



HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 HERREGISTRATIE TOELATING

Gelet op de aanvraag d.d. 30 maart 2010 (20100387 THB) van

Hoetmer B.V.
Singel 271 D
3311 KS DORDRECHT

tot herregistratie van de toelating als bedoeld in artikel 49, eerste lid, Wet gewasbeschermingsmiddelen en biociden voor de biocide op basis van de werkzame stof propiconazool,

Embalit P

gelet op artikel 66, eerste lid, Wet gewasbeschermingsmiddelen en biociden,

BESLUIT HET COLLEGE als volgt:

1.1 Herregistratie toelating

1. De toelating van het biocide Embalit P, welke expireert op 31 maart 2012 wordt voor de in bijlage I genoemde toepassingen verlengd onder nummer 11575. Voor de gronden van dit besluit wordt verwezen naar bijlage II bij dit besluit.
2. De toelating geldt tot 31 maart 2020.

1.2 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.3 Gebruik

Het middel mag slechts worden gebruikt met inachtneming van hetgeen in bijlage I onder A bij dit besluit is voorgeschreven.

1.4 Classificatie en etikettering

Gelet op artikel 50, eerste lid, sub d, Wet gewasbeschermingsmiddelen en biociden,

1. De aanduidingen, welke ingevolge artikelen 9.2.3.1 en 9.2.3.2 van de Wet milieubeheer en artikelen 14, 15a, 15b, 15c en 15d van de Nadere regels verpakking en aanduiding milieugevaarlijke stoffen en preparaten op de verpakking moeten worden vermeld, worden hierbij vastgesteld als volgt:

aard van het preparaat: vloeistof

<i>werkzame stof:</i>	<i>gehalte:</i>
propiconazool	100 g/l

letterlijk en zonder enige aanvulling:

andere zeer giftige, giftige, bijtende of schadelijke stof(fen):

-

<i>gevaarsymbool:</i>	<i>aanduiding:</i>
Xi	Irriterend
N	Milieugevaarlijk

Waarschuwingzinnen:

R43	-Kan overgevoeligheid veroorzaken bij contact met de huid.
R51/53	-Vergiftig voor in het water levende organismen; kan in het aquatisch milieu op lange termijn schadelijke effecten veroorzaken.

Veiligheidsaanbevelingen:

S21	-Niet roken tijdens gebruik.
S36/37	-Draag geschikte handschoenen en beschermende kleding.
S61	-Voorkom lozing in het milieu. Vraag om speciale instructies / veiligheidsgegevenskaart.

Specifieke vermeldingen:

-

- 1) Behalve de onder 1. bedoelde en de overige bij de Wet Milieugevaarlijke Stoffen en Nadere regels verpakking en aanduiding milieugevaarlijke stoffen en preparaten voorgeschreven aanduidingen en vermeldingen moeten op de verpakking voorkomen:

- letterlijk en zonder enige aanvulling:
het wettelijk gebruiksvoorschrift
De tekst van het wettelijk gebruiksvoorschrift is opgenomen in Bijlage I, onder A.
- hetzij letterlijk, hetzij naar zakelijke inhoud:
de gebruiksaanwijzing
De tekst van de gebruiksaanwijzing is opgenomen in Bijlage I, onder B.
De tekst mag worden aangevuld met technische aanwijzingen voor een goede bestrijding mits deze niet met die tekst in strijd zijn.

1.5 Aflever- en opgebruiktermijn

Op grond van artikel 68, vijfde lid, Wet gewasbeschermingsmiddelen en biociden en het Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007, mag het middel Embalit P voor de niet meer toegelaten etikettering:

1. voor de periode van 30 juni 2011 tot 31 december 2012 nog worden gebruikt en in voorraad of voorhanden worden gehouden;
2. voor de periode van 30 juni 2011 tot 31 december 2011 nog op de markt worden gebracht.

2 DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraag

Het betreft een aanvraag tot herregistratie van de toelating van het middel Embalit P (11575 N), een middel op basis van de werkzame stof propiconazool. De herregistratie wordt aangevraagd voor de toelating als houtverduurzamingsmiddel

- 1) voor het preventief behandelen van hout binnen- en buitenshuis (gebruiksklasse 2 en 3) tegen schimmels, met uitzondering van hout dat in permanent contact zal komen met grond en/of water
- 2) voor het preventief behandelen van hout tegen aantasting door blauwschimmels en andere houtverkleurende schimmels

2.2 Informatie met betrekking tot de stof

De werkzame stof propiconazool is bij Richtlijn 2008/78/EC, dd 25 juli 2008 van de Europese Commissie van de Europese Gemeenschappen opgenomen in Bijlage I van Richtlijn 98/8/EG.

2.3 Karakterisering van het middel

Embalit P is a wood preservative (PT8) based on propiconazole. Like other triazole fungicides propiconazole inhibits the C14 demethylation step in the ergosterol biosynthesis of fungi. All four isomers of propiconazole provide biological activity. The intrinsic activity of each isomer is different from pathogen to pathogen. The broad spectrum and high level of activity of propiconazole is the result of the combined activity of the single isomers.

2.4 Voorgeschiedenis

De aanvraag is op 30 maart 2010 ontvangen; op 31 maart 2010 zijn de verschuldigde aanvraagkosten ontvangen. Bij brief d.d. 16 december 2010 is de aanvraag in behandeling genomen.

2.5 Eindconclusie

Bij gebruik volgens het Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing is het middel Embalit P op basis van de werkzame stof propiconazool voldoende werkzaam en heeft het geen schadelijke uitwerking op de gezondheid van de mens en het milieu (artikel 49, Wet gewasbeschermingsmiddelen en biociden).

