4032/393 = 1.54 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. For amateurs, a time duration of 60 minutes and an inhalation rate of 1.25 $m^3$/hour is assumed. The density for soft wood is used as a worst case and a more realistic value than the density for hardwood (0.8g/$cm^3$) 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, 2011).

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: 1.54 mg/cm$^3$ × 0.0156 cm³ = 0.0241 mg tebuconazole
Exposure (inhalation, adult, 60 kg) = 0.00040 mg tebuconazole/kg bw

*Dermal exposure*

The tebuconazole concentration on the surface of timber is 0.15 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:

0.15 mg/cm$^2$ x 168 cm$^2$ x 0.02 = 0.504 mg tebuconazole on hands
Systemic exposure = 0.504 x 100% = 0.504 mg tebuconazole
Exposure (dermal, adult 60 kg) = 0.0084 mg tebuconazole/kg bw

Total Systemic Dose (inhalation + dermal): **0.0088 mg tebuconazole/kg bw** (60 kg adult)

**b) Infants chewing wood off-cut - ingestion route**

It is assumed that the infant (10 kg bw) 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 0.15 mg tebuconazole/cm$^2$.

40 cm$^2$ x 0.15 mg tebuconazole/cm$^2$ = 6 mg tebuconazole
Exposure (oral, infant, 10 kg) = (6 mg tebuconazole x 10%)/ 10 kg =
**0.06 mg tebuconazole/kg bw**

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

*Refinement:*

As a refinement leaching data might be used[4]:
40 cm$^2$ x 0.001341 mg a.s./cm$^2$ = 0.0536 mg a.s
Exposure (oral, infant, 10 kg) = 0.0536 mg tebuconazole/10 kg ≈
**0.0054 mg tebuconazole/kg bw**

[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.

## 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$^3$) are equivalent to 0.0938cm³ wood
0.0938 cm³ wood contains (1.54 mg/cm$^3$ × 0.0938 cm³/day) =
0.144 mg tebuconazole/day

Exposure (inhalation, adult, 60 kg) = 0.0024 mg tebuconazole/kg bw/day

*Dermal exposure*

The tebuconazole concentration on the surface of timber is 0.15 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:

0.15 mg/cm$^2$ x 168 cm$^2$ x 0.02 = 0.504 mg tebuconazole on hands
Systemic exposure = 0.504 x 100% (dermal uptake) = 0.504 mg tebuconazole
Exposure (dermal, adult 60 kg) = 0.0084 mg tebuconazole/kg bw/day

Total Systemic Dose (inhalation + dermal): 0.0108 mg tebuconazole/kg/day (60 kg adult)
≈ **0.011 mg tebuconazole/kg/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 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).

The concentration of tebuconazole at the wood surface is assumed to be 0.15 mg/cm$^2$.

0.15 mg/cm$^2$ × 840 cm² × 0.2 × 0.02 = 0.504 mg tebuconazole on hands
Systemic dose = 0.504 mg × 100% (dermal uptake) = 0.504 mg tebuconazole
Exposure (adult, 60 kg bw) = 0.0084 mg tebuconazole/kg/day

### c) Adult/Infant inhaling volatilised residues indoors

This is not considered relevant as the product is only for use on outdoor timbers.

### d) Child - playing on 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 transfer efficiency is taken from the TNsG as 2% for transfer of dried fluid to skin. The dermal absorption is 100% (default).
The concentration of tebuconazole at the wood surface is assumed to be 0.15 mg/cm².

0.15 mg/cm² × 200 cm² × 0.2 × 0.02 = 0.12 mg tebuconazole on hands
Systemic dose = 0.12 mg × 100% (dermal absorption) = 0.12 mg tebuconazole
Exposure (child, 15 kg bw) = **0.008 mg tebuconazole/kg/day**

### e) Infants - playing on 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 transfer efficiency is taken from the TNsG as 2%.
The concentration of tebuconazole on the wood surface is assumed to be 0.15 mg/cm².

0.15 mg/cm² × 200 cm² × 0.2 × 0.02 = 0.12 mg tebuconazole on hands
Systemic dose = 0.12 mg × 100% (dermal absorption) = 0.12 mg tebuconazole

*Oral exposure:*

In addition; licking the hands and assuming an oral uptake of 100%:

0.15 mg/cm² × 200 cm² × 0.2 × 0.02 = 0.12 mg tebuconazole on hands
Systemic dose = 0.12 mg tebuconazole

Exposure (infant, 10 kg bw) = 0.012 mg/kg bw tebuconazole per day via skin
+ 0.012 mg/kg bw tebuconazole per day oral uptake

Overall exposure (infant, 10 kg bw) = **0.024 mg tebuconazole/kg/day**

### f) Adults - cleaning work wear at home

Exposure duration is acute to short-term.
An additional scenario for home laundry of clothes has been introduced in several CA-reports for wood preservatives. Washing of contaminated work clothing (e.g. a coverall) is assumed to occur mechanically without any exposure to humans. Contact with effluent is unlikely to

occur. The only likely exposure will occur during handling of the contaminated clothing prior to introduction into the washing machine. The exposure route is dermal (mainly to hands) and is dependent on the area concentration of dislodgeable residues on the surface of the clothing and the transfer coefficient to the human skin.

It is assumed, that the clothing to be washed is a coverall used by a professional applicator (representing the worst case). The total surface of a medium size coverall is estimated to be 22,700 $cm^2$. Body contamination (without hands and feet) as calculated for a working day for professionals applying wood preservative by brushing are re-expressed as mg a.s./$cm^2$.

> The daily deposit of tebuconazole is 0.00161 mg/$cm^2$ (6084 mg x 0.6%/22700$cm^2$ = 0.00161 mg/$cm^2$)

It is assumed that the coverall is washed after one working week, i.e.5 working days, and the total residues accumulate during this time (account for 5-times the daily deposits). The total contamination for one working week accounts for 0,00805 mg/$cm^2$. Part of this residues will be dislodgeable, being on the surface of the tissue, but part will be within the tissue and therefore non-dislodgeable.

**Table 2.7.15.The applied assumptions and parameter are:**

| | |
|---|---|
| Surface of medium size coverall | 22,700 $cm^2$ |
| Maximum daily contamination of coverall (75%-ile) | 0.00161 mg a.s./$cm^2$ |
| No of working days before washing | 5 |
| Contamination after one working week | 0.00805 mg a.s./$cm^2$ |
| Transfer Coefficient for contamination (dried fluid) from cotton, knitwear to wet hands (TNsG, part 2, p. 206) | 30% |
| Total surface of two hands (front and back) | 840 $cm^2$ |
| Dermal absorption | 100 % |
| Body weight | 60 kg (females) |

Exposure calculations:

> Potential hand exposure during washing a contaminated coverall:
> (a.s on coverall x hand surface area x transfer coefficient x dermal absorption)/body weight
> (0.00805 mg tebuconazole/$cm^2$ x 840$cm^2$ x 0.3 x 100% )/60 kg =
> **0.0338 mg tebuconazole/kg ≈ 0.034 mg tebuconazole/kg bw**

**Table 2.7.16. Summary - Secondary exposure to tebuconazole - Surface treated wood**

| | **Scenario** | **Systemic dose** mg kg/bw (per day) | |
|---|---|---|---|
| | | **Tier I** | **Tier II** |
| Acute scenarios | Adult cutting and sanding treated wood | 0.0088 | - |
| | Infant chewing wood | **0.060** | 0.0054 |
| Chronic scenarios | Adult cutting and sanding treated wood | 0.011 | - |
| | Adults handling treated wood | 0.0084 | - |
| | Child playing on playground structure | 0.008 | - |
| | Infant playing on weathered (playground) structure and mouthing | 0.024 | - |
| | Home laundry of clothes | **0.034** | - |

*Values in bold exceed the A(O)EL value of tebuconazole of 0.03 mg kg$^{-1}$ bw per day*

### 2.7.2.4 Exposure to residues in food

Visir Oljegrunning Pigmentert 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 Users

**Table 2.17.Risk characterisation for Professional Users - Combined exposure (Brushing + washing out of the brush)**

| Exposure Scenario (indicate duration) | | Estimated Internal Exposure | | | | Relevant NOAEL [mg/kg bw/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) | 2 days/ week 47 weeks/ year | - | 0.00122 | 0.821 + 0.000658 | **0.823** | NOAEL: 3 (1yr dog) A0EL: 0.03 | 100 | **3.65** | **27.4** |
| **Tier IIa** (5% dermal absorption Cotton coverall: 25% penetration, gloves) | 2 days/ week 47 weeks/ year | | 0.00122 | 0.00867 + 0.0000658 | 0.00996 | NOAEL: 3 (1yr dog) A0EL: 0.03 | 100 | 301 | 0.332 |
| **Tier IIb** (5% dermal absorption Coated coverall, 10% penetration, gloves) | 2 days/ week 47 weeks/ year | - | 0.00122 | 0.00411 + 0.0000658 | 0.0054 | NOAEL: 3 (1yr dog) A0EL: 0.03 | 100 | 556 | 0.18 |

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

**Conclusion:**
Based on the exposure data presented in the TNsG 2002/User guidance (Consumer product painting model 3) and the HEEG opinion of August 2010 on washing out of brushes, the estimated exposure to professional is below the A(O)EL value, assuming use of protective clothing and protective gloves.

### 2.7.3.2 Risk for non-professional users

**Table 2.18. Risk characterisation for Non-Professional Users - Combined exposure (Brushing + washing out of the brush)**

| Exposure Scenario (indicate duration) | | Estimated Internal Exposure | | | | Relevant NOAEL [mg/kg bw/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) | 2 days/ week 1 week/ year | - | 0.000527 | 0.354 + 0.000658 | 0.356 | NOAEL: 3 (1yr dog) A0EL: 0.03 | 100 | **8.43** | **11.9** |
| **Tier II** (5% dermal absorption Minimal clothing, 50% penetration) | 2 days/ week 1 week/ year | - | 0.000527 | 0.0111 + 0.000658 | 0.0123 | NOAEL: 3 (1yr dog) A0EL: 0.03 | 100 | 244 | 0.41 |

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

**Conclusion:**
Based on the exposure data presented in the TNsG 2002/User guidance (Consumer product painting model 3) and the HEEG opinion of August 2010 on washing out of brushes, the estimated exposure to non-professional is below the A(O)EL value, assuming use of long sleeved shirts, trousers and footwear - but without gloves.

### 2.7.3.3 Risk for secondary exposure (indirect exposure)

**Table 2.19. Risk characterisation - Secondary (indirect) exposure**

| Exposure Scenario (indicate duration) | | Estimated Internal Exposure | | | | Relevant NOAEL [mg/kg bw/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] | | | | |
| **Acute scenarios** | | | | | | | | | |
| Adult cutting and sanding treated wood | Tier I | - | 0.00040 | 0.0084 | 0.0088 | NOAEL: 3 (1yr dog) A0EL: 0.03 | 100 | 341 | 0.29 |
| Infant chewing wood | Tier I | 0.060 | - | - | 0.060 | NOAEL: 3 (1yr dog) A0EL: 0.03 | 100 | **50** | **2** |
| | Tier II | 0.0054 | - | - | 0.0054 | | 100 | 555 | 0.18 |
| **Chronic scenarios** | | | | | | | | | |
| Adult cutting and sanding treated wood | Tier I | - | 0.0024 | 0.0084 | 0.011 | NOAEL: 3 (1yr dog) A0EL: 0.03 | 100 | 272 | 0.37 |
| Adults handling treated wood | Tier I | - | - | 0.0084 | 0.0084 | NOAEL: 3 (1yr dog) A0EL: 0.03 | 100 | 357 | 0.28 |
| Child playing on playground structure | Tier I | - | - | 0.008 | 0.008 | NOAEL: 3 (1yr dog) A0EL: 0.03 | 100 | 375 | 0.27 |
| Infant playing on weathered (playground) structure and mouthing | Tier I | 0.012 | - | 0.012 | 0.024 | NOAEL: 3 (1yr dog) A0EL: 0.03 | 100 | 125 | 0.8 |
| Home laundry of clothes | Tier I | - | - | - | 0.034 | NOAEL: 3 (1yr dog) A0EL: 0.03 | 100 | **88** | **1.1** |

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

The MOE is more than 100 for all scenarios, but the scenario for cleaning of work wear at home. For this latter scenario a (borderline) risk is identified. However, it should be kept in mind that a dermal absorption of 100% is used which is obviously a very conservative value.

