Product Assessment Report

Jotun Industri Grunning Visir Gul Base

Revised February 2018

Addendum added June 2012
Addendum added June 2014
Addendum added February 2018

Replaces 1 November 2012

R4BP ref no:	2012/2093/17948/NO/AA/32607
Authorisation/Registration no:	NO-2012-0023
Granting date/entry into force of authorisation/ registration:	1 November 2012
Expiry date of authorisation/ registration:	1 November 2022, provided that the active substance is still included in the Union List of Approved Substances
Active ingredient:	Tebuconazole
Product type:	PT 8

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

Contents

1 General information about the product application

1.1 Applicant

Company Name:	Jotun AS
Address:	P.O.Box 2021
City:	Sandefjord
Postal Code:	N-3248
Country:	Norway
Telephone:	+47 33 45 70 00
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

Jotun Industri Grunning Visir Gul Base 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 for this product. Hence, no current authorisation holder is available.

However, Jotun is authorisation holder for an almost identical product (Jotun Industri Grunning Visir; NO-2011-0005).

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:	6 June 2012
Application reported complete:	14 September 2012
Type of application:	Authorisation
Further information:	-

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	Jotun Industri Grunning Visir Gul Base
Manufacturer's development code number(s), if appropriate:	
Product type:	PT 8 (wood preservative)
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Active substance: 0.60 % tebuconazole, CAS-No. 107534-96-3 Substances of concern regarding environment: 0.1-0-5% Cobalt, borate neodecanoate; CAS-No. 68457-13-6 Detailed information regarding the composition of the biocidal product is confidential and can be found in R4BP.
Formulation type:	Alkyd-oil primer for exterior wood with water as main solvent
Ready to use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); **If yes: authorisation/registration no. and product name:** **or** **Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):**	Yes. The formulation of this product contains identical raw materials as the already approved product "Jotun Industri Grunning Visir", colour white (NO-2011-0005), except for the substitution of some pigments in low concentrations in Jotun Industri Grunning Visir Gul Base to provide the correct colour (yellow). No

1.5.2 Information on the intended use(s)

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

1.5.3 Information on active substance(s)

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

1.5.4 Information on the substance(s) of concern

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

1.6 Documentation

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

Data for the relevant formulation has been submitted for the product Jotun Industri Grunning Visir (colour white), which was authorised in Norway in 2011 (authorisation number NO-2011-0005). Jotun Industri Grunning Visir Gul Base contains identical raw materials as those

contained in the already approved product "Jotun Industri Grunning Visir" (colour white), apart from the substitution of some pigments in low concentrations.

2 Summary of the product assessment

2.1 Identity related issues

Jotun Industri Grunning Visir Gul Base contains identical raw materials as those contained in the already approved product "Jotun Industri Grunning Visir" (colour white; NO-2011-0005), and differs only in the content of pigments in low concentrations to provide the correct colour (yellow).

2.2 Classification, labelling and packaging

The substitution of a small amount of pigments does not change the classification and labelling of the biocidal product. Therefore, classification and labelling of Jotun Industri Grunning Visir Gul Base is identical to classification and labelling of Jotun Industri Grunning Visir (colour white), which was authorised in Norway in 2011 (NO-2011-0005).

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

2.3 Physico/chemical properties and analytical methods

Data on physico/chemical properties have been submitted and evaluated in the Product Assessment Report for Jotun Industri Grunning Visir (colour white), authorisation number NO-2011-0005. The differences in composition with respect to the substitution of a small amount of pigments is regarded as insignificant and is not expected to change the nature of the products (other than the colour).

The analytical method for determination of active substance in the formulation has been validated and accepted for Jotun Industri Grunning Visir (colour white, NO-2011-0005). The method is considered valid also for Jotun Industri Grunning Visir Gul Base.

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

2.4 Risk assessment for Physico-chemical properties

The risk assessment for physico-chemical properties was performed on the product Jotun Industri Grunning Visir (colour white; NO-2011-0005). The raw materials in both formulations are identical, apart from the substitution of a small amount of pigments in Jotun

Industri Grunning Visir Gul Base and this substitution is not expected to have any influence on the risk assessment for physico-chemical properties.