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 119, eerste lid, Wet gewasbeschermingsmiddelen en biociden en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 29 juni 2011

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN
BIOCIDEN,

dr. D. K. J. Tommel
voorzitter

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I bij het besluit d.d. 29 juni 2011 tot herregistratie van de toelating van het middel Embalit P, toelatingnummer 11575 N

A.

WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als houtverduurzamingsmiddel:

1. voor het preventief behandelen van hout binnens- en buitenshuis (gebruiksklasse 2 en 3) tegen schimmels (houtrot, houtverkleurende- en blauwschimmels), met uitzondering van hout dat in permanent contact zal komen met grond en/of water.
2. voor het preventief behandelen van pas geveld hout tegen aantasting door blauwschimmels en andere houtverkleurende schimmels;

Hierbij moeten de retenties zoals aangegeven in de gebruiksaanwijzing worden aangehouden.

Dit middel is gevaarlijk voor vissen en andere waterorganismen; voorkom verontreiniging van bodem, grond- en oppervlaktewater.

Behandeling en opslag van hout dienen plaats te vinden onder dak en/of boven een vloeistofdichte vloer.

Lozing op het riool van het middel is niet toegestaan. Resten die het middel bevatten, dienen te worden hergebruikt of verwijderd als chemisch afval.

Hout behandeld met dit product mag niet worden toegepast over of vlakbij water.

Het ter plaatse aanbrengen van het product met borstel of spuit in de buurt van waterlopen mag niet gebeuren op plaatsen waar niet vermeden kan worden dat het product in het aquatische milieu kan terechtkomen.

Elke bodem in de buurt van een te behandelen voorwerp moet mechanisch beschermd worden tijdens de duur van de behandeling (bijv. met behulp van een dekzeil of plastic doek).

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.

GEBRUIKSAANWIJZING

1. De concentratie van de te gebruiken oplossing is afhankelijk van houtsoort, houtafmeting, toepassings-techniek en bestemming. De retentie is alleen afhankelijk van de toepassing.

1A.

Het hout behandelen in een industriële installatie, bijvoorbeeld dompel/drenk installatie of een vacuüm- en drukinstallatie. De concentratie van de te gebruiken oplossing is afhankelijk van houtsoort, houtafmeting, toepassings-techniek en bestemming. De retentie is alleen afhankelijk van de toepassing. Zie voor de retentie de volgende tabel.

Gebruik	Toepassingstechniek	Concentratie (van product)	Retentie
Bescherming tegen houtaantastende/ houtverkleurende schimmels voor hout onderdak en hout buiten, niet in contact met de grond	Vacuüm en druk / dubbel vacuüm	2% (maar kan variëren naargelang de omstandigheden)	onverdund product: 2,5 tot 6 kg/m ³ 2% verdund product: 125 tot 300 kg/m ³

De controle of de juiste gebruikconcentratie is bereikt kan geschieden met behulp van een areometer en/of een refractometer (voor concentraties $\geq 1\%$). Wanneer de temperatuur van de oplossing beneden de 5°C daalt dient het impregneren gestaakt te worden.

De druktijden bij de vacuüm- en drukmethode en de dubbelvacuümmethode en de duur van het dompelen en drenken zijn afhankelijk van de houtsoort, houtdikte en de op te nemen hoeveelheid verduurzamingsmiddel.

Alvorens te verduurzamen dient het hout alle benodigde bewerkingen zoals boren en inkepen te hebben ondergaan.

1B.

Het hout bestrijken, dompelen of bespuiten met een lage druk en grove druppel met een 5 of een 10%-ige oplossing. Zie voor de retentie de volgende tabel.

Gebruik	Toepassingstechniek	Concentratie (van product)	Retentie
Bescherming tegen houtaantastende/ houtverkleurende schimmels	Bestrijken Bespuiten Dompelen	10% (maar kan variëren naargelang de omstandigheden)	onverdund product: 13,5 g/m ² 10% verdund product: 135 g/m ²

2. Ter voorkoming van blauwschimmelgroei moet het hout zo spoedig mogelijk na het zagen behandeld worden met een Embalit P oplossing. Zie voor de retentie de volgende tabel.

Gebruik	Toepassingstechniek	Concentratie (van product)	Retentie
Tijdelijke bescherming van pas geveld hout	Bespuiten Dompelen Bestrijken	2% (maar kan variëren naargelang de omstandigheden)	onverdund product: 3,8 g/m ² 2% verdund product: 190 g/m ²

**HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN
BIOCIDEN**

BIJLAGE II bij het besluit d.d. 29 juni 2011 tot herregistratie van de toelating van het middel
Embalit P, toelatingnummer 11575 N

Product Assessment Report

Embalit P

27 May 2011

Internal registration/file no:	20100387 THB
Authorisation/Registration no:	11575 N
Granting date/entry into force of authorisation/ registration:	29/06/2011
Expiry date of authorisation/ registration:	31/03/2020
Active ingredient:	Propiconazole
Product type:	PT 8

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

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1 General information about the product application

1.1 Applicant

Company Name:	Hoetmer b.v.
Address:	Singel 271-D (P.O. Box 1)
City:	Dordrecht
Postal Code:	NL-3311 KS (NL-3300 AA)
Country:	The Netherlands
Telephone:	+31 78 6350720
Fax:	+31 78 6133029
E-mail address:	hoetmerbv@hoetmer.com

1.1.1 Person authorised for communication on behalf of the applicant

Name:	MSc Julien Trompetter
Function:	Beleidsmedewerker
Address:	Singel 271-D (P.O. Box 1)
City:	Dordrecht
Postal Code:	NL-3311 KS (NL-3300 AA)
Country:	The Netherlands
Telephone:	+31 78 6350720
Fax:	+31 78 6133029
E-mail address:	jtrompetter@hoetmer.com