#### 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 (primer for exterior wood; product not to be used on materials which are in direct contact with food or feeding stuff) is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

### 2.7.4 Summary of the Human health Risk Assessment

Based on the available exposure data and assuming use of PPE (protective clothing and gloves) the estimated exposure to professional users applying Visir Oljegrunning Pigmentert by brushing is below the established threshold limit (A(O)EL) for tebuconazole.

The estimated exposure to non professionals is correspondingly acceptable assuming use of long sleeved shirts, trousers and footwear - but without making the assumption that gloves are worn. This is in compliance with Annex VI, paragraph 73 of Dir. 98/8/EC: “If for non-professional users the wearing of personal protection equipment would be the only possible method for reducing exposure, the product shall not normally be authorised.”

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), handle treated wood or clean the work wear at home. 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, but the scenario for cleaning of work wear where a borderline risk is identified. However, it should be kept in mind that a dermal absorption of 100% was used in the calculation which is obviously a very conservative value. Hence, it can be concluded that the normal use of tebuconazole-treated material should not pose an acute or chronic health risk for humans.

Adults are the only subpopulation who may reasonably experience both primary and secondary exposure to tebuconazole originating from Visir Oljegrunning Pigmentert. Professionals who are involved in application of wood preservatives as well as cutting and sanding of treated wood will, according to the exposure calculations, still have an exposure below the threshold limit.The estimated exposure for home laundry of work wear is high, and the estimated combined exposure from professionals’ brushing and home laundring of work wear, is above the AEL. However, the estimated exposure from home laundry of work wear is based on conservative default values.

The use of tebuconazole in Visir Oljegrunning Pigmentert can be considered safe for professional and non-professional users. Furthermore, the use of wood treated with Visir Oljegrunning Pigmentert does not pose an unacceptable risk for human health through secondary exposure . Thus 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 Visir Oljegrunning Pigmentert and wood treated with it, is considered safe for all subpopulations.

## 2.8 Risk assessment for the environment

Visir Oljegrunning Pigmentert contains 0.6 % tebuconazole as the only PT 8 active substance and 0.1-0.25 % cobalt borate neodecanoate complexes (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-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 2.8.1: 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 for tebuconazole, the following PNEC values 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 complexes**

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 ECHA's database ECHA CHEM, under Registered Substances (link to ECHA CHEM see Appendix 1 – reference list). The PNEC values seem to be based on data on both cobalt borate neodecanoate and other cobalt compounds. 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 complexes 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., 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 122 mg/m$^2$. The 30 days average leach rate is therefore 4.07 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 using samples both without a topcoat and with topcoat 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, 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 by brushing. One litre of the product covers 4-8 $m^2$ of wood, depending on the properties of the wooden surface. The maximum application rate is therefore 4 $m^2$/L. The density of the product is 1.02 kg/L and with this the maximum retention of Visir Oljegrunning Pigmentert can be calculated:

4 $m^2$ wood /L product = 0.25 L product /$m^2$ wood = 0.255 kg product / $m^2$ wood = 1.53 g teb./$m^2$.

The retention in semi-field leaching study was 1.40 g tebuconazole / $m^2$. As the maximum retention applied for is 1.53 g teb. / $m^2$, the results of the leaching study have to be multiplied with a correction factor of 1.093.

To comply with the efficacy claim, a topcoat has to be applied. This topcoat should be applied within one month after application of Visir Oljegrunning Pigmentert. 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 one month, 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 2.8.2: Data from semi-field study for tebuconazole for uncoated samples**

| | Days | Rain (mm) | Volume/L | Tebuconazole (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 | 2.5 | 2.40 | 1 | 7.35 | 7.35 | 0.349 |
| | 76 | 143.3 | 1.9 | 1.20 | 2 | 2.79 | 10.15 | 0.052 |
| | 138 | 266.7 | 7.3 | 0.92 | 3 | 8.23 | 18.38 | 0.128 |
| | 198 | 483.4 | 18 | 0.56 | 4 | 12.35 | 30.73 | 0.109 |
| | 355 | 678.7 | 22.9 | 0.34 | 5 | 9.40 | 40.13 | 0.092 |
| **Replicate 2** | 29 | 40.4 | 2.3 | 2.05 | 1 | 5.78 | 5.78 | 0.274 |
| | 76 | 143.3 | 1.6 | 1.20 | 2 | 2.35 | 8.13 | 0.044 |
| | 138 | 266.7 | 7.2 | 0.92 | 3 | 8.12 | 16.25 | 0.126 |
| | 198 | 483.4 | 17.6 | 0.60 | 4 | 12.94 | 29.19 | 0.115 |
| | 355 | 678.7 | 22.3 | 0.30 | 5 | 8.20 | 37.39 | 0.081 |
| **Replicate 3** | 29 | 40.4 | 2.4 | 2.40 | 1 | 7.06 | 7.06 | 0.335 |
| | 76 | 143.3 | 1.9 | 1.25 | 2 | 2.91 | 9.97 | 0.054 |
| | 138 | 266.7 | 7.3 | 0.91 | 3 | 8.14 | 18.11 | 0.127 |
| | 198 | 483.4 | 18.3 | 0.60 | 4 | 13.46 | 31.57 | 0.119 |
| | 355 | 678.7 | 23.6 | 0.415 | 5 | 12.00 | 43.57 | 0.118 |

<u>Interpretation of the tebuconazole data</u>

- Time 1 = 30 days:

  The cumulative amount leached out during the first 30 days was 9.58 $mg/m^2$. This value was calculated by using the amount leached out during the first period over 29 days (6.73 $mg/m^2$, which is the mean of 3 replicates) and normalizing it to 700 mm precipitation. This calculation results in a leaching rate of 0.319 $mg/m^2$ day. Applying the correction factor of 1.093 to account for the maximum retention applied for leads to the leach rate of **0.349 $mg/m^2$ day**, which will be used for PEC calculations for tebuconazole for Time 1.

- Time 2 = 5 years:

  The study was conducted over one year and as the service life of wood preservative products applied by brushing is 5 years (1825 days), a long-term leach rate has to be established.

  When using the extrapolation approach as outlined in Annex II of ESD for PT 8 results show that leach rates after 5 years are as high as after 1 year (for this calculation the period 2 value was excluded due to very low sampled rain volume). The reason for this finding is presumably that the leaching rate after 138 days was only slightly decreasing;

from 0.127 mg/m$^2$ per day at day 138 to 0.114 mg/m$^2$ per day at 198 days and finally to 0.097 mg/m$^2$ per day after one year. Therefore, extrapolating with the measured values of the 1 year semi-field study leads to a fitted curve, where leaching is constant after one year.

Therefore, as a first tier, long-term PECs were calculated using the cumulative leaching over one year (41.6 mg/m$^2$, mean of three replicates, normalized to standard rainfall) and by dividing it by 365 days resulting in a one-year leach rate of 0.114 mg/m$^2$ day. Applying the correction factor of 1.093 leads to the following leach rate of **0.125 mg/m$^2$** day, which will be used for Time 2 PEC calculations for tebuconazole.

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 2.8.3: Data from semi-field study for cobalt for uncoated samples**

| | Days | Rain (mm) | Volume/L | Cobalt (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 | 2.5 | 1.88 | 1 | 5.76 | 5.76 | 0.273 |
| | 76 | 143.3 | 1.9 | 1.13 | 2 | 2.63 | 8.39 | 0.049 |
| | 138 | 266.7 | 7.3 | 0.87 | 3 | 7.77 | 16.2 | 0.121 |
| | 198 | 483.4 | 18 | 0.28 | 4 | 6.15 | 22.3 | 0.054 |
| | 355 | 678.7 | 22.9 | 0.13 | 5 | 3.58 | 25.9 | 0.035 |
| **Replicate 2** | 29 | 40.4 | 2.3 | 1.74 | 1 | 4.90 | 4.90 | 0.233 |
| | 76 | 143.3 | 1.6 | 1.27 | 2 | 2.49 | 7.39 | 0.046 |
| | 138 | 266.7 | 7.2 | 0.92 | 3 | 8.11 | 15.5 | 0.126 |
| | 198 | 483.4 | 17.6 | 0.25 | 4 | 5.45 | 21 | 0.048 |
| | 355 | 678.7 | 22.3 | 0.14 | 5 | 3.85 | 24.8 | 0.038 |
| **Replicate 3** | 29 | 40.4 | 2.4 | 1.92 | 1 | 5.63 | 5.63 | 0.267 |
| | 76 | 143.3 | 1.9 | 1.24 | 2 | 2.88 | 8.5 | 0.054 |
| | 138 | 266.7 | 7.3 | 0.96 | 3 | 8.56 | 17.1 | 0.133 |
| | 198 | 483.4 | 18.3 | 0.30 | 4 | 6.75 | 23.8 | 0.060 |
| | 355 | 678.7 | 23.6 | 0.14 | 5 | 4.11 | 27.9 | 0.040 |

Interpretation of the cobalt data

Cobalt borate neodecanoate complexes 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 0.258 mg/m$^2$ day and 0.074 mg/m$^2$ d, respectively. Applying the correction factor of 1.093 leads to **Time 1 and Time 2 leach rates of 0.282 mg/m$^2$ day and 0.081 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 for STP, surface water, sediment and soil

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

During formulation of Visir Oljegrunning Pigmentert, 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 Visir Oljegrunng Pigmentert, 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 Visir Oljegrunning Pigmentert, 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”.

Regarding the use-phase of Visir Oljegrunning Pigmentert, calculations of predicted environmental concentrations (PECs) for tebuconazole and cobalt for tier 1 (without taking into account degradation/dissipation) have been carried out according to the Emission Scenario Document (ESD) for wood preservatives (OECD, 2003) and the Technical Guidance Document on Risk Assessment (TGD; ECB, 2003). Tier 2 PECs (including degradation/dissipation) have been calculated 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 using the ESD equations, relatively large differences between the Time 2 (5 year) soil PECs from professional and amateur use in the house scenario were found, which would have to originate from the in-situ brushing of the wood. When calculating the in-situ PECs at Time 2 separately, using single first order kinetics, these were negligible (in the order of 1E-08 mg/kg wwt soil) for both professional and amateur use. The PECs resulting from service life leaching are approximately $10^6$ times higher; therefore the in-situ emission will not affect the total soil PEC at Time 2. However, using the ESD equation which is meant to take into account both the in-situ emissions and service life leaching, there were differences between the PECs resulting from professional and amateur use at Time 2. This did not seem correct, and it was considered more appropriate to follow the guidance given in FOCUS instead.

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

As the product is only to be applied by brushing, emissions from industrial application and hence from storage do not have to be taken into consideration.

Visir Oljegrunning Pigmentert is intended to be used 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 can be considered worst case and therefore cover emissions from the fence scenario. Regarding the noise barrier scenario, no in-situ treatment is assumed and only losses due to leaching during service life are considered. This is considered to be in accordance with the ESD for wood preservatives.

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**

The following leach rates are used for PEC calculations:

- Time 1 PECs (30 days) were calculated using the leach rate of 0.349 mg/m$^2$ day.
- Time 2 PECs (5 years) were calculated using the leach rate of 0.125 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. Where relevant, the concentrations resulting from emissions during in-situ brushing and leaching during service life were added.

Tier 2 PECs of tebuconazole were calculated in soil and surface water in the bridge over pond scenario, taking into account degradation and dissipation. In the noise barrier scenario, tier 2 PECs were only calculated for the soil compartment as 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 in-situ treatment (one emission event with subsequent degradation/dissipation), a single first-order kinetics equation was used to calculate the residual amount of a.s. after Time 1 and Time 2 ($PEC_0$ is the initial PEC directly after the brushing event):

$$PEC_t = PEC_0 \times e^{-kt}$$

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):

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

For scenarios where both in-situ treatment and service life leaching is foreseen, the in situ $PEC_t$ and the service life $PEC_{twa}$ were added.

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, average 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 2.8.4 Tier 1 PECs for tebuconazole**

| 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, amat. | 0.51 | 1.79 | - | - | - | - | - | - |
| House, prof. | 0.33 | 1.61 | - | - | - | - | - | - |
| Noise barrier | 0.02 | 0.48 | 0.03 | 0.01 | 6.5E-04 | 2.3E-07 | 0.29 | 0.10 |
| Bridge, amat. | - | - | 43.5 | 152 | 0.97 | 3.40 | - | - |
| Bridge, prof. | - | - | 28.2 | 137 | 0.63 | 3.06 | - | - |

**Table 2.8.5 Tier 2 PECs for tebuconazole, 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, amat. | 0.40 | 0.08 | - | - | - | - | - | - |
| House, prof. | 0.26 | 0.08 | - | - | - | - | - | - |
| Noise barrier | 0.02 | 0.03 | - | - | - | - | - | - |
| Bridge, amat. | - | - | 27.7 | 3.88 | 0.92 | 0.43 | - | - |
| Bridge, prof. | - | - | 18.3 | 3.88 | 0.60 | 0.41 | - | - |

## PECs for cobalt

The following leach rates are used for PEC calculations:

- Time 1 PECs (30 days) were calculated using the leach rate of 0.282 $mg/m^2$ day.
- Time 2 PECs (5 years) were calculated using the leach rate of 0.081 $mg/m^2$ day.