2.5 Effectiveness against target organisms

Efficacy studies have been validated and accepted for Jotun Industri Grunning Visir (colour white; NO-2011-0005). The substitution of a small amount of pigments in Jotun Industri Grunning Visir Gul Base is not assumed to have an influence on the efficacy of the product.

2.6 Exposure assessment

Jotun Industri Grunning Visir Gul Base is used in the same way as the already approved Jotun Industri Grunning Visir (colour white; NO-2011-0005). Therefore, the exposure assessment of Jotun Industri Grunning Visir (colour white) also covers the use of Jotun Industri Grunning Visir Gul Base.

Jotun Industri Grunning Visir Gul Base is intended to be handled by the end user at their premises, using the Jotun Multicolor system to add further pigments in order to obtain a variety of end colours, usually the same colour as the top coat to be used. The process is automatic, except from the removal of the lid, and is not expected to constitute any additional risk for exposure.

No new calculations have been conducted.

2.7 Risk assessment for human health

The risk assessment for human health was performed on the product Jotun Industri Grunning Visir (colour white; NO-2011-0005). The formulation of Jotun Industri Grunning Visir Gul Base contains identical raw materials to the already approved product Jotun Industri Grunning Visir (colour white), except for the substitution of a small amount of pigments in Jotun Industri Grunning Visir Gul Base. This substitution is not expected to have any influence on the human health risk assessment.

Jotun Industri Grunning Visir Gul Base is intended to be handled by the end user at their premises, using the Jotun Multicolor system to add further pigments in order to obtain a variety of end colours, usually the same colour as the top coat to be used. The process is automatic, except from the removal of the lid, and is not expected to constitute any additional risk for exposure. According to the MSDSs for the pigments used in the Jotun Multicolour system, none of the pigments are classified as dangerous or contain any substances of concern, and are thus not expected to have any influence on the human health risk assessment of both primary and secondary exposure.

No new calculations have therefore been conducted.

2.8 Risk assessment for the environment

The risk assessment for the environment was performed on the product Jotun Industri Grunning Visir (colour white; NO-2011-0005). The formulation of Jotun Industri Grunning Visir Gul Base contains identical raw materials to the already approved product Jotun Industri Grunning Visir (colour white). The substitution of a small amount of pigments as well as the addition of additional pigments in the end users premices, using the Jotun Multicolor system in Jotun Industri Grunning Visir Gul Base is not expected to have any influence on the environmental risk assessment and no new calculations have therefore been conducted.

2.9 Measures to protect man, animals and the environment

The proposed measures for Jotun Industri Grunning Visir Gul Base are identical to the measured proposed for Jotun Industri Grunning Visir (colour white; NO-2011-0005).

3 Proposal for decision

The decision on Jotun Industri Grunning Visir Gul Base is the same as for Jotun Industri Grunning Visir (colour white; NO-2011-0005).

3.1 Summary of Use Conditions and Restrictions

Use conditions and restrictions for Jotun Industri Grunning Visir Gul Base are identical to the ones for Jotun Industri Grunning Visir (colour white; NO-2011-0005).

3.2 Necessary Issues Accounted for in the Product Label

Additional labelling for Jotun Industri Grunning Visir Gul Base is identical to the labelling for Jotun Industri Grunning Visi (colour white; NO-2011-0005).

3.3 Requirement for Further Information

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

Norwegian Competent Authority

November 2012

Appendix 1 – Reference list

See product assessment report for Jotun Industri Grunning Visir (colour white;authorisation number NO-2011-0005).

Appendix 2 – Documents III-B

See product assessment report for Jotun Industri Grunning Visir (colour white;authorisation number NO-2011-0005).

Appendix 3 – Exposure calculations for Human Health

See product assessment report for Jotun Industri Grunning Visir (colour white; authorisation number NO-2011-0005).