1.2 Current authorisation holder

Company Name:	Hoetmer b.v.
Address:	Singel 271-D (P.O. Box 1)
City:	Dordrecht
Postal Code:	NL-3311 KS (NL-3300 AA)
Country:	The Netherlands
Telephone:	+31 78 6350720
Fax:	+31 78 6133029
E-mail address:	hoetmerbv@hoetmer.com
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	Not applicable

1.3 Proposed authorisation holder

Company Name:	Hoetmer b.v.
Address:	Singel 271-D (P.O. Box 1)
City:	Dordrecht
Postal Code:	NL-3311 KS (NL-3300AA)
Country:	The Netherlands
Telephone:	+31 78 6350720
Fax:	+31 78 6133029
E-mail address:	hoetmerbv@hoetmer.com
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	Not applicable

1.4 Information about the product application

Application received:	31-03-2010
Application reported complete:	16-12-2010
Type of application:	First authorisation (re-registration)
Further information:	-

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	Embalit P
Manufacturer's development code number(s), if appropriate:	-
Product type:	PT8
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	The biocidal product contains 9.7% w/w propiconazole (pure active substance). The biocidal product contains no substance of concern
Formulation type:	SL
Ready to use product (yes/no):	No
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	The Biocidal Product Embalit P has the same identity and composition as the product evaluated in connection with the approval for listing of propiconazole on to Annex I to directive 98/8/EC.

in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):	
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1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	The proposed field of use of Embalit P is: For use only as a wood preservative for the treatment of timber as a fungicide against wood destroying fungi and blue stain in use classes 2 and 3 (UC 2 and 3); sap stain and moulds in fresh felled logs and green timber. The product is to be used for professional and industrial use only.		
Target organisms:	Fungi: sap stain fungi, wood destroying Basidiomycetes, blue stain		
Category of users:	Industrial and professional users		
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:			
Description	Application	Application method	Retention of undiluted product
Sapstain and Moulds	Fresh felled logs and green timber	Dipping and spraying	3.8 g/m ²
Blue stain (1)	UC 2 en 3 in service	Dipping, brushing and spraying	13.5 g/m ²
Blue stain (2)	UC 2 en 3 in service	Vacuum	5 kg/m ³
Wood destroying Basidio-mycetes	UC 2 en 3 in service	Penetrative methods	6 kg/m ³
Potential for release into the environment (yes/no):	yes		
Potential for contamination of food/feedingstuff (yes/no)	no		
Proposed Label:	<ul style="list-style-type: none"> • For professional use only • To be used as wood preservative <ul style="list-style-type: none"> - control of wood destroying (decay) and wood discolouring fungi (blue stain) in Use Class 2 and 3. - control of discolouration in fresh felled logs and green timber (sap stain and moulds). <p>The application rates as stated above should also be included on the label.</p>		
Use Restrictions:	<p>Based on the risk assessment for the professional operator and the sensitising properties gloves and coverall are prescribed on the label.</p> <p>In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect</p>		

	those compartments. In particular, the label and safety-data sheet of Embalit P shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
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1.5.3 Information on active substance(s)

Active substance chemical name:	Propiconazole	
CAS No:	60207-90-1	
EC No:	262-104-4	
Purity (minimum, g/kg or g/l):	≥ 93 % w/w	
Inclusion directive:	2008/78/EC	
Date of inclusion:	01-04-2010	
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:	See SPC (confidential data)	
Company Name:		
Address:		
City:		
Postal Code:		
Country:		
Telephone:		
Fax:		
E-mail address:		

1.5.4 Information on the substance(s) of concern

Not applicable

1.6 Documentation

1.6.1 Data submitted in relation to product application

Two additional studies related to the active substance have been submitted for the environmental section (a terrestrial plant and an algae study), see §2.6.2.

Three additional studies related to the active substance have been submitted, two for the physical chemical properties of Embalit P, see physical chemical properties section (§2.3.1) and one for the environmental section (wood leaching study), see §2.6.2.

The studies are listed in Annex 2A 'List of studies reviewed'.

Study summaries (including evaluation) from the three environmental studies are included after Annex 2B.

1.6.2 Access to documentation

The applicant (Hoetmer B.V.) has submitted a letter of access (22-03-2010) to the data owned by Syngenta and filed in support of the registration of propiconazole in the Netherlands.

The applicant (Hoetmer B.V.) has submitted a letter of access (09-03-2010) to the data owned by Janssen PMP and filed in support of the registration of Wocosen 100 SL in the Netherlands.

2 Summary of the product assessment

2.1 Identity related issues

2.1.1 Identity of the Biocidal Product

Trade name	Embalit P			
Active ingredient	Purity (%w/w)	CAS No.	EC No.	Content (%w/w)
Propiconazole	≥ 93	60207-90-1	262-104-4	9.7 (pure active)
Remark: Propiconazole is a racemic mixture of four isomers, present in equal amounts. No substance of concern is present in Embalit P.				

2.1.2 Statement of technical equivalence

The Annex I Inclusion Directive describes propiconazole with a minimum purity of 930 g/kg.

The active substance is considered to be equivalent to the active substance as included in Annex I of directive 98/8/EC. The source of the active substance is identical.

The propiconazole dossier gives the minimum purity of the active substance, 930 g/kg which is the same as stated in the Inclusion Directive for propiconazole PT8. As such, no concerns were raised in relation to the technical equivalence of the active ingredient for the product Embalit P.

The formulation is identical to that assessed for the inclusion of the active substance in Annex I of Directive 98/8/EC.

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification and labelling of the biocidal product

2.2.1.1 Proposal for the classification and labelling of the formulation concerning physical chemical properties

Proposed classification based on Directive 1999/45/EC

Symbol:	-	
Indication of danger:	-	
R-phrases:	-	
S-phrases:	S21	When using, do not smoke.