The ecotoxicity of cobalt borate neodecanoate complexes 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 the noise barrier scenario, release to an STP is foreseen. As no adsorption data for cobalt is available, as a simplification and worst case for the aquatic compartment, 100 % partitioning to the water phase is assumed.

The Bridge over Pond scenario PECs were not calculated for cobalt, since risks were already identified for tebuconazole alone in this scenario (please 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 2.8.6 Tier 1 PECs for cobalt**

| 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, amat. | 0.23 | 1.05 | - | - | - | - | - | - |
| House, prof. | 0.16 | 0.98 | - | - | - | - | - | - |
| Noise barrier | 0.02 | 0.31 | 0.03 | 0.01 | 2.3E-05 | 6.6E-09 | 0.30 | 0.08 |

## 2.8.3 Risk characterisation

A risk characterisation for tebuconazole and cobalt – and the combined risk assessment based on mixture toxicity approach – has been carried out for the uncoated samples. For tebuconazole, tier 2 PECs taking into account degradation/dissipation were used for risk assessment, while for cobalt, the risk assessment is based on Tier 1 PECs.

### 2.8.3.1 Risk Characterisation of Tebuconazole in Visir Oljegrunning Pigmentert

**Table 2.8.7 PEC/PNEC ratios for tebuconazole 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, amat. | **3.97** | 0.82 | - | - | - | - | - | - |
| House, prof. | **2.60** | 0.82 | - | - | - | - | - | - |
| Noise barrier* | 0.19 | 0.29 | 0.03 | 0.01 | 1.2E-03 | 4.2E-07 | 9.0E-04 | 3.2E-04 |
| Bridge, amat. | - | - | **27.7** | **3.88** | **1.67** | 0.77 | - | - |
| Bridge, prof. | - | - | **18.3** | **3.88** | **1.08** | 0.75 | - | - |

* 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.

**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 tebuconazole concentrations (without biodegradation/dissipation). For Bridge over Pond a risk was identified for Time 1 for surface water and sediment both for amateur and professional use. When looking at the in-situ and service life scenarios separately, it is clear that the risks for Bridge over Pond during Time 1 are caused both by losses due to application and by leaching during Time 1.
- Soil: No risk was identified for the Noise Barrier scenario in soil for Time 1, even if PEC/PNEC ratios are based on Tier 1 concentrations. In the House scenario, a risk is identified for soil for Time 1. However, this risk results primarily from losses during in-situ treatment of wood and not from leaching during Time 1 service life, as shown in the Table below.

**Table 2.8.8 PECs tebuconazole – differentiated between in-situ treatment and service life**

| Scenario | PEC soil ($mg/kg_{wwt}^{-1}$) | | | |
|---|---|---|---|---|
| | In-situ treatment | | Service life (leaching) | |
| | Time 1 | Time 2 | Time 1 | Time 2 |
| House, amateurs | **0.34*** | 3.3E-08 | 0.05* | 0.08 |
| House, professionals | **0.21*** | 2.0E-08 | | |

* With a PNECsoil for tebuconazole of 0.1 mg/kg wwt it becomes clear that the risk after 30 days results from in-situ treatment.

**Summary tebuconazole for Time 2**

- STP, surface water and sediment: No risk was identified for STP, surface water and sediment in the Noise Barrier scenario and for sediment in the Bridge over Pond scenario. However, a risk to surface water at Time 2 was identified in the Bridge over Pond scenario.

- Soil: At Time 2, no risk was identified for soil in the Noise Barrier scenario even if PEC/PNEC ratios are based on Tier 1 concentrations. No risk was identified for soil in the House scenario, neither for amateur nor professional use.

No secondary poisoning risk assessment has been conducted due to very low surface water concentrations in the Noise Barrier scenario. Higher PECs were calculated for the Bridge over Pond scenario; however, the use of Visir Oljegrunning Pigmentert will be restricted near surface water (see chapter 2.8.4).

### 2.8.3.2 Risk characterisation of cobalt in Visir Oljegrunning Pigmentert

**Table 2.8.9 PEC/PNEC ratios for cobalt 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, amat. | 0.03 | 0.15 | - | - | - | - | - | - |
| House, prof. | 0.02 | 0.14 | - | - | - | - | - | - |
| Noise barrier | 2.6E-03 | 0.04 | 0.06 | 0.02 | 1.1E-05 | 3.2E-09 | 8.0E-04 | 2.3E-04 |

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 for amateur and professional use.

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

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<br>Time 2: < 0.01 |
| Surface water: | Time 1: 0.09<br>Time 2: 0.03 |
| Sediment: | Time 1: < 0.01<br>Time 2: < 0.01 |
| Soil: | Time 1: 0.19<br>Time 2: 0.33 |

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, amateurs: **4.0**
  Time 1, professionals: **2.62**

- Time 2, amateurs: 0.97
  Time 2, professionals: 0.96

The combined Time 1 PEC/PNECs are only above one due to high emissions during in-situ treatment. The Time 1 PEC/PNEC ratio based solely on in-service leaching emissions is below one also for the combined risk assessment. The PEC/PNEC for Time 1, in-service leaching, based on mixture toxicity is 0.56 (PEC/PNEC tebuconazole = 0.5 and PEC/PNEC cobalt = 0.06).

### 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 the Use Class 3 scenarios Noise Barrier, House and Bridge over Pond with brushing as application mode. For calculation of environmental concentrations for Time 1 = 30 days and Time 2 = 5 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 complexes is a substance of concern with respect to environment). For tebuconazole, tier 2 PECs taking into account degradation/dissipation were used for risk assessment, while for cobalt, the risk assessment is based on Tier 1 PECs.

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 for Time 2, amateur and professional use, and for the Noise Barrier scenario (Time 1 and 2)

In the House scenario, a risk to soil was identified for Time 1, amateur and professional use; however, this risk is due to losses from application. PEC/PNEC ratios based only on 30 days in-service leaching show safe use.

For the Bridge over Pond scenario a risk to surface water for Time 1 and Time 2 was identified for tebuconazole alone (amateur and professional use). Therefore, no combined risk characterisation with cobalt has been carried out.

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) The soil has to be covered during application of the wood preservative product.

(ii) The product must not be used near surface water

(iii)Run-off to surface water has to be prevented.

(iv)Not to be used on materials which are 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, CO2, 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.

# 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 Visir Oljegrunning Pigmentert. The authorisation of the product Visir Oljegrunning Pigmentert as wood preservative is therefore granted with the use conditions and restrictions outlined in chapter 3.1.The registration number is NO-2011-0003.

Visir Oljegrunning Pigmentert 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 Visir Oljegrunning Pigmentert will then be sent to the Norwegian Competent Authority.

## 3.1 Summary of Use Conditions and Restrictions for Visir Oljegrunning Pigmentert

Visir Oljegrunning Pigmentert 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 amateur and professional use

(ii) Application method: Brush only

(iii) For external use only in Use Class 3

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

(v) The maximum application rate is 4 $m^2$/L (1.53 g tebuconazole /$m^2$ corresponding to 0.25 L or 0.255 kg product /$m^2$)

(vi) To comply with the efficacy claim, a topcoat has to be applied. The topcoat should be applied within one month after application of Visir Oljegrunning Pigmentert.

(vii) Appropriate and suitable PPE (coverall and gloves) has to be used by professionals.

(viii) The soil has to be covered during application of the wood preservative product.

(ix) The product must not be used near surface water and run-off to surface water has to be prevented.

(x) Not to be used on materials which are in direct contact with water and/or soil.

(xi) Not to be used on materials which are in direct contact with food or feeding stuff.

(xii) 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) S2 Keep out of reach of children

(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 Visir Oljegrunning Pigmentert 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 Visir Oljegrunning Pigmentert in PP/PPE has to be submitted. Moreover, new efficacy testing of Visir Oljegrunning Pigmentert will have to be required in case of a re-formulation involving changes in use of film preservative.

Norwegian Competent Authority

November 2011

# Appendix 1 – Reference list

| Author(s) | Year | Title | Data protection claimed | Owner |
|---|---|---|---|---|
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| Balloch, S. | 2010 | Validation of Methodology for Tebuconazole, Propiconazole, Thiachloprid and Iodocoarb<br>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<br>Report Amendment 1 | Yes | Jotun A/S |
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| 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":<br>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., Guiver, R. and Rimmer, D.A. | 2000 | Potential exposure of amateurs (consumers) through painting wood and preservative and antifouling preparations. Annals of Occupational Hygiene 2000;**44**(6):pp 421 – 426.<br>Published | No | Public |
| Human Exposure Expert Group | 2010a | HEEG opinion on default protection factors for protective clothing and gloves, Agreed at TMI2010. Published | No | Public |

| Author(s) | Year | Title | Data protection claimed | Owner |
|---|---|---|---|---|
| (HEEG) | | | | |
| Human Exposure Expert Group (HEEG) | 2010b | HEEG opinion on Exposure model. Primary exposure scenario – washing out of a brush which has been used to apply a paint. Agreed at TMIII 2010. Published. | No | Public |
| Klamer, M. and Venås, T. M. | 2011 | Leaching of IPBC and Tebuconazole from Wood Treated with Jotun Visir Oljegrunning Pigmentert – One year of Exposure. Danish Technological Institute. Project 1900026; Order no. 345846-3 | Yes | Jotun A/S |
| Klamer, M. and Venås, T. M. | 2011 | Leaching of Cobalt from wood treated with Jotun Visir Oljegrunning Pigmentert – One year of Exposure. Danish Technological Institute, Project no 1900026, Order no 345846-3A | Yes | Jotun A/S |
| Lindegaard, B. | 2009 | Test Report Visir Oljegrunning Pigmentert. Danish Technological Institute, Wood and Textile, Taastrup, Denmark. Project no 1006657-17, Ordre No. 319962-B | 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 | Efficacy testing according to DIN EN 113: 1996 Wood preservatives. Test method for determining the protective effictiveness against wood destroying basidiomycetes. Determination of Toxic values in combination with DIN EN 73: 1990 Wood preservatives. Accelerated ageing test of treated wood prior to biological testing – evaporative ageing procedure". BAM Bundesanstalt für Materialforschung und –prüfung, Lab. report no. IV.18316 BaB | Yes | Jotun A/S |
| Toner, F. | 2006 | The In vitro Percutaneous Absorption of Radiolabelled Tebuconazole in Two Wood Protection Formulations through Human Skin. | Yes | Lanxess |

| Author(s) | Year | Title | Data protection claimed | Owner |
|---|---|---|---|---|
| | | Included in the Competent Autority Report on Tebuzonazole from December 2007, Document IIIB, section B6.4 | | |

# 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**<br>**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.<br>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.<br>Routine samples were supported with double and single blank | |

| | | |
|---|---|---|
| | samples of the same formulation in addition to quality control samples prepared in triplicate.<br><br>The following reagents were used during the study. Chemicals were of analytical grade unless otherwise stated:<br>MilliQ Water In House Charles River<br>Acetonitrile HPLC Grade Rathburn Chemicals<br>Glacial Acetic Acid Analytical Grade Fisher<br><br>The following equipment was used throughout the study:<br>Balance: Mettler Toledo AE100<br>Pipettes: Gilson Microman<br>Vortex mixer: IKA MS3 Basic<br>Centrifuge: Jouan GR422<br>Sonic Bath: Decon F5400b<br>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.<br><br>HPLC: Waters Alliance 2695 with Waters 486 Tunable detector<br><br>Column: Zorbax RX-C8, 250 x 4.6 mm, 5 µm<br><br>Injection Volume: 5 µL<br><br>Mobile Phase: 50:50 (v/v) 0.5% Acetic Acid (aq.) / Acetonitrile<br><br>Flow Rate: 1.0 mL/min<br><br>Temperature: Ambient<br><br>Detection: u.v. at 225 nm<br><br>Run Time: 30 min<br><br>Retention Times: Tebuconazole at ca 12.6 min<br><br>Penconazole at ca 15.5 min<br><br>Data Handling: Thermo LabSystems Atlas 2002, Release 1<br><br>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 4** **Assay Accuracy and Precision: Tebuconazole in Visir Oljegrunning Pigmentert 2 Formulation – Method No. 1533A**

| Concentration (µg/mL) | Equivalent Concentration (% w/w) | Determined Concentration (µg/mL) | Recovery (%) | Mean Recovery (%) | Coefficient of Variation (%) |
|---|---|---|---|---|---|
| 149 | 0.15 | 148<br>153<br>150 | 99.3<br>102.7<br>100.7 | 100.9 | 1.7 |
| 250 | 0.25 | 268<br>263<br>266 | 107.2<br>105.2<br>106.4 | 106.3 | 0.9 |