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

Addendum to Product Assessment Report

Jotun Industri Grunning Visir

19 September 2012

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

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

1. Introduction

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

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

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

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

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

2.3 Physico/chemical properties and analytical methods

2.3.1 Physico-chemical properties

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

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

Endpoint	Method	Results	Comments
Physical state and nature	Charles River SOP	Viscous Liquid	*
Colour	ASTM D1535-89	N 8.5 68.4% R (Grey)***	*
Odour	Charles River SOP	Turpentine	*
Explosive properties	-	Not an explosive product	Theoretical assessment, Expert statement. See chapter 2.4
Oxidizing properties	-	Not an oxidising product	Theoretical assessment, Expert statement. See chapter 2.4
Flash point	EC Test A.9	Not detected below 100ºC	*
Autoflammability	EC Test A.15	490 ± 10ºC	*

Endpoint	Method	Results	Comments
Other indications of flammability	n.a.		
Acidity / Alkalinity	CIPAC MT 75	6.43	*
Relative density / bulk density	OECD 109 OJEC A3	1.107	*
Storage stability – stability and shelf life	2 years storage stability in warehouse-condition, dark and ambient temperature	Result after two years storage: Tebuconazole concentration: 0.37% w/w initial concentration 0.47% w/w after 12 months storage 0.44% w/w after 24 months storage.	* Steel container
Storage stability – Accelerated Storage	Results from Accelerated Storage (CIPAC MT 46.1)	Tebuconazole concentration: 0.37% w/w initial 0.38% w/w after 14 days at 54 ± 2°C.	* Steel container
Storage stability – Accelerated Storage	Results from Accelerated Storage (CIPAC MT 46.1)	Tebuconazole concentration: 0.440 % w/w initial 0.429 % w/w after 8 weeks storage at 40 °C.	** Plastic container
Storage stability – effects of temperature	Results from low temperature storage (CIPAC MT 39.1)	Storage at 0 ± 1°C for 7 days. *ca* 10% of material separated out at the bottom and *ca* 5% at the top following centrifugation	*
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.

Endpoint	Method	Results	Comments
Surface tension	n.a.	-	According to Annex IIB to 98/8/EC this is not a data requirement for biocidal products.
Viscosity	OECD 114	Prior to storage: 289mPas (20°C) 208mPas (40°C) After 12 months storage: 294mPas (20°C) 218mPas (40°C) After 24 months storage: 278 mPas (20°C) 207 mPas (40°C)	*
Particle size distribution	n.a.	Only applicable for products that are supplied as powders or granulates.	

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

Risk assessment for Physico-chemical properties

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

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

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

An expert statement on the oxidizing properties of the test item was conducted in lieu of performing the EC Test A.21. The result of the theoretical assessment was that Jotun Industri Grunning Visir is not an oxidizing formulation. Jotun Industri Grunning Visir contains [redacted]% w/w sodium nitrite, a well-known oxidizing substance, but the other components of the formulation are either known not to be oxidizing substances or, based on considerations of chemical structure, could not possess oxidizing properties. It is therefore reasonable to assume that the presence of sodium nitrite at such a low level in a formulation, which otherwise comprises only of non-oxidizing materials, would be sufficient to derive the overall conclusion that the product does not have oxidizing properties. Consequently, Jotun Industri

Grunning Visir will not give rise to highly exothermic reactions when it comes into contact with other substances, particularly flammable ones, in the way in which recognized oxidizing substances/formulations do.

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

The two-years storage stability study was conducted with Jotun Industri Grunning Visir stored in steel containers. No information on storage stability of the product in PP/PE containers was available. Before Jotun Industri Grunning Visir can be marketed in PP/PE containers an accelerated storage stability study was therefore required. The study is now available and results show that tebuconazole can be considered stable in PP/PE containers during accelerated storage (8 weeks, 40°C). Mean concentrations (3 parallels of 4 samples, respectively) show a content of 0.440 % w/w tebuconazole initial and 0.429 % w/w after accelerated storage. In addition, a positive control in steel was also run in parallel. The initial concentration of tebuconazole in steel was 0.440 % w/w (mean) and after 8 weeks at 40°C 0.432 % w/w (mean). As tebuconazole has been shown to be stable in steel containers over 2 years at room temperature, it can also be assumed that the active substance should also be stable in PP/PE containers over a 2 years period at room temperature.