Proposed classification based on Regulation EC 1272/2008

Signal word:	-		
Pictogram:	-		
	Hazard class-and-Category	Code	Hazard statement
Hazard statements:	-	-	-
Precautionary statements:	-	-	-

Supported shelf life of the formulation: 3 years

2.2.1.2 Proposal for the classification and labelling of the formulation concerning human toxicology properties

Proposed classification based on Directive 1999/45/EC

Symbol:	Xi	
Indication of danger:	Irritant	
R-phrases:	R43	May cause sensitization by skin contact.
S-phrases:	S36/37	Wear suitable protective clothing and gloves.

Proposed classification based on Regulation EC 1272/2008

Signal word:	Warning		
Pictogram:	GHS07		
	Hazard class-and-Category	Code	Hazard statement
Hazard statements:	Skin Sens. 1	H317	May cause an allergic skin reaction.
Precautionary statements:		P280	Wear protective gloves/protective clothing.

2.2.1.3 Proposal for the classification and labelling of the formulation concerning environmental properties

Proposed classification based on Directive 1999/45/EC

Symbol:	N	
Indication of danger:	Dangerous for the environment	
R-phrases:	R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
S-phrases:	S61	Avoid release to the environment. Refer to special instructions/Safety data sheets.

Proposed classification based on Regulation EC 1272/2008

Signal word:	-		
Pictogram:	GHS09		
	Hazard class-and-Category	Code	Hazard statement

Hazard statements:	Aquat.chron.2	H411	Toxic to aquatic life with long lasting effects.
Precautionary statements:		P273 P391 P501	Avoid release to the environment. Collect spillage. Dispose of contents/container ... (in accordance with local/regional/national/international regulation (to be specified)).

2.2.2 Packaging of the biocidal product

Material:	HDPE
Capacity:	25 l jerrycan, 200L drum or 1000 L industrial bulk containers (IBC)
Type of closure and size of opening:	25 l jerrycan: sealable cap, DIN 61 200 l drum: 2x2" Tri-sure cap 1000 l IBC: screw cap, opening DIN 150
Other information	UN/ADR compliant

2.3 Physico/chemical properties and analytical methods

The applicant has submitted a Letter of Access for the propiconazole studies and results presented in the Annex I dossier. The physico/chemical properties for the active substance propiconazole are detailed in the Annex I dossier, Doc IIIA, Section 3.

The physico/chemical properties for the formulation Embalit P are identical to Wocosen 100SL and are detailed in the Annex I dossier, Doc IIIB, Section B3.

The methods for the active substance propiconazole, the impurities and the cis/trans ratio of the active substance in the technical active substance are detailed in the Annex I dossier, Doc IIIA, Section 4.1.

The methods for the active substance propiconazole in soil, air, water animal matrices and crops are detailed in the Annex I dossier, Doc IIIA, Section 4.2.

2.3.1 Physico-chemical properties

The applicant has submitted the following additional studies:

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

Technical characteristics in dependence of the formulation type	Method	Purity/Specification	Results	Reference
Persistent foaming	CIPAC MT47.2	100 g/l nominal concentration, batch 2629-101109	Concentration: 140 g/l: after 1 minute: 38 ml foam	de Ryckel B (2010)
Autoflammability	A.15	100 g/l nominal concentration, batch 2629-101109	232 °C	Mak W.A. (2011)

2.3.2 Analytical methods

	Principle of method
Technical active substance as manufactured:	GC-FID

Ratio cis/trans isomers of active substance	HPLC-UV
Impurities in technical active substance:	Confidential information:
Active substance in the formulation:	HPLC-UV

Please refer to Annex 3 to this section, Analytical methods residues – active substance.

2.4 Risk assessment for Physico-chemical properties

No new data/information on physico-chemical properties has been submitted for the product or for the active substance that provides additional data for the risk assessment.

2.5 Effectiveness against target organisms

2.5.1 Function

Embalit P is a wood preservative (PT8) based on propiconazole (100g/l). The product is to be used for professional and industrial use only.

2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Organisms to be controlled are wood attacking fungi: sap stain fungi, moulds, wood destroying Basidiomycetes (decay), blue stain fungi.

The product is used to protect wood in use classes 2 and 3.

The product is to be used by professional and industrial users only.

2.5.3 Effects on target organisms

No efficacy studies performed with Embalit P have been submitted. For demonstrating the efficacy of the product a letter of access to the dossier of an identical product (Wocosen 100 SL) is provided. This is acceptable.

Laboratory studies of surface application and penetrating treatment processes were submitted. The submitted studies have demonstrated a sufficient degree of efficacy of Wocosen100 SL against sap stain and moulds, blue stain and decay in most of the evaluated applications. Efficacy against dry rot fungi (*Serpula lacrymans*) was demonstrated in mortar.

These studies confirm that the product is an effective fungicide for the control of wood destroying Basidiomycetes (decay) and wood discolouring fungi (blue stain) in Use Class 2 and 3. Apart from controlling rot and discolouration fungi in service life of processed timber, it can control discolouration fungi in fresh felled logs and green timber (sap stain and moulds).

No studies were provided to demonstrate efficacy in curative treatment in wood. Therefore this is excluded from the intended use.