Overall mean recovery = 103.6%
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 (Appendix 1).
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<br>1.3734<br>1.3731<br>1.3747<br>1.3764<br>1.3722<br>1.3701<br>1.3748<br>1.3744<br>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 Visir Oljegrunning Pigmentert were assayed for active ingredient content by addition of internal standard solution and mobile phase followed by HPLC with u.v. detection.<br><br>A validated analytical method for the analysis of tebuconazole in Visir Oljegrunning Pigmentert was required. The method was validated with respect to linearity of response, system suitability, assay accuracy and precision, system precision and specificity.<br><br>Fungicide free Visir Oljegrunning Pigmentert 2 batch number TGV-0509 formulation was received from the sponsor on 20 May 2009. It had a neutral, yellow 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.<br><br>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.<br>Linearity was established for Tebuconazole at 0.1 to 0.3 % w/w equivalents in the formulation.<br>The analytical methods were acceptable in terms of column efficiency, calculated tailing factor and resolution ratio.<br>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.<br>The accuracy and precision (coefficient of variance, CV) of each method was assessed and found to be acceptable for the analyte in the formulation.<br><br>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**

## Section B4 Analytical methods for detection and identification

**Annex Point IIB IV.4.1**

| | 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 | | | Official use only |
|---|---|---|---|
| **5.1** | **Product type(s) and field(s) of use envisaged (IIB5.1)** | Visir Oljegrunning Pigmentert is a water repellent primer for wood protection (PT8).<br>Visir Oljegrunning Pigmentert is used for protection of exterior wood surfaces like house cladding and fences (use class 3). To be applied outdoors on wood by using a brush. | |
| **5.1.1** | **Product type(s)** | MG02: Preservatives Product type PT08 | |
| **5.1.2** | **Overall use pattern** | To be applied by brush once in the lifetime of the cladding/ fence. | x |
| **5.2** | **Method of application including description of system used (IIB5.2)** | Not to be diluted. Ready to use. To be applied on wood by using a brush.<br>Topcoat to be applied as soon as possible and within 1 month after applying primer. | 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 4-8 $m^2$ of wood depending on properties of the wooden surface. Concentration of a.i. 0,6% | |

| **Section B5** | | **Effectiveness against target organisms and intended uses** | |
|---|---|---|---|
| **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). On wood endings; 3-4 coatings (wet-in-wet).<br>To be over coated with a top coat within 1 month (2-3 layers of top-coat) | x |
| **5.5** | **Function (IIB5.5)** | Wood preservative, PT 8 for use class 3.<br>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 (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** | Visir Oljegrunning Pigmentert 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.<br>Ref. dossier of Tebuconazole. | |
| **5.9** | **User: industrial, professional, general public (non-professional) (IIB5.9)** | | |
| | **1. Industrial** | Not applicable. | |
| | **2. Professional** | Professionals will apply the product by brush. | |
| | **3. General public** | Non-professionals will apply the product by brush. | |
| **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 Ref Label Folder Doc I | |
| **5.10.2** | **Efficacy data** | Protective effectiveness against wood destroying basidiomycetes: The mean toxic value for Visir Oljegrunning Pigmentert is 123 g/m$^2$.<br>This corresponds to 0,74 g/m$^2$ tebuconazole. | x |

| **Section B5** | | **Effectiveness against target organisms and intended uses** |
|---|---|---|
| **5.11** | **Any other known limitations on efficacy including resistance (IIB5.10)** | Resistance against the actives used in Visir Oljegrunning Pigmentert for wood preservation is not reported or known up to the time being. More detailed information regarding the active ingredients can be found in the active ingredient dossiers. |
| **5.11.1** | **Use-related restrictions** | None |
| **5.11.2** | **Prevention of the development of resistance** | None |
| **5.11.3** | **Concomitant use with other (biocidal) products** | Standalone product. No data available on mixtures with other substances or biocidal 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 | Manual application by brushing | |

**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 | Brushing | Only one coat (application). On wood endings; 3-4 coatings (wet-in-wet). | On wood endings; 3-4 coatings (wet-in-wet). | Not applicable | |

| **Evaluation by Competent Authority** | |
|---|---|
| **Date** | March 7th 2011 |
| **Comments** | **Comment (5.1.2):** In the use instruction also use on previously treated surfaces is indicted. Also on the label it is stated that previously treated woodwork had to be cleaned with a suitable detergent and that loose paint and wood fibreshad to be removed prior to treatment.<br><br>**Comment (5. 2 and 5.4):** According to the label and technical data sheet a topcoat has to be applied within 1 month<br><br>**Comment (5.10.2):** The EN113 tests were run only with one retention corresponding to an application rate of 123 g/m$^2$ and this retention passes the criteria for all three fungi tested. This concentration cannot be regarded as an indication for being 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 in the active substances dossier for Tebuconazole. The mean toxic value is thus below the tested uptake of 123 g/m$^2$ corresponding to 0.74 g/m$^2$ tebuconazole. The calculated critical value for the application of tebuconazole of 0.74 g/m$^2$ is based on the nominal concentration (0.6 % tebuconazole). Based on the measured concentration (0.52 % tebuconazole) the critical value is below 0.64 g/m$^2$. |
| **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.<br><br>The studies submitted for Visir Oljegrunding Pigmentert 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 |
|---|---|---|---|
| | | **REFERENCE** | |
| **1.1** | **Reference** | **Author:** Dr. R. Plarre<br>**Year:** 2010<br>**Title:** Test report Visir Oljegrunning Pigmentert 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 84: 1997 Wood preservatives. Accelerated ageing of treated wood prior to biological testing. Leaching procedure.<br>**Lab. name:** BAM Bundesanstalt für Materialforschung und -prüfung<br>**Lab. report no**: IV.1/8316 BaA<br>**Report date:** 3.11.2010 | 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 | Visir Oljegrunning Pigmentert | |
| 2.1.2 | Composition of Product tested | Visir Oljegrunning Pigmentert alt 28.<br>Detailed composition is given in Confidential folder. Concentration of ai tebuconazole 0,6% | |
| 2.1.3 | Physical state and nature | Liquid | |
| 2.1.4 | Monitoring of active substance concentration | Yes, analysis report I IV.1/8316 Ch. The concentration of a.i tebuconazole was found to be 0,52%. | |

| **Section B5.10**<br>**Annex Point IIB5.10**<br>**TNsG: Pt. I-B5.10,**<br>**Pt. III-Ch. 6** | **Efficacy Data**<br>**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. | |
| **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:<br>Coniophora puteana BAM Ebw. 15<br>Poria placenta FPRL 280<br>Gloeophyllum trabeum BAM Ebw. 109<br>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.<br>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;<br>Untreated control specimens equal in number to the treated test specimens (5 for each concentration of biocidal product per fungus)<br>6 untreated virulence control specimens for each fungus.<br>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: Mass loss of wood. | |
| 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.<br>Mass loss is calculated by expressing the loss in mass (m0 – m3) as a percentage of initial dry mass. | |

| **Section B5.10**<br>**Annex Point IIB5.10**<br>**TNsG: Pt. I-B5.10,**<br>**Pt. III-Ch. 6** | **Efficacy Data**<br>**Wood rotting fungi, laboratory study EN 113 in combination with EN 84.** |
|---|---|

| | | |
|---|---|---|
| 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. |
| 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** | |

| Test fungus | Mean retention of product | Mean mass loss | Critical value surface treatment* |
|---|---|---|---|
| C.puteana | 60,9 kg/m$^3$ | 0,4 % | 121,8 g/m$^2$ |
| P.placenta | 60,6 kg/m$^3$ | 0,3 % | 121,2 g/m$^2$ |
| G.trabeum | 61,0 kg/m$^3$ | 0,1 % | 122 kg/m$^2$ |

Visir Oljegrunning Pigmentert provides adequate protection for wood at a mean load of 122 g/m$^2$ (*Ref §5.2.15 in EN 599-1:2009).

X

| **Section B5.10**<br>**Annex Point IIB5.10**<br>**TNsG: Pt. I-B5.10,**<br>**Pt. III-Ch. 6** | **Efficacy Data**<br>**Wood rotting fungi, laboratory study EN 113 in combination with EN 84.** |
|---|---|

| | | |
|---|---|---|
| **3.6** | **Efficacy limiting factors** | |
| 3.6.1 | Occurrences of resistances | Resistance against the actives used in Visir Oljegrunning Pigmentert for wood preservation is not reported or known up to the time being. More detailed information regarding the active ingredients can be found in the active ingredient dossiers. |
| 3.6.2 | Other limiting factors | No other limiting factors. |
| | **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.<br>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** | Recommended application rate of biocidal product is 4-8 $m^2$/L depending on properties of the wooden surface. This corresponds to 125-223g/$m^2$. |
| **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.<br>The application method in the laboratory test is by vacuum impregnation, while Visir Oljegrunning Pigmentert 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.<br>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. |

| **Section B5.10**<br>**Annex Point IIB5.10**<br>**TNsG: Pt. I-B5.10,**<br>**Pt. III-Ch. 6** | **Efficacy Data**<br>**Wood rotting fungi, laboratory study EN 113 in combination with EN 84.** | |
|---|---|---|
| | 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 122 $g/m^2$ for Visir Oljegrunning Pigmentert corresponding to 0,73 $g/m^2$ tebuconazole corresponds well with expected efficacy as stated by the producers of the a.i. | X |
| **5.4 Conclusion** | The laboratory test is regarded valid and well suited to show efficacy of Visir Oljegrunning Pigmentert | |
| **5.5 Proposed efficacy specification** | The Critical value for Visir Oljegrunning Pigmentert is below 122 $g/m^2$. This corresponds to 0,73 $g/m^2$ tebuconazole. | X |

| **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."*<br><br>This indicates that the toxic value is not determined, but the toxic effect of only one concentration. This title is thus not correct.<br><br>**Comment (2.3.2):** See Tab 1.3 and comments on 2.3.6 and 2.3.7 regarding replicates<br><br>**Comment (2.3.6):** Number of replicates performed: There are 6 replicates for the one concentration tested of the biocidal product per fungus<br><br>**Comment (2.3.7):** Controls: 6 virulent replica and 6 control replica<br><br>**Comment (3.5):** Tabular and/or graphical presentation of the summarised results:<br><br>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 this calculation is: $kg/m^3$ equals 2 times $g/m^2$.<br><br>**Comment (5.1):** Materials and methods**:** Only one concentration was tested. Regarding Table 1.3 see comments on point 2.3.6 and 2.3.7<br><br>**Comment (5.3 and 5.5):** The calculated critical value for the application of tebuconazole of 0.73 $g/m^2$ is based on the nominal recipe concentration (0.6 % tebuconazole). Based on the measured concentration (0.52% tebuconazole) the critical value is below 0.63 $g/m^2$. |
| **Summary and conclusion** | The results show that the product applied by penetration treatment after aging according to EN 73 pass the criteria for efficacy as outlined in EN599-1. The retention rate is comparable to the application rate to be used for surface treatment of Visir Oljegrunning Pigmentert 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 |
|---|---|---|---|
| | | **REFERENCE** | |
| **1.1** | **Reference** | Efficacy studies ongoing at BAM institute in Germany. Results expected October 2010<br>**Author:** Dr. R. Plarre<br>**Year:** 2010<br>**Title:** Test report Visir Oljegrunning Pigmentert 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.<br>**Lab. name:** BAM Bundesanstalt für Materialforschung und -prüfung<br>**Lab. report no**: IV.18316 BaB<br>**Report date:** 3.11.2010 | 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 | Visir Oljegrunning Pigmentert | |
| 2.1.2 | Composition of Product tested | Visir Oljegrunning Pigmentert alt 28.<br>Detailed composition is given in Confidential folder. Concentration of ai tebuconazole 0,6% | |
| 2.1.3 | Physical state and nature | Liquid | |
| 2.1.4 | Monitoring of active substance concentration | Yes, analysis report I IV.1/8316 Ch. The concentration of a.i tebuconazole was found to be 0,52%. | |

| **Section B5.10**<br>**Annex Point IIB5.10**<br>**TNsG: Pt. I-B5.10,**<br>**Pt. III-Ch. 6** | **Efficacy Data**<br>**Wood rotting fungi, laboratory study EN 113 in combination with EN 73.** | |
|---|---|---|
| 2.1.5 Method of analysis | Quantitative determination of Tebuconazole according to BAM- test procedures. | |
| **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 | According to EN 113; *Coniophora puteana* BAM Ebw. 15,<br>*Poria placenta* FPRL 280, *Gloeophyllum trabeum* BAM Ebw. 109.<br>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 73, 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;<br>Untreated control specimens equal in number to the treated test specimens (5 for each concentration of biocidal product per fungus)<br>6 untreated virulence control specimens for each fungus.<br>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: Mass loss of wood. | |
| 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.<br>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. | |