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

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

3.3 Requirement for Further Information

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

Norwegian Competent Authority

September 2012

Appendix 1 – Reference list

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

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

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

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

Appendix 5 – Addendum to PAR June 2014

Addendum to

Product Assessment Report

Industri Grunning Visir Gul base

June 2014

Minor change of the product formulation

R4BP3 asset no:	NO-0003183-0000
Authorisation no	NO-2012-0023
Date of authorisation	1 November 2012
Expiry date of Authorisation	1 November 2022, provided that the active substance is still included in the Union list of approved substances
Active ingredient:	Tebuconazole
Product type:	PT 8

1.Background

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

Jotun Industri Grunning Visir Gul base contains identical raw materials as those contained in the approved product "Jotun Industri Grunning Visir" (colour white; NO-2011-0005). This product is undergoing the same formulation change as JIGV Gul base, as well as a name change into "Jotun Industri Grunning Visir Hvit" (JIGV Hvit), and all studies/evaluations on the relevant formulations has been performed on this product. The difference in composition between these two products is limited to the substitution of pigments in low concentrations. This difference is regarded as insignificant and is not expected to change the nature of the product (other than the colour). The studies and evaluations performed on JIGV Hvit are thus considered valid also for JIGV Gul base.

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

2. Assessment of some important points

2.1. Classification

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

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

Xn: R22 - Harmful if swallowed

Xi: R38 - Irritating to skin

Xi: R43 - May cause sensitisation by skin contact

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

Xi: R43 - May cause sensitisation by skin contact

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

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

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

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

Not classified.

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

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

Not classified.

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

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

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

EUROPEAN WASTE CATALOGUE (EWC)

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

2.2. Evaluation of the risk for human health

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

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

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

Noise Barrier

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

House

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

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

Groundwater

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

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

2.4. Storage Stability Study

A new accelerated storage stability test of the active substance tebuconazole and the film preservative Iodoproponyl butylcarbamate (IPBC) in steel containers was performed for the new formulation. The levels of the active substances were measured prior to and after storage of samples for 4 weeks at 40 °C. The study was conducted according to internal standard

methods for the two active substances (AWPA A 28-2005 and an internal standard method for IPBC). The analytical results indicated that the concentration of active substances in the samples were stable following the storage period.
In connection with the authorisation of Jotun Industri Grunning Visir Hvit/Gul base the final results of the 2-year stability test, as well as an accelerated stability test in plastic containers was submitted in 2012 (See addendum to PAR June 2012 for details). The accelerated study in plastic containers showed no difference in the storage stability between steel and plastic containers. The change in the formulation is considered to be minor and is not expected to influence the stability of the active substance in neither of the two packaging types. (Christiansen, R., 2014).

2.5. Efficacy

The Danish Technological Institute (DTI) has evaluated whether the change in the formulation has an effect on the efficacy of JIGV Hvit/Gul base. Some changes of a preservative formulation are considered minor and no new biological testing is required. Guidance document EN 599-1 gives guidance to which changes are considered minor. However, as some minor changes, nevertheless, may influence the efficacy of the product, DTI has conducted an individual assessment and concluded that there was no need for a new biological test for efficacy. The product has earlier been tested for efficacy for wood destroying fungi and the substitution of the cobalt compound in the product is assessed not to influence the efficacy.

2.6. Conclusion

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

1 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. Jotun Industri Grunning Visir.	Yes	Jotun A/S
Christiansen, Rune	2014	Statement Stability test	Yes	Jotun A/S

Appendix 6

Addendum to Product Assessment Report

Jotun Industri Grunning Visir Gul base

February 2018

Minor change of the product formulation

R4BP3 case no :	BC-GX027901-17
Authorisation/Registration no:	NO-2012-0023
Date:	February 2018
Active ingredient:	Tebuconazole
Product type:	PT 8

1.Background

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

2. Description of the changes

2.1. Change in the formulation of the product

The change in the product formulation regards a substitution of some of the raw materials used in the production of the product. The substitution results in the removal or reduction of some of the co-formulants in the product. The concentration of the film preservative (PT7) IPBC is reduced in the product. The difference in the added volume of raw material is substituted with water. The details are described in the confidential annex to this addendum.

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

2.2. Change in classification of the product

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

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

Existing classification and labelling of JIGV Gul base according to CLP:

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

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

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

New classification and labelling of JIGV Gul base:

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

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

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

2.5. Conclusion

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

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