Table 2.5-1: Experimental data on the effectiveness of the product against target organisms

Test substance	Test organism(s)	Test system / exposure time	Test results
Test Product (containing 100 g propiconazole/l)	Sap stain and moulds ⁽¹⁾	Lab trial with freshly cut wood (Nordic standard NWPC 1413/79) 3 weeks	Good protection is obtained between 0.23 and 0.38 g a.s./m ²
Test Product (containing 100 g	Blue stain ⁽²⁾	EN152 part 1 + artificial weathering	Good protection is obtained at 135 g a.s./m ²

propiconazole/l)		6 weeks	
Test Product (containing 100 g propiconazole/l)	Decay ⁽³⁾	EN113 + EN 73+ EN84 16 weeks	To control the most tolerant decay fungi (<i>Coniophora puteana</i>) 600 g a.s./m ³ is needed. Effective range is 250 to 600g a.s. /m ³ .
Test Product (containing 100 g propiconazole/l)	Blue stain ⁽²⁾	EN152 part 2 6 weeks	483 g a.s./m ³ is found effective
Test Product (containing 100 g propiconazole/l)	Dry rot ⁽⁴⁾	BAM method: EMPA modified, EMPA SOP N°000'592, on mortar 12 weeks	Good protection obtained with 7.5 g and 12.5 g a.i./m ² of mortar

(1) e.g.: *Ceratocystis pilifera*, *Cladosporium* sp, *Penicillium* sp, *Sclerophoma entoxylina*, *Trichoderma viride* etc.

(2) e.g.: *Aureobasidium pullulans* and *Sclerophoma pityophila* etc.

(3) e.g.: *Coriolus versicolor*, *Coniophora puteana*, *Poria placenta*, *Gloeophyllum trabeum*

(4) e.g. *Serpula lacrymans*

2.5.3.1 Dose

The following retentions of Embalit P for wood preservation in use classes 2 and 3 are supported on the basis of the submitted efficacy studies (table 2.5-2). The studies make no difference between UC2 and UC3.

Table 2.5-2: Application dose of Embalit P

Description	Application	Application method	Mid Toxic Value (MTV)	Test range active substance	Retention of undiluted product
Sapstain and moulds	Fresh felled logs and green timber	Dipping and spraying	0.3 g a.s./m ²	0.23 – 0.38 g a.s./m ²	3.8 g/m ²
Blue stain (1)	UC 2 en 3 in service	Dipping, brushing and spraying	1.35 g a.s./m ²	-	13.5 g/m ²
Blue stain (2)	UC 2 en 3 in service	Vacuum	483 g a.s./m ³	-	5 kg/m ³
Wood destroying Basidiomycetes	UC 2 en 3 in service	Penetrative methods	430 g a.s./m ³	250 - 600 g a.s./m ³	2.5 - 6 kg/m ³

2.5.3.2 Mode of action

Like other triazole fungicides propiconazole inhibits the C14 demethylation step in the ergosterol biosynthesis of fungi. All four isomers of propiconazole provide biological activity. The intrinsic activity of each isomer is different from pathogen to pathogen. The broad spectrum and high level of activity of propiconazole is the result of the combined activity of the single isomers.

2.5.3.3 Limitations

After application of Embalit P a several hours waiting period is needed to dry the treated material.

2.5.4 Resistance

Resistance to fungicides is a normal phenomenon embodied in the natural process of the evolution of biological systems and all DMIs (demethylation inhibitor) including propiconazole have a similar resistance risk but resistance factors may be different. There are no specific resistance cases to propiconazole reported and the activity of all four isomers of propiconazole may reduce the formation of resistance. Therefore, occurrence of resistance to propiconazole is not considered further.

Resistance management strategies

Propiconazole should be strictly used as all DMIs according to the Fungicide Resistance Action Committee guidelines. However, there are no specific resistance prevention measures for biocides identified. It is therefore only recommended to pay attention to prevention of the evolution of tolerant fungal strains and report to Competent Authorities any new information on development of fungal resistance to propiconazole.

2.5.5 Evaluation of the label claim

Efficacy of Embalit P has been demonstrated for the following intended uses:

- control of wood destroying (decay) and wood discolouring fungi (blue stain) in Use Class 2 and 3.
- control of discolouration in fresh felled logs and green timber (sap stain and moulds).

Efficacy has not been demonstrated for curative treatment in wood. Therefore this is excluded from the intended use on the label.

The doses as stated in table 2.5-2 should be used on the label.

On the Dutch label provided by the applicant use against wood destroying (decay) and wood discolouring fungi (blue stain) is combined. In this case the application rate is 6 kg/m³, to cover both uses.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

Please refer to §1.5.2.

Wocosen 100 SL is the representative product in the CAR. Embalit P is identical to the representative product in the CAR with an identical intended use. No studies were however provided to demonstrate efficacy in curative treatment in wood and this is therefore excluded from the label. Curative treatment is however taken into account in the exposure and risk assessment.

2.6.2 Assessment of exposure to humans and the environment

Environmental exposure occurs when Embalit P is released from application and storage of treated wood prior to shipment and from treated wood in service. The environmental exposure of Wocosen 100 SL, a wood protection product with an identical composition as Embalit P, was assessed during the Annex I active review stage. For the current assessment a new wood leaching study for Wocosen 100 SL, and a terrestrial plant and algae study for propiconazole have been submitted. The terrestrial plant and algae studies are part of Doc IIIA of the first draft CAR of propiconazole for PT9.

A new exposure and risk assessment (Doc IIB and Doc IIC) for Wocosen 100 SL is prepared by the applicant which is based on the new leaching study for the product. The applicant has also updated the effect and risk assessment for the product Wocosen 100 SL (Doc IIA and Doc IIC) using the results from new terrestrial plant study. The results from the new algae study were not included in the risk assessment from the applicant for Wocosen 100 SL but are included in the PAR for the product. All new studies submitted for the PAR of Embalit P are evaluated by the RMS NL, see Appendix 2.

See for more detail section 2.8 below.

2.7 Risk assessment for human health

No new studies on the product Embalit P have been provided. Embalit P is identical to the representative product in the CAR with an identical intended use.

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR.

The threshold limits and labelling regarding human health risks listed in Annex 4 „Toxicology and metabolism” must be taken into consideration.

2.7.1.2 Toxicology of the substance(s) of concern

No substance of concern is present in Embalit P.