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

| | | |
|---|---|---|
| 2.4.4 | Statistics | Calculations according to EN 113. |
| 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** | |

| Test fungus | Mean retention of product | Mean mass loss | Critical value surface treatment* |
|---|---|---|---|
| C.puteana | 61,7 kg/m$^3$ | 0,7% | 123,4g/m$^2$ |
| P.placenta | 61,4 kg/m3 | 0,7% | 122,8 g/m$^2$ |
| G.trabeum | 61,0 kg/m3 | 0,5% | 122,0 kg/m$^2$ |

Visir Oljegrunning Pigmentert provides adequate protection for wood at a mean load of 123,4 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 actives used in Visir Oljegrunning Pigmentert for wood preservation is not reported or known up to the time being. More detailed information regarding the active ingredients can be found in the active ingredient dossiers. |
| 3.6.2 | Other limiting factors | No other limiting factors. |

**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.<br><br>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** | Recommended application rate of biocidal product is 4-8 $m^2$/L depending on properties of the wooden surface. This corresponds to 125-223g/$m^2$. |
| **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.<br><br>The application method in the laboratory test is by vacuum impregnation, while Visir Oljegrunning Pigmentert 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** | No 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.<br><br>Test specimens of scots pine softwood was impregnated with test |

| | | | |
|---|---|---|---|
| | | product. The samples was aged according to EN 73 evaporative method and exposed to fungal attack for 16 weeks according to EN 113.<br><br>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 123,4 $g/m^2$ for Visir Oljegrunning Pigmentert corresponding to 0,74 $g/m^2$ tebuconazole corresponds well with expected efficacy as stated by the producers of the a.i. | x |
| **5.4** | **Conclusion** | The laboratory test is regarded valid and well suited to show efficacy of Visir Oljegrunning Pigmentert. | |
| **5.5** | **Proposed efficacy specification** | The Critical value for Visir Oljegrunning Pigmentert is below 123,4 $g/m^2$. This corresponds to 0,74 $g/m^2$ tebuconazole. | x |

| 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."*<br><br>This indicates that the toxic value is not determined, but the toxic effect of only one concentration. This title is thus not correct.<br><br>**Comment (2.3.2):** See Tab 1.3 and comments on 2.3.6 and 2.3.7 regarding replicates<br><br>**Comment (2.3.6):** Number of replicates performed: There are 6 replicates for the one concentration tested of the biocidal product per fungus<br><br>**Comment (2.3.7):** Controls: 6 virulent replica and 6 control replica<br><br>**Comment (3.5):** Tabular and/or graphical presentation of the summarised results:<br><br>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 $g/m^2$ I for surface treatment with topcoat is correct. The factor to be used for this calculation is: $kg/m^3$ equals 2 times $g/m^2$.<br><br>**Comment (5.1):** Materials and methods**:** Only one concentration was tested.<br><br>Tab 1.3 See comments on point 2.3.6 and 2.3.7<br><br>**Comment (5.3 and 5.5):** The calculated critical value for the application of tebuconazole of 0.74 $g/m^2$ is based on the nominal recipe concentration (0.6 % tebuconazole). Based on the measured concentration (0.52% tebuconazole) the critical value is below 0.64 $g/m^2$. |
| **Summary and conclusion** | The results show that the product applied by penetrating treatment after aging according to EN 73 pass the 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 Visir Oljegrunning Pigmentert according to the calculation method prescribed in EN599-1 |

**Table 1.2: Test organism**

| **Criteria** | **Details** |
|---|---|
| Species | *Coniophora puteana* |
| Strain | BAM Ebw. 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 Ebw.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.<br>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<br>6 untreated specimens for virulence control for each fungus<br>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.<br>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):<br>8,21% |
| 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 | give details on any other details relevant for the specific test system |

## 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 Visir Oljegrunning Pigmentert 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. | X |
| **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.<br><br>A dermal absorption of 100 % and 5 % tebuconazole (rounded off value due to the fact that Visir Oljegrunning Pigmentert differs somewhat from the tested guide recipe) have been used in the risk assessment of Visir Oljegrunning Pigmentert in tier I and II respectively. |
| **Acceptability** | Acceptable |
| **Remarks** | - |

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

**Annex Point IIB7.1**

| | | | | Official use only |
|---|---|---|---|---|
| | | **REFERENCE** | | |
| **1.1** | **Reference** | **B7.1/01** | **Author:** Berit Lindegaard<br>**Year:** 2009<br>**Title:** Test Report Visir Oljegrunning Pigmenteret<br>**Lab. name:** DTI Danish Technological Institute,<br>**Lab. report no**: Proj. No 1006657-17, Order No. 319962-B<br>**Report date:** 28-08-2009 | |
| **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** | Visir Oljegrunning Pigmentert | | |
| 3.1.1 | Lot/Batch number | n.a. | | |
| 3.1.2 | Specification | Contains 0,86 % w/w Tebuconazole (reg. no. 34920, Chemistry and Water Technology, Danish Technological Institute) | | 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 (reg. no. 34920, Chemistry and Water Technology, Danish Technological Institute).<br>Limit of quantification of tebuconazole: 0,002 µg/ml. | x |

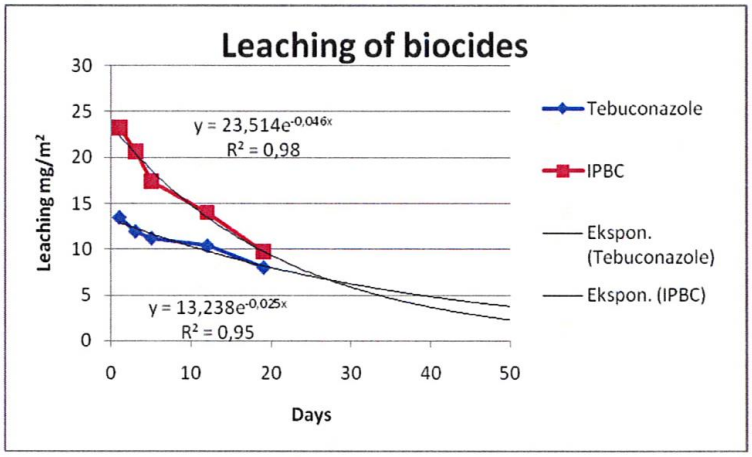
**4 RESULTS**

| | | | |
|---|---|---|---|
| **4.1** | **Determination of treatment solution uptake** | Retention of product 250g/m$^2$ | |
| **4.2** | **Concentration in treated material** | Retention of a.i tebuconazole 2,146 g/m$^2$ | |
| **4.3** | **Leaching rate** | | x |

| Immersion days | Leaching (mg/m$^2$/immersion day) | |
|---|---|---|
| | Tebuconazole | IPBC |
| 1 | 13.41 | 23.23 |
| 3 | 11.90 | 20.65 |
| 5 | 11.16 | 17.41 |
| 8 | n.a. | n.a. |
| 10 | n.a. | n.a. |
| 12 | 10.32 | 13.99 |
| 15 | n.a. | n.a. |
| 17 | n.a. | n.a. |
| 19 | 7.99 | 9.73 |

n.a.: Not analysed.

The best mathematical curve which fits the leaching of Tebuconazole is a log function




| Estimated Leaching of tebuconazole $y = 13.238e^{-0,025x}$ and $R^2 = 0.95$ | | |
|---|---|---|
| Dipping day | Leaching pr. day mg/m² | Accumulated leaching mg/m² |
| 1 | 12.9 | 12.9 |
| 3 | 12.3 | 25.2 |
| 5 | 11.7 | 36.9 |
| 8 | 10.8 | 47.7 |
| 10 | 10.3 | 58.0 |
| 12 | 9.8 | 67.8 |
| 15 | 9.1 | 76.9 |
| 17 | 8.7 | 85.6 |
| 19 | 8.2 | 93.8 |
| 22 | 7.6 | 101.5 |
| 24 | 7.3 | 108.7 |
| 26 | 6.9 | 115.6 |
| 29 | 6.4 | 122.0 |
| 31 | 6.1 | 128.1 |

The 30 days leaching of tebuconazole is estimated to 122 mg/m².

## 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 122 mg/m²

**5.3 Conclusion**

5.3.1 Reliability

1, reliable without restrictions

x

| **Section B7.1/01**<br>**Annex Point IIB7.1** | **OECD Guidance on the estimation of emissions from wood preservative. Laboratory study.** |
|---|---|

| | | |
|---|---|---|
| 5.3.2 Deficiencies | None | x |

## 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. |
| | **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):** 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 and Thomas Mark Venås<br>**Year:** 2011<br>**Lab. name:** DTI Danish Technological Institute<br><br>**Title:** Leaching of IPBC and Tebuconazole from wood treated with Jotun Visir Oljegrunning Pigmentert – One year of Exposure<br>**Lab. report no**: Proj. No 1900026, Order No. 345846-3<br>**Report date:** 14-09-2011<br>and<br>**Title:** Leaching of Cobalt from wood treated with Jotun Visir Oljegrunning Pigmentert – One year Exposure<br>**Lab. report no**: Proj. No. 1900026, Order No. 345846-3A<br>**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 | |
| | **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 | |
| | **MATERIALS AND METHODS** | |
| **3.1 Test material** | Visir Oljegrunning Pigmentert | |
| 3.1.1 Lot/Batch number | Alt 27 | |
| 3.1.2 Specification | Visir Oljegrunning Pigmentert, brushing application, average uptake 161 g/m$^2$<br>Concentration of active ingredients: 0,87% tebuconazole<br>Average retention of active ingredient: 1,40 g/m$^2$<br>Concentration of film preservative (PT7): 0,3% IPBC<br>The formulation tested here is identical to the actual biocidal product apart form the concentration of a.i tebuconazole and the concentration of water. The concentration of tebuconazole in the actual biocidal product Visir | |

| | | | |
|---|---|---|---|
| | | Oljegrunning Pigmentert is 0,6%.<br><br>Visir Oljegrunning Pigmentert 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.<br>Topcoat: Drygolin Oljemaling, Brushing application, 2 coats 120um total film thickness.<br>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.<br><br>The testing contains three test-setups for each combination of products.<br><br>156-158: Visir Oljegrunning Pigmentert with topcoat<br><br>168-170: Visir Oljegrunning Pigmentert without topcoat.<br><br>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 Visir Oljegrunning Pigmentert was confirmed by analysis at DTI (Reg.no 35211-3).<br>The concentration of tebuconazole was found to be: 0,87%.<br>The concentration of the film preservative IPBC (PT7) was also analysed. Th e degradation product of IPBC, PBC was included in the chemical analyses. The concentration of IPBC was found to be 0,31%.<br>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$^2$ |
| 156 | 162 | 0.50 | 1.40 |
| 157 | 162 | 0.50 | 1.40 |
| 158 | 161 | 0.50 | 1.39 |
| 168 | 157 | 0.49 | 1.35 |
| 169 | 161 | 0.50 | 1.39 |
| 170 | 162 | 0.50 | 1.41 |

## 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 156 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/m$^2$) | |
|---|---|---|---|---|---|
| | | mm | L | IPBC | Tebuconazole |
| 22-04-2010 | 29 | 40.4 | 1.6 | 0.76 | 0.08 |
| 08-06-2010 | 76 | 143.3 | 1.4 | 0.43 | 0.08 |
| 09-08-2010 | 138 | 266.7 | 5.9 | 1.83 | 0.60 |
| 08-10-2010 | 198 | 483.4 | 16.6 | 3.68 | 1.56 |
| 14-03-2011 | 355 | 678.7 | 25.1 | 1.62 | 0.71 |

Table 10. Chemical analysis of leachates from test set-up no 157 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/m$^2$) | |
|---|---|---|---|---|---|
| | | mm | L | IPBC | Tebuconazole |
| 22-04-2010 | 29 | 40.4 | 1.6 | 0.77 | 0.10 |
| 08-06-2010 | 76 | 143.3 | 1.3 | 0.51 | 0.10 |
| 09-08-2010 | 138 | 266.7 | 6.1 | 1.95 | 0.72 |
| 08-10-2010 | 198 | 483.4 | 16.7 | 3.89 | 1.75 |
| 14-03-2011 | 355 | 678.7 | 25.1 | 1.56 | 0.66 |

Table 11. Chemical analysis of leachates from test set-up no 158 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/m$^2$) | |
|---|---|---|---|---|---|
| | | mm | L | IPBC | Tebuconazole |
| 22-04-2010 | 29 | 40.4 | 1.6 | 0.78 | 0.10 |
| 08-06-2010 | 76 | 143.3 | 1.5 | 0.54 | 0.08 |
| 09-08-2010 | 138 | 266.7 | 5.9 | 1.84 | 0.67 |
| 08-10-2010 | 198 | 483.4 | 16.2 | 3.96 | 1.64 |
| 14-03-2011 | 355 | 678.7 | 25.5 | 1.81 | 0.84 |

x

Table 12. Chemical analysis of leachates from test set-up no 168 treated with primer.

| Sampling date | Days since start | Accu-mulated amount of rain | Collected leachate at each sam-pling date | Leached amount of active ingredi-ent (mg/m$^2$) | |
|---|---|---|---|---|---|
| | | mm | L | IPBC | Tebuconazole |
| 22-04-2010 | 29 | 40.4 | 2.5 | 6.31 | 7.21 |
| 08-06-2010 | 76 | 143.3 | 1.9 | 1.18 | 2.85 |
| 09-08-2010 | 138 | 266.7 | 7.3 | 2.44 | 8.22 |
| 08-10-2010 | 198 | 483.4 | 18.0 | 3.68 | 12.38 |
| 14-03-2011 | 355 | 678.7 | 23.0 | 2.01 | 9.43 |

Table 13. Chemical analysis of leachates from test set-up no 169 treated with primer.

| Sampling date | Days since start | Accu-mulated amount of rain | Collected leachate at each sam-pling date | Leached amount of active ingredi-ent (mg/m$^2$) | |
|---|---|---|---|---|---|
| | | mm | L | IPBC | Tebuconazole |
| 22-04-2010 | 29 | 40.4 | 2.3 | 5.84 | 5.76 |
| 08-06-2010 | 76 | 143.3 | 1.6 | 1.05 | 2.32 |
| 09-08-2010 | 138 | 266.7 | 7.2 | 2.48 | 8.12 |
| 08-10-2010 | 198 | 483.4 | 17.6 | 3.90 | 12.81 |
| 14-03-2011 | 355 | 678.7 | 22.3 | 2.18 | 8.22 |

Table 14. Chemical analysis of leachates from test set-up no 170 treated with primer.

| Sampling date | Days since start | Accu-mulated amount of rain | Collected leachate at each sam-pling date | Leached amount of active ingredi-ent (mg/m$^2$) | |
|---|---|---|---|---|---|
| | | mm | L | IPBC | Tebuconazole |
| 22-04-2010 | 29 | 40.4 | 2.4 | 6.85 | 7.11 |
| 08-06-2010 | 76 | 143.3 | 1.9 | 1.33 | 2.87 |
| 09-08-2010 | 138 | 266.7 | 7.3 | 2.59 | 8.08 |
| 08-10-2010 | 198 | 483.4 | 18.3 | 4.46 | 13.43 |
| 14-03-2011 | 355 | 678.7 | 23.6 | 2.30 | 11.99 |

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

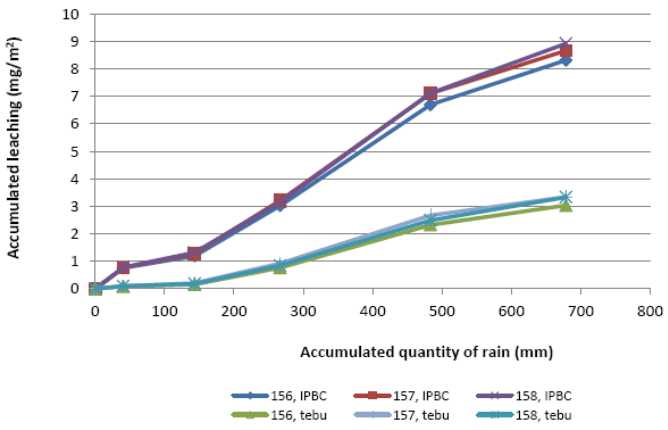



*Figure 3. Accumulated amount of active ingredients leached in mg/m$^2$ as a function of accumulated rainfall for the test set-ups treated with primer and top coat.*

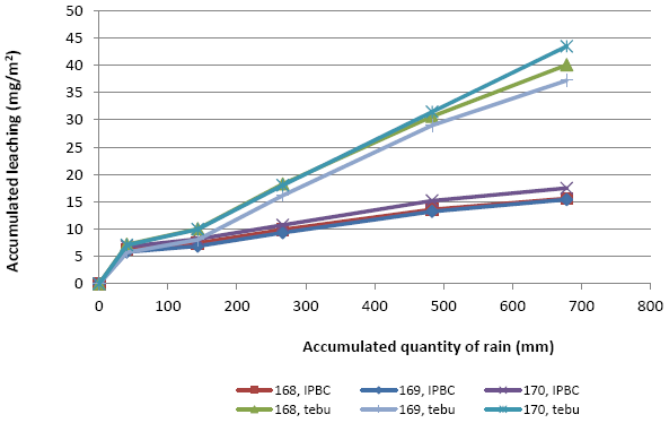



*Figure 4. Accumulated amount of active ingredients leached in mg/m² as a function of accumulated rainfall for the test set-ups treated with primer only.*

Visir Oljegrunning Pigmentert contains 0.1-0.25 % 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 156 treated with primer and top coat.

| Sampling date | Days since start | Accu-mulated amount of rain | Collected leachate at each sam-pling date | Concentration of cobalt in leachate | |
|---|---|---|---|---|---|
| | | mm | L | mg/L | mg/m² |
| 22-04-2010 | 29 | 40.4 | 1.6 | 0.10 | 0.19 |
| 08-06-2010 | 76 | 143.3 | 1.4 | 0.15 | 0.25 |
| 09-08-2010 | 138 | 266.7 | 5.9 | 0.16 | 1.12 |
| 08-10-2010 | 198 | 483.4 | 16.6 | 0.07 | 1.47 |
| 14-03-2011 | 355 | 678.7 | 25.1 | 0.05 | 1.67 |

Table 4. Chemical analysis of leachates from test set-up no 157 treated with primer and top coat.

| Sampling date | Days since start | Accu-mulated amount of rain | Collected leachate at each sam-pling date | Concentration of cobalt in leachate | |
|---|---|---|---|---|---|
| | | mm | L | mg/L | mg/m² |
| 22-04-2010 | 29 | 40.4 | 1.6 | 0.13 | 0.25 |
| 08-06-2010 | 76 | 143.3 | 1.3 | 0.17 | 0.26 |
| 09-08-2010 | 138 | 266.7 | 6.1 | 0.17 | 1.28 |
| 08-10-2010 | 198 | 483.4 | 16.7 | 0.08 | 1.56 |
| 14-03-2011 | 355 | 678.7 | 25.1 | 0.06 | 1.94 |

Table 5. Chemical analysis of leachates from test set-up no 158 treated with primer and top coat.

| Sampling date | Days since start | Accu-mulated amount of rain | Collected leachate at each sam-pling date | Concentration of cobalt in leachate | |
|---|---|---|---|---|---|
| | | mm | L | mg/L | mg/m$^2$ |
| 22-04-2010 | 29 | 40.4 | 1.6 | 0.09 | 0.18 |
| 08-06-2010 | 76 | 143.3 | 1.5 | 0.09 | 0.17 |
| 09-08-2010 | 138 | 266.7 | 5.9 | 0.15 | 1.08 |
| 08-10-2010 | 198 | 483.4 | 16.2 | 0.08 | 1.55 |
| 14-03-2011 | 355 | 678.7 | 25.5 | 0.06 | 1.85 |

Table 6. Chemical analysis of leachates from test set-up no 168 treated with primer.

| Sampling date | Days since start | Accu-mulated amount of rain | Collected leachate at each sam-pling date | Concentration of cobalt in leachate | |
|---|---|---|---|---|---|
| | | mm | L | mg/L | mg/m$^2$ |
| 22-04-2010 | 29 | 40.4 | 2.5 | 1.88 | 5.65 |
| 08-06-2010 | 76 | 143.3 | 1.9 | 1.13 | 2.68 |
| 09-08-2010 | 138 | 266.7 | 7.3 | 0.87 | 7.80 |
| 08-10-2010 | 198 | 483.4 | 18.0 | 0.28 | 6.17 |
| 14-03-2011 | 355 | 678.7 | 23.0 | 0.13 | 3.59 |

Table 7. Chemical analysis of leachates from test set-up no 169 treated with primer

| Sampling date | Days since start | Accu-mulated amount of rain | Collected leachate at each sam-pling date | Concentration of cobalt in leachate | |
|---|---|---|---|---|---|
| | | mm | L | mg/L | mg/m$^2$ |
| 22-04-2010 | 29 | 40.4 | 2.3 | 1.74 | 4.89 |
| 08-06-2010 | 76 | 143.3 | 1.6 | 1.27 | 2.46 |
| 09-08-2010 | 138 | 266.7 | 7.2 | 0.92 | 8.11 |
| 08-10-2010 | 198 | 483.4 | 17.6 | 0.25 | 5.44 |
| 14-03-2011 | 355 | 678.7 | 22.3 | 0.14 | 3.86 |

Table 8. Chemical analysis of leachates from test set-up no 170 treated with primer.

| Sampling date | Days since start | Accu-mulated amount of rain | Collected leachate at each sam-pling date | Concentration of cobalt in leachate | |
|---|---|---|---|---|---|
| | | mm | L | mg/L | mg/m$^2$ |
| 22-04-2010 | 29 | 40.4 | 2.4 | 1.89 | 5.60 |
| 08-06-2010 | 76 | 143.3 | 1.9 | 1.25 | 2.87 |
| 09-08-2010 | 138 | 266.7 | 7.3 | 0.96 | 8.53 |
| 08-10-2010 | 198 | 483.4 | 18.3 | 0.30 | 6.74 |
| 14-03-2011 | 355 | 678.7 | 23.6 | 0.14 | 4.10 |

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

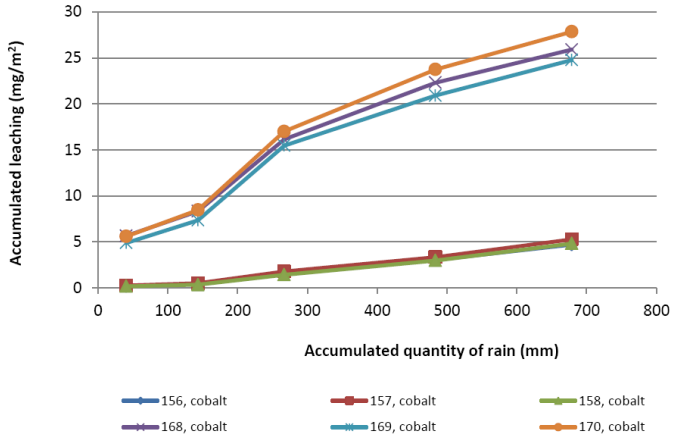



*Figure 3. Accumulated amount of cobalt leached in mg/m$^2$ as a function of accumulated rainfall for the test set-ups treated with primer and with (156-158) and without (168-170) top coat.*