2.7.1.3 Toxicology of the biocidal product

No new studies on the product Embalit P have been provided. Embalit P is identical to the representative product (Wocosen 100 SL) in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC. Acute toxicity and irritation studies are conducted with the product Wocosen 100 SL-C, which contains 100 g/l propiconazole and 5 g/l cypermethrin and is considered worst-case for Embalit P. The basis for the health assessment of the biocidal product is laid out in Annex 5 ”Toxicology – biocidal product”.

Based on these studies Embalit P is considered not acutely hazardous by the oral, dermal or inhalation routes of exposure. Embalit P is not classified as irritating to eyes or skin. During the product evaluation at Annex 1 stage a Buehler study was accepted. The Buehler method as such is considered to be less sensitive test compared to the Maximisation test. In the case of propiconazole, which has sensitizing properties in a Maximisation test, the NL CA is not convinced that a Buehler test will generate a reliable result. Under these conditions the Buehler test can only be accepted when a justification is given why this test is preferred. The justification given by the applicant addresses general pitfalls and limitations of a Maximisation test, however based on this information the NL CA does not anticipate problems with reading of skin reactions. Therefore, the NL CA does not accept the Buehler study with Wocosen 100 SL and proposes to label the biocidal product Embalit P with R43 based on the amount of propiconazole.

2.7.2 Exposure

The biocidal product contains 9.7% w/w propiconazole (pure active substance).

2.7.2.1 Exposure of professional users

Embalit P is for use by professional operators. The application techniques are vacuum-pressure/double-vacuum treatment and automated spraying or dipping for preventive treatment. For curative treatment Embalit P is to be used by spraying, brushing and injection techniques both in- and outdoors.

Embalit P is identical to the representative product in the CAR and the intended use is identical, the exposure calculations from the CAR is still valid for the product authorisation of Embalit P.

2.7.2.2 Exposure of non-professional users and the general public

Embalit P is not to be used by non-professionals. Secondary exposure of humans may occur by the following routes:

Acute phase: sanding treated wood (adult), touching wet wood after spraying (child) and chewing treated wood off-cuts (infant)

Chronic phase: inhalation of volatilised residues indoors (adult and infant), professional sanding, playing on playground structure (child), playing on weathered playground structure and making hand-to-mouth contact (infant) and cleaning work wear at home (adult).

A risk assessment for the above scenario's was made in the CAR. As Embalit P is identical to the representative product in the CAR and the intended use is identical, the conclusion from the CAR is still valid for the product authorisation of Embalit P.

2.7.2.3 Exposure to residues in food

For the use of Embalit P no residues in food and feed are anticipated.

2.7.3 Risk Characterisation

The risk characterisation CAR's conclusion gives only general recommendations for the use of personal protective equipment. In order to present what type of personal protective equipment for which application is necessary, the risk assessment for Embalit P is shown here. The exposure calculations were copied from the CAR. Exposure was compared to the AELmedium/long-term of 0.08 mg/kg bw/day (based on the NOAEL-value of 8 mg/kg bw/day of the 2-generations study in rat and assessment factor of 100).

2.7.3.1 Risk for Professional Users

Workplace operation	Exposure path	PPE		Exposure expressed as mg a.s./kg bw/day	% of AOEL (Exposure/AOEL)
Double vacuum impregnation – water-based formulation	Dermal and inhalation	No PPE (100% clothing penetration)	Worst case	0.59	738%
		Gloves and skin protection	75%-ile	0.027	34%
Cleaning of impregnation/ dipping tank after use	Dermal and inhalation	No PPE (100% clothing penetration)	Worst case	0.10	125%

Workplace operation	Exposure path	PPE		Exposure expressed as mg a.s./kg bw/day	% of AOEL (Exposure/AOEL)
		Gloves and skin protection	75%-ile	0.005	6.3%
Industrial dipping – water-based formulation	Dermal and inhalation	No PPE (100% clothing penetration)	Worst case	1.19	1488%
		Gloves and skin protection	75%-ile	0.055	69%
Professional <i>in situ</i> spraying (indoor) including mixing/loading and application, maintenance/repair and cleaning -2 events/day	Dermal and inhalation	No PPE (100% clothing penetration)	Worst case	1.07	1338%
		Gloves and skin protection	75%-ile	0.045	56%
Mixing and loading only by pouring	Dermal and inhalation	No PPE (100% clothing penetration)	Worst case (max)	0.0045	5.6%
Mixing and loading only by pumping	Dermal and inhalation	No PPE (100% clothing penetration)	Worst case (max)	0.026	33%
		Gloves and skin protection	max	0.025	31%
		Gloves and skin protection	75%	0.0045	5.6%
Small-scale dipping	Dermal and inhalation	No PPE (100% clothing penetration)	Worst case (max)	0.047	59%
Product painting, indoor -Model 1	Dermal and inhalation	No PPE (100% clothing penetration)	Worst case (max)	0.513	641%
		Gloves and skin protection	75%-ile	0.0433	54%
Product painting, outdoor -Model 3	Dermal and inhalation	No PPE (100% clothing penetration)	Worst case (max)	0.223	279%
		Gloves and skin protection	75%-ile	0.0113	14.1%
Product painting, outdoor -Model 2	Dermal and inhalation	No PPE (100% clothing penetration)	Worst case (max)	0.243	304%
		Gloves and skin protection	75%-ile	0.0133	16.6%

Based on the risk assessment of the active substance, a risk for professional users resulting from the intended use is not expected when personal protective equipment (gloves and coverall) are used. Only the applications mixing and loading (pouring and pumping) and small scale dipping has shown to be safe for the unprotected professional, however as these application in general are performed by the same professional user in combination with other applications, gloves and coverall will be prescribed for handling the product.