## 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 3.24 mg/m$^2$, the relative average leaching was 0,23%.<br>The total average leaching of tebuconazole from test set-ups treated with primer only was: 40.27 mg/m$^2$, the relative average leaching was 2,91%.<br>The application of a top coat reduced the leaching of tebuconazole by a factor of about 12.<br>Regarding cobalt the results were as follows: From the test set-ups treated with primer and top coat the total average leaching of cobalt was 4.4 mg/m$^2$.<br>From test set-ups treated with primer only the leaching was: 26.2 mg/m$^2$.<br>The application of a top coat reduced the leaching of cobalt by a factor of about 6.<br>This study is planned to continue at least until 2 years of exposure or 1440 mm of rain is reached.<br><br>The concentration of active ingredient tebuconazole in the tested formulation was: 0.87%, while the concentration of a.i in the actual product is 0,6% tebuconazole. The formulation tested here is identical to the actual biocidal product apart form the concentration of a.i tebuconazole and the concentration of water.<br>From the results above long time leaching can be calculated (see dossier doc IIB). | x |
| **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.<br><br>**Comment (3.2)**: Temperature at the exposure sites was not reported.<br><br>**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. Moreover, there is one small inconsistency in reporting the concentrations of cobalt in the leachate. In table 8 of this study summary mg/L-values of 1.89 and 1.25 mg/L are reported for the first two sampling dates, respectively, whereas in Appendix 4b 1.92 and 1.24 mg/L are inserted. For risk assessment, figures in Appendix 4a and 4b are used.<br><br>**Comment (5.2):** Using the figures in Appendix 4a, the total average leaching of tebuconazole from test set-ups treated with primer only was: 40.4 mg/m$^2$, the total average relative leaching was 2.88 %.<br><br>From the test set-ups treated with primer and top coat the total average leaching of tebuconazole was 3.27 mg/m$^2$, the relative average leaching was 0.23%. Thereby, leaching of tebuconazole was reduced by a factor of 12 when applying a top coat.<br><br>Regarding cobalt, from test set-ups treated with primer only the total average leaching was: 26.2 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 4.9 mg/m$^2$. The application of a top coat reduced the leaching of cobalt by a factor of about 5.<br><br>**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 HH

| | Professionals<br>Consumer product painting model 3 | | |
|---|---|---|---|
| **VISIR OLJEGRUNNING PIGMENTERT** | **Tier I** | **Tier IIa** | **Tier IIb** |
| active substance % (w/w) | **0.60** | **0.60** | **0.60** |
| **Potential body exposure** | | | |
| Indicative value (mg/min) | **16.9** | **16.9** | **16.9** |
| Duration min | **360** | **360** | **360** |
| Potential dermal deposit (mg) | 6084 | 6084 | 6084 |
| Clothing type | 100% penetration | 25% penetration | 10% penetration |
| Clothing penetration % | **100** | **25** | **10** |
| Actual dermal deposit [*product*] mg | 6084 | 1521 | 608.4 |
| **Hand exposure** | | | |
| Indicative value (mg/min) (potential) | **5.91** | **5.91** | **5.91** |
| Duration (min) | **360** | **360** | **360** |
| Hand deposit (mg) | 2127.6 | 2127.6 | 2127.6 |
| Mitigation by gloves | **1** | **0.1** | **0.1** |
| Actual hand deposit [*product*] (mg) | 2127.6 | 212.76 | 212.76 |
| **Total dermal exposure** | | | |
| Total dermal deposit [*product]* (mg) | 8211.6 | 1733.76 | 821.16 |
| Active substance (mg) | 49.2696 | 10.40256 | 4.92696 |
| Dermal absorption (%) | **100** | **5** | **5** |
| Systemic exposure via dermal route (mg) | 49.2696 | 0.5201 | 0.2463 |
| **Exposure by inhalation** | | | |
| Indicative value (mg/m$^3$) | **1.63** | **1.63** | **1.63** |
| Duration (min) | **360** | **360** | **360** |
| Inhalation rate (m$^3$/h) | 1.25 | 1.25 | 1.25 |
| Mitigation by RPE (PF) | **1** | **1** | **1** |
| Inhaled [*product*] (mg) | 12.23 | 12.23 | 12.23 |
| Systemic exposure via inhalation route (mg) | 0.0734 | 0.0734 | 0.0734 |
| **Systemic exposure** | | | |
| Total systemic exposure a.s. (mg) | 49.3430 | 0.5935 | 0.3197 |
| Body weight (kg) | 60 | 60 | 60 |

| | | | |
|---|---|---|---|
| Systemic exposure (mg $kg^{-1}$ $day^{-1}$) | **0.822** | **0.00989** | **0.00533** |

| **Non-professionals<br>Consumer product painting model 3** | | |
|---|---|---|
| **VISIR OLJEGRUNNING PIGMENTERT** | **Tier I** | **Tier II** |
| active substance % (w/w) | **0.60** | **0.60** |
| **Potential body exposure** | | |
| Indicative value (mg/min) | **16.9** | **16.9** |
| Duration min | **155** | **155** |
| Potential dermal deposit (mg) | 2619.5 | 2619.5 |
| Clothing type | 100% penetration | Minimal clothing, 50% penetration |
| Clothing penetration % | **100** | **50** |
| Actual dermal deposit [*product*] mg | 2619.5 | 1309.75 |
| **Hand exposure** | | |
| Indicative value (mg/min) (potential) | **5.91** | **5.91** |
| Duration (min) | **155** | **155** |
| Hand deposit (mg) | 916.05 | 916.05 |
| Mitigation by gloves | **1** | **1** |
| Actual hand deposit [*product*] (mg) | 916.05 | 916.05 |
| **Total dermal exposure** | | |
| Total dermal deposit [*product]* (mg) | 3535.55 | 2225.8 |
| Active substance (mg) | 21.2133 | 13.3548 |
| Dermal absorption (%) | **100** | **5** |
| Systemic exposure via dermal route (mg) | 21.2133 | 0.6677 |
| **Exposure by inhalation** | | |
| Indicative value (mg/m$^3$) | **1.63** | **1.63** |
| Duration (min) | **155** | **155** |
| Inhalation rate (m$^3$/h) | 1.25 | 1.25 |
| Mitigation by RPE (PF) | **1** | **1** |
| Inhaled [*product*] (mg) | 5.26 | 5.26 |
| Systemic exposure via inhalation route (mg) | 0.0316 | 0.0316 |
| **Systemic exposure** | | |
| Total systemic exposure a.s. (mg) | 21.2449 | 0.6993 |
| Body weight (kg) | 60 | 60 |
| Systemic exposure (mg kg$^{-1}$ day$^{-1}$) | **0.35408** | **0.01166** |

## WASHING OUT OF A BRUSH WHICH HAS BEEN USED TO APPLY A PAINT

| **Activity and parameters** | | **Tier 1 No gloves** | **Tier 2 Gloves** |
|---|---|---|---|
| Volume of brush | 200 | | |
| Vol paint remaining on brush after painting | 1/8 of 200ml = 25 ml | | |
| Weight of a.s. on brush after painting | 25 ml x 0.6/100 = 150 mg | | |
| | | | |
| **Residues of a.s. on brush after 1st. Wash** | **10% of 150 mg = 15 mg** | | |
| Amount of a.s. removed from the brush into the cleaning fluid = 150 mg - 15 mg = 135 mg | | | |
| Weight of a.s. squeezed out from brush onto cloth | 50% of 15 mg = 7.5 mg | | |
| Cloth absorbs *90% of a.s. squeezed out of brush therefore, weight of a.s available to contaminate the hand | 10% of 7.5 mg = 0.75 mg | | |
| Penetration of a.s. through gloves | 10 % | | |
| Weight of a.s. on hand | | 0.75 | 0.075 |
| Dermal absorption of a.s. | 5 % | | |
| Weight of a.s. entering the body | | **0.0375** | **0.00375** |
| Amount of a.s. left on the brush after 1st. wash and squeezing | 15 mg – 7.5 mg = 7.5 mg | | |
| | | | |
| **Residues of a.s. on brush after 2nd. wash** | **10% of 7.5 mg = 0.75 mg** | | |
| Amount of a.s. removed from the brush into the cleaning fluid = 7.5 mg - 0.75 mg = 6.75 mg | | | |
| Weight of a.s. squeezed out from brush onto cloth | 50% of 0.75 mg = 0.375 mg | | |
| Cloth absorbs *90% of a.s. squeezed out of brush therefore, weight of a.s available to contaminate the hand | 10% of 0.375 mg = 0.0375 mg | | |
| Penetration of a.s. through gloves | 10 % | | |
| Weight of a.s. on hand | | 0.0375 | 0.00375 |
| Dermal absorption of a.s. | 5 % | | |
| Weight of a.s. entering the body | | **0.001875** | **0.0001875** |
| Amount of a.s. left on the brush after 2nd. Wash and squeezing | 0.75 mg – 0.375 mg = 0.375 mg | | |
| | | | |

| | | | |
|---|---|---|---|
| **Residues of a.s. on brush after 3rd. wash** | **10% of 0.375 mg = 0.0375 mg** | | |
| Amount of a.s. removed from the brush into the cleaning fluid = 0.375 mg - 0.0375 mg = 0.3375 mg | | | |
| Weight of a.s. squeezed out from brush onto cloth | 50% of 0.0375 mg = 0.01875 mg | | |
| Cloth absorbs *90% of a.s. squeezed out of brush therefore, weight of a.s available to contaminate the hand | 10% of 0.01875 mg = 0.001875 mg | | |
| Penetration of a.s. through gloves | 10 % | | |
| Weight of a.s. on hand | | 0.001875 | 0.0001875 |
| Dermal absorption of a.s. | 5 % | | |
| Weight of a.s. entering the body | | **9.375E-05** | **9.375E-06** |
| | | | |
| **Total weight of a.s. entering the body** | | **0.0395** | **0.00395** |
| **Total systemic dose of active substance for 60 kg adult** | | **6.58E-04** | **6.58E-05** |

## Appendix 4 - Addendum to PAR June 2012

# Addendum to Product Assessment Report

# Visir Oljegrunning Pigmentert

27 June 2012

| | |
|---|---|
| R4BP2 ref no: | 2010/2093/5866/NO/AA/7005 |
| Authorisation/Registration no: | NO-2011-0003 |
| Granting date/entry into force of authorisation/ registration: | 16 November 2011 |
| Expiry date of authorisation/ registration: | 16 November 2021, provided that the active substance is still included in Annex I. |
| Active ingredient: | Tebuconazole |
| Product type: | PT 8 |

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

# 1. Introduction

When granting authorisation for Visir Oljegrunning Pigmentert in November 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 Visir Oljegrunning Pigmentert 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 Visir Oljegrunning Pigmentert.

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 Visir Oljegrunning Pigmentert, 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 1.1**: Physico-chemical properties of the biocidal product

| Endpoint | Method | Results | Comments |
|---|---|---|---|
| Physical state and nature | Charles River SOP | Viscous Liquid | * |
| Colour | ASTM D1535-89 | 8/4 10 YR (Beige) | * |
| 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 100ºC | * |
| Autoflammability | EC Test A.15 | 450 ± 10ºC | * |
| Other indications of flammability | n.a. | | |
| Acidity / Alkalinity | CIPAC MT 75 | 6.88 | * |
| Relative density / bulk density | OECD 109<br>OJEC A3 | 1.0239 | * |
| Storage stability – stability and shelf life | 2 years storage stability in warehouse-condition, dark and ambient temperature | Tebuconazole concentration:<br>No storage: 0.51% w/w<br>12 months: 0.65% w/w<br>20 and 24 months: 0.65 % w/w | * |
| Storage stability – Accelerated Storage | Results from Accelerated Storage (CIPAC MT 46.1) | Tebuconazole concentration:<br>0.51 % w/w initial<br>0.53 % after 14 days at 54 ± 2°C. | *<br>Steel container |
| Storage stability – Accelerated Storage | Results from Accelerated Storage (CIPAC MT 46.1) | Tebuconazole concentration:<br>0.47 % w/w initial<br>0.48 % after 8 weeks at 40 °C | **<br>Plastic container |
| Storage stability – effects of | Results from low temperature | Storage at 0 ± 1°C for 7 days. The test item was found to | * |

| Endpoint | Method | Results | Comments |
|---|---|---|---|
| temperature | storage (CIPAC MT 39.1) | remain homogenous and no material settled out following centrifugation. | |
| 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:<br>205 mPas (20°C)<br>181 mPas (40°C)<br><br>After 12 months storage:<br>222 mPas (20°C)<br>198 mPas (40°C)<br>After 24 months storage:<br>219 mPas (20°C)<br>200 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)

## 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.

Visir Oljegrunning Pigmentert 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 Visir Oljegrunning Pigmentert 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 Visir Oljegrunning Pigmentert is not an oxidizing formulation. Visir Oljegrunning Pigmentert contains 0.039% 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, Visir Oljegrunning Pigmentert 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 show that the measured concentration increased from 0.51 % w/w initial to 0.65 % w/w both after 12 and 24 months. No real explanation for this initial low concentration could be provided. It does, however, not seem likely that the concentration really increased by 35 % 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 (0.51 % w/w initial, 0.53 % w/w after 14 days) and also storage at low temperature showed stability. 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 and during low temperature storage. This is also in line with the initial nominal concentration of 0.68 % w/w in samples used for the phys.-chem. studies (se chapter 1.6.1). All values are mean values of three measurements. Results from T0 of the 2 years storage study and from the accelerated study are slightly different compared to the interim results due to re-processing of the data.

The 2 years storage stability study was conducted with Visir Oljegrunning Pigmentert stored in steel containers. No information on storage stability of the product in PP/PE containers was available. Before Visir Oljegrunning Pigmentert 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 0.47 % w/w tebuconazole initial and 0.48 % after accelerated storage. In addition, a positive control in steel was also run in parallel. The initial concentration of tebuconazole in steel was 0.43 % (mean) and after 8 weeks at 40 °C 0.44 % (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 a period of 7 days, the test item was found to remain homogenous and no material settled out following centrifugation.

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 Visir Oljegrunning Pigmentert will have to be required in case of a re-formulation involving changes in use of film preservative.

Norwegian Competent Authority

June 2012

## Appendix 1 – Reference list

| Author(s) | Year | Title | Data protection claimed | Owner |
|---|---|---|---|---|
| Balloch, S. and Allan, G. | 2012 | Two Year Storage Stability, Accelerated Storage Stability and Physical Chemistry Testing on Jotun's Visir Oljegrunning Pigmentert<br>Draft 1 Report Charles River Tranent Edinburgh EH33 2NE UK. Test Facility Study No. 215356 Report No. 30707. Sponsor's Ref. No. BIO1308. Test Site Reference: HT09/219 | 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<br>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<br>Report Amendment 1 | Yes | Jotun A/S |
| European Chemicals Agency<br>(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 | 2007 | Technical Notes for Guidance. Human Exposure to biocidal products. (Version 2, June 2007). | No | Public |

| Author(s) | Year | Title | Data protection claimed | Owner |
|---|---|---|---|---|
| (ECB) | | Guidance on exposure estimation. Published. | | |
| European Chemicals Bureau (Ex-ECB) | 2009 | TNsG on Annex I inclusion, revision of chapter 4.1, Quantitative Human Health Risk | No | Public |
| Ex-European Chemicals Bureau (Ex-ECB) | 2011 | Manual of Technical Agreements (MOTA) Biocides Technical Meeting<br>Version 4; 2011.<br>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:<br>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":<br>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., Guiver, R. and Rimmer, D.A. | 2000 | Potential exposure of amateurs (consumers) through painting wood and preservative and antifouling preparations. Annals of Occupational Hygiene 2000;**44**(6):pp 421 – 426.<br>Published | No | Public |
| Human Exposure Expert Group (HEEG) | 2010a | HEEG opinion on default protection factors for protective clothing and gloves, Agreed at TMI2010. Published | No | Public |

| Author(s) | Year | Title | Data protection claimed | Owner |
|---|---|---|---|---|
| Human Exposure Expert Group (HEEG) | 2010b | HEEG opinion on Exposure model. Primary exposure scenario – washing out of a brush which has been used to apply a paint. Agreed at TMIII 2010. Published. | No | Public |
| Jotun AS | 2012 | Accelerated Storage Stability Test of "Visir Oljegrunning Pigmentert" in Plastic (PP) and Metal Containers | Yes | Jotun A/S |
| Klamer, M. and Venås, T. M. | 2011 | Leaching of IPBC and Tebuconazole from Wood Treated with Jotun Visir Oljegrunning Pigmentert – One year of Exposure. Danish Technological Institute. Project 1900026; Order no. 345846-3 | Yes | Jotun A/S |
| Klamer, M. and Venås, T. M. | 2011 | Leaching of Cobalt from wood treated with Jotun Visir Oljegrunning Pigmentert – One year of Exposure. Danish Technological Institute, Project no 1900026, Order no 345846-3A | Yes | Jotun A/S |
| Lindegaard, B. | 2009 | Test Report Visir Oljegrunning Pigmentert. Danish Technological Institute, Wood and Textile, Taastrup, Denmark. Project no 1006657-17, Ordre No. 319962-B | 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 | Efficacy testing according to DIN EN 113: 1996 Wood preservatives. Test method for determining the protective effictiveness against wood destroying basidiomycetes. Determination of Toxic values in combination with DIN EN 73: 1990 Wood preservatives. Accelerated ageing test of treated wood prior to biological testing – evaporative ageing procedure". BAM Bundesanstalt für Materialforschung und – prüfung, Lab. report no. IV.18316 BaB | Yes | Jotun A/S |
| Toner, F. | 2006 | The In vitro Percutaneous Absorption of Radiolabelled Tebuconazole in Two Wood Protection Formulations through Human Skin. | Yes | Lanxess |

| Author(s) | Year | Title | Data protection claimed | Owner |
|---|---|---|---|---|
| | | Included in the Competent Autority Report on Tebuzonazole from December 2007, Document IIIB, section B6.4 | | |

## Appendix 5 - Addendum to PAR June 2014

# Addendum to Product Assessment Report

# Visir Oljegrunning Pigmentert

Minor change of the product formulation

| | |
|---|---|
| R4BP3 case no : | BC-LQ002982-25 |
| Authorisation/Registration no: | NO-2011-0003 |
| Date: | 2. June 2014 |
| Active ingredient: | Tebuconazole |
| Product type: | PT 8 |

# 1.Background

A minor formulation change according to Regulation No 354/2013 in the approved product 'Visir Oljegrunning Pigmentert (VOP)' has been applied for by the manufacturer JOTUN AS. The change in the formulation is related to the substitution of a non-active ingredient containing cobalt with an alternative ingredient and compensating the concentrations with an insignificant amount of water. The new ingredient does not contain any substance of concern. There will be no change in the concentration of the active component tebuconazole (0.6%) and since cobalt is a substance of concern with an environmental classification, the substitution will bring about a change in the environmental classification of the product. All other ingredients will remain unaltered. A 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 VOP 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 VOP 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). May produce an allergic reaction.

## 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 VOP 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 Iodopropynyl butylcarbamate (IPBC) were performed for the new formulation in a steel container. Levels of the active substances were measured prior to and after storage of the sample 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 indicate that the concentration of active substances in the sample is stable following the storage period. In connection with the authorization of Visir Oljegrunning Pigmentert a stability study was submitted 31/01-12. The study was performed both in plastic and steel containers and showed no difference in the stability of the active substance in the two packaging types. According to JOTUN they consider the change in the new formulation to be minor and do not expect that the change will cause the stability of the active substance to be different in the two packaging types. They have therefore performed the stability test in steel coontainers only (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 the new formulation of VOP. 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 may influence the efficacy of the product, DTI has also 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 minor change of the formulation of VOP is considered acceptable and desirable from an environmental and human health point of view and will not influence the efficacy or storage stability of the product.

# 4 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 a BPD approved product. Visir Oljegrunning Pigmentert. | Yes | Jotun A/S |
| Christiansen, Rune | 2014 | Statement Stability test | Yes | Jotun A/S |

## Appendix 6 - Addendum to PAR August 2016

# Addendum to

# Product Assessment Report

# Visir Oljegrunning Pigmentert

## August 2016

### Minor change of the product formulation

| | |
|---|---|
| R4BP3 case no : | BC-PP020015-40 |
| Authorisation/Registration no: | NO-2011-0003 |
| Date: | August 2016 |
| Active ingredient: | Tebuconazole |
| Product type: | PT 8 |

# 1.Background

The manufacturer JOTUN AS has applied for a minor change in accordance with Regulation No 354/2013 to the authorized product Visir Oljegrunning Pigmentert. The change concerns a minor change in non-active constituents of the formulation.

In addition, due to a change in the classification of one of the constituents, the classification of the product is changed.

# 2. Description of the changes

## 2.1. Change in the product formulation

The change in the product formulation regards a change in the supplier of binder. The composition of the binders from the two suppliers is almost identical, and none of the binders are classified as dangerous. The binder content in the new formulation is marginally higher than in the old one, with an increase of 1.2%. Consequently, the content of water is correspondingly reduced by 1.2%. The new binder product contains Zinc pyrithione (zinc bis(2-thioxopyridin-1(2H)-olate), CAS no. 13463-41-7) as an in-can preservative which results in a final concentration of 0.01% in Visir Oljegrunning Pigmentert. This substance has no biocidal function in Visir Oljegrunning Pigmentert and has no influence on the classification.
The applicant has also been made aware that there has been made a minor change in the composition of the yellow dye raw material used in Visir Oljegrunning Pigmentert, in which Fe(OH)O (CAS no. 20344-49-4) has been substituted with $Fe_2O_3$ (CAS no. 51274-00-1) as pigment. The identity of the dye raw material is unchanged. None of the pigments are classified as dangerous and the substitution has been evaluated to be of no toxicological concern.
There is no change in the concentration of active substance or the substance of concern.

## 2.2. Change in classification

The environmental classification of the product is changed as a result of a change in the classification of the film preservative IPBC (3-iodo-2-propynyl-butyl-carbamate, CAS No 55406-53-6) in the 6$^{th}$. ATP to Regulation (EC) 1272/2008 (CLP).
The resulting classification of Visir Oljegrunning Pigmentert according to CLP is:
Aquatic chronic 3; H412 Harmful to aquatic life with long lasting effects
The corresponding labelling of Visir Oljegrunning Pigmentert according to CLP is:
Pictogram: None
Signal word: None
H412 Harmful to aquatic life with long lasting effects
P102 Keep out of reach of children
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.

## 2.3. Evaluation of the change in formulation

The applications concerns a change in the supplier of binder. The composition of the binders from the two suppliers are almost identical, and none of the constituents are classified as dangerous. The change also results in a minor residue of the raw material in-can preservative zinc pyrithione in the product with a final concentration of 0.01%. Further, it has been noticed that Fe(OH)O (CAS no. 20344-49-4) has been substituted with $Fe_2O_3$ (CAS no. 51274-00-1) as pigment in the dye raw material. It is not anticipated that the change will have any impact on the risk assessment performed for the product, neither with regard to leaching, nor on the dermal absorption of the active substance.

## 2.4. Evaluation of the change in classification

As the updated classification of IPBC results in a classification of the product, IPBC is now considered to be a substance of concern for the environment. At the time of the initial authorisation of Visir Oljegrunning Pigmentert, the Norwegian Environment Agency accepted the applicants' argumentation that IPBC had the function of a film preservative only. Hence, no individual risk assessment was performed for this ingredient. Being a substance of concern, such an evaluation is now required. Further, this is regarded as a major change of the product authorisation, which must be applied for without undue delay.

## 2.5. Conclusion

The change in the formulation of Visir Oljegrunning Pigmentert is regarded as acceptable and is considered not to have any likely impact on the properties of the product with regard to human health, the environment, the storage stability or the efficacy of the product. Regarding the new Substance of Concern, IPBC, the applicant has been informed of our decision and has started the process to comply.

## Appendix 7 - Addendum to PAR February 2018

# Addendum to

# Product Assessment Report

# Visir Oljegrunning Pigmentert

## February 2018

### Minor change of the product formulation

| | |
|---|---|
| R4BP3 case no : | BC-VT028243-15 |
| Authorisation/Registration no: | NO-2011-0003 |
| Date: | 15 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 authorized product Visir Oljegrunning Pigmentert (VOP). 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 raw materials used in the production of Visir Oljegrunning Pigmentert

The change in the product formulation regards a substitution of several raw materials used in the production of Visir Oljegrunning Pigmentert. The details are described in the confidential annex to this addendum.

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

The classification of IPBC was changed with the 6. ATP to Regulation (EC) 1272/2008 (CLP). In the previous application for minor change of VOP, accepted in August 2016, it was identified that this change in classification would trigger an environmental classification of VOP, and thus qualify IPBC as a substance of concern in the product. Please see addendum to PAR August 2016 (appendix 6) for further details on this issue. By lowering the concentration of IPBC in the product, the concentration falls under the classification limit for Aquatic chronic 3; H412. Hence, IPBC no longer qualifies for being a substance of concern in the product.

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. As IPBC has the function as a film preservative in VOP, the efficacy of the product is not expected to be affected. The applicant has submitted an assessment of the applied change by the Danish Technological Institute (DTI) (Klamer and Lindegaard 2017). The DTI assessment concludes that the efficacy test submitted for the initial authorisation still should be regarded as valid for the re-formulated product, as the application rate for IPBC still is within the initially accepted 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.

## 2.3. 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 7. 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 VOP as Aquatic chronic 2; H411.

Existing classification and labelling of VOP 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
P102 Keep out of reach of children
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 VOP:

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
P102 Keep out of reach of children
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 changes in raw materials used in the production of Jotun Visir Oljegrunning Pigmentert are regarded as acceptable.

The change in classification of the product is due to the change in the classification of the active substance, tebuconazole, with the 7$^{th}$ ATP to CLP. The change 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 is regarded acceptable and will not alter the existing conditions for use or restrictions.