2.7.3.2 Risk for non-professional users and the general public

Copied from doc I, 2.7.4.2:

Secondary exposure was found highest for infants chewing wood off-cuts treated by dipping (acute phase) and adults cleaning work ware (chronic phase) with the MOEs of 750 and 520, respectively. For child touching wet wood after spraying (acute phase) the MOE is 880. As a conclusion, the health risk is acceptable in secondary exposure.

2.8 Risk assessment for the environment

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

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

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

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

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

Furthermore, in the Competent Authority Report for Propiconazole (December 2007, Rapporteur : Finland), it is confirmed that

“application solutions must be collected and reused or disposed of as hazardous waste and they must not be released to soil, surface water or any kind of sewer.”

The Competent Authority Report also notes that

“These requirements may be determined in detail in the environmental permits of the application plants on the basis of the Council Directive 96/61/EC on Integrated Pollution Prevention and Control (IPPC) but should be listed in the instructions for use of a biocidal product.”

On the basis of the above provisions, no further assessment of emissions from industrial treatment processes using Embalit P, and subsequent storage of treated wood, has been undertaken. The appropriate instructions are included in the label for Embalit P.

2 - In the case of professional in situ treatments – Brushing and spraying outdoors – the following scenarios have been run for Embalit P in hazard class 3.

Brushing outdoors – House, fence (PT8)

Spraying outdoors – treatment of a façade (adapted from PT10)

3 - In the case of treated wood in service, the following emission scenarios have been run for Embalit P for hazard class 3:

- House
- Fence

- Noise barrier
- Bridge over pond

Detailed calculations of PEC values, based on the Emission Scenario Documents are in Appendix 2 to this document. All PEC calculations are based on the maximum recommended application rates of 1.35 g/m² (brush/spray/dip application) and 200 g/m³ (vacuum pressure applications). Where lower application rates are employed (e.g. to fulfil a lesser claim), it may be assumed that PEC values will be proportionately lower.

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

	Air (outdoors)	Sewage treatment plant	Surface water and sediment	Soil	Ground Water ¹
Treated wood in service	No	✓	✓	✓	✓
In-situ treatment	No	✓	✓	✓	✓

¹ Indirect exposure via leaching of the substance in soil

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

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

It is most unlikely that Embalit P wastes will result in an environmental risk during incineration under controlled conditions required in the waste legislation. The propiconazole emissions from a landfill site due to disposal of propiconazole containing wood are evaluated to be less significant than that described for the house scenario for wood in service during the period from up to 20 years because the amount of treated wood per m² soil is assumed to be less. Therefore, it is unlikely that propiconazole treated timber wastes will result in an environmental risk from a normal landfill site. If treated wood is collected and disposed in special areas of a landfill it is assumed that special precaution has been taken for this part of the landfill.

No new data related to the environment have been submitted by the applicant.

2.8.1 Effects Assessment

New Data

Two studies that were not evaluated during the Annex I active review stage were submitted with the new product authorisation application. The new studies are as follows:

- Propiconazole – Toxicity to *Pseudokirchneriella subcapitata* in a 96-hour algal growth inhibition test (Höger S, 2011)
- Propiconazole formulation (Lag 2008 045): Chronic Toxicity in Higher Plants (Porch J.R., Martin K.H., Krueger H.O, 2009)

As these were new data, the RMS NL briefly reviewed the environmental summaries produced by the applicant and/or RMS Finland (who is RMS of the CAR for propiconazole), and compared it with the conclusions of the study reports.

Terrestrial plant toxicity study

A rapid-cycling variant of rape (*Brassica rapa* CrGC syn Rbr) was tested for effects on seedling growth and reproductive capability according to DIN ISO Guideline 22030. Amounts of test substance were weighed out, acetone added to dissolve and added to sand by mixing. The spiked sand was then added to known amounts of soil and mixed to produce the test concentrations. Half of the replicates were harvested on Day 16 of the test in order to assess potential effects on early seedling growth. The remaining replicates were harvested on Day 40 in order to assess potential effects on reproductive capability.

Soil-incorporation of LAg 2008 045 (a formulation containing nominally 1.22% w/w propiconazole) at nominal concentrations of up to 81 mg formulation/kg (corresponding nominally to 0.96 mg propiconazole/kg) resulted in no effects on any test parameter. Therefore, the NOEC was determined to be 81 mg formulation/kg, and the EC50 was determined to be greater than 81 mg formulation/kg. The test was conducted with a soil containing 1.7% organic matter. The RMS NL converted these endpoints to standard soils which is according to the TGD defined as soils with an organic matter content of 3.4%. The conversion of the NOEC of 0.96 mg propiconazole/kg and the EC50 > 0.96 mg propiconazole/kg result in a NOEC of 1.92 mg propiconazole/kg and an EC50 > 1.92 mg propiconazole/kg.

The applicants, RMS Finland (first draft CAR propiconazole for PT9) and RMS NL conclusions is as follows:

Based on this additional endpoint for soil organisms with regard to the Annex I data a revised PNEC_{soil} can be calculated for propiconazole.

The lowest effect concentration of propiconazole in soil is NOEC from earthworm (0.998 mg/kg wet soil, 3.4% organic matter). According to the TGD the assessment factor 10 is applied in the derivation of PNEC_{soil} for propiconazole because there are short-term and long-term studies from three trophic levels (microorganisms, earthworms and plants) in the soil environment available. Hence PNEC_{soil} = **0.0998** mg a.i./kg wet soil at 3.4% organic matter.

Algae toxicity study

The influence of the test item propiconazole on the growth of the freshwater green algal species *Pseudokirchneriella subcapitata* was investigated in a 96-hour static test according to the OECD Guideline 201 (2006) and the Commission Regulation (EC) No 761/2009, C.3, as well as according to the OPPTS Guideline No. 850.5400 (Public Draft, April 1996) and JMAFF Test Guidelines, 2-7-7 (2005).

The 72 h EC50 for growth rate was determined to be 8.95 mg/L

The 72 h NOEC for growth rate was determined to be 0.46 mg/L

The 96 h EC50 for growth rate was determined to be 8.9 mg/L

The 96 h NOEC for growth rate was determined to be 0.13 mg/L

The RMS Finland (first draft CAR propiconazole for PT9) conclusion is as follows:

On the basis of the algae study on the plant protection product Desmel A 6097-G (7.1.4.3/08), which was flagged as key-study on the first phase of the BPD evaluation program for PT8 (wood preservatives), propiconazole is very toxic to algae. In response to rapporteur's proposal for harmonised classification and labelling with respect to specific concentration limits (M factor) the applicant has submitted a new algae study on the active substance propiconazole (7.4.1.3/10) to the rapporteur in January 2011. Preferring a study on the active substance to a study with a formulation propiconazole is considered toxic to algae.

The applicant has submitted a new algae study (Höger S, 2011) on the active substance propiconazole to the rapporteur in January 2011. Preferring this study with the active substance to the algae study with a formulation propiconazole would have a remarkable effect on PNEC_{surfacewater}. The lowest long-term NOEC from three trophic levels (fish, invertebrates and algae) would be 0.31 mg ai/l (*Daphnia magna*) and PNEC_{surfacewater} = 0.31/10 = 31 µg a.i./l. This is approximately 19 times

higher than $PNEC_{\text{surfacewater}}$ of 1.6 $\mu\text{g a.i./l}$ used in the first phase of the BPD evaluation program for PT8 (wood preservatives).

The RMS NL conclusion is as follows:

Based on this additional endpoint for aquatic organisms with regard to the Annex I data the $PNEC_{\text{water}}$ will not alter as this endpoint is not the lowest acute toxicity endpoint from the trophic groups for which already acute toxicity data were available in the CAR for propiconazole.

NL: We do not agree with the amendment that the $PNEC_{\text{surface water}}$ in the CAR for propiconazole for PT9 was increased to 31 $\mu\text{g/L}$. the applicant has submitted a study for the less sensitive (>200 times less sensitive) species *Selenastrum capricornutum* of the two algae species tested under PPP. Furthermore, the TGD states that if the algae are the most sensitive group then a second species should have been tested before it can be used as a chronic endpoint: The TGD states that *the NOEC from this algae test may be used as an additional NOEC when other long-term data are available. In general, an algal NOEC should not be used unsupported by longterm NOECs of species of other trophic levels. However, if the short-term algal toxicity test is the most sensitive of the short-term tests, the NOEC from this test should be supported by the result of a test on a second species of algae.*

This indicates that the applicant should submit a second algae study or accept the studies from the PPP. We decided to use the PPP studies and not to alter the $PNEC_{\text{surface water}}$.

2.8.2 Exposure Assessment

A substantial exposure assessment has been conducted on the representative product Wocosen 100 SL, at the Annex I evaluation stage, full details of which are available in Annex I Doc IIB section 3.3.

For the national product authorisation of Embalit P a leaching study additional to the Annex I leaching study was submitted: Leaching of Wocosen 100 SL from treated timber (Willems W, 2010).

The leaching of propiconazole was studied with wooden panels of scots pine sapwood (*Pinus sylvestris*) treated for hazard class 3 and subjected to outdoor exposure under natural weather conditions in northern Belgium. The panels were treated by dipping with the water based product Wocosen 100 SL.

The diluted product was applied to achieve 500 ml/m^2 (propiconazole uptake 1.46 g/m^2 for superficial treatment, 730 g/m^3 for impregnation) in excess of the maximum recommended rates (1.35 g/m^2 for superficial treatment, 600 g/m^3 for impregnation).

No topcoat is applied. Rainfall was recorded throughout the exposure period, and the accumulated rainfall at each sampling interval was recorded. Exposure continued for approximately twenty one months, with water being taken for analysis at twenty nine intervals during this period.

The leaching values for TIME1 (30 days) in emission scenarios for wood in service were calculated from the cumulative leaching amount at 30 days using daily average leaching amounts. Leaching rates were corrected for an annual rainfall of 720 mm.

For TIME2 in emission scenarios the following service-lives were determined in connection with the leaching workshop held in Arona:

- vacuum-pressure treatment: 20 years
- double vacuum treatment: 20 years
- flow coating, dipping and spraying: 15 years
- brushing: 5 years

Daily leaching rates based on application rate of 1.35 g/m^2 (brush/spray/dip application) and extrapolated to 600 g/m^3 (vacuum pressure applications) obtained from the Willems (2010) study are:

30 days: 1.29 $\text{mg/m}^2/\text{day}$ (brush/spray/dip application), 1.15 $\text{mg/m}^2/\text{day}$ (vacuum pressure applications)

1825 days (brush application): 0.081 $\text{mg/m}^2/\text{day}$

5475 days (dip application): 0.032 mg/m²/day

7300 days (vacuum-pressure/double-vacuum pressure application): 0.022 mg/m²/day.

The RMS NL conclusion was as follows:

These leaching rates are corrected for a yearly rainfall of 720 mm. However, the TGD assumes a yearly rainfall of 700 mm. Recalculating the leaching rates for application rates of 1.35 g/m² and 600 g/m³ for the yearly rainfall of 700 mm (in line with the CAR for propiconazole) gives the following results:

Daily leaching rates based on application rate of 1.35 g/m² (brush/spray/dip application) and extrapolated to 600 g/m³ for vacuum-pressure applications obtained from the Willems (2010) study are:

30 days: 1.26 mg/m²/day (brush/spray/dip application), 1.12 mg/m²/day (vacuum-pressure application)

1825 days (brush application): 0.079 mg/m²/day

5475 days (dip application): 0.031 mg/m²/day

7300 days (vacuum-pressure/double-vacuum pressure application): 0.022 mg/m²/day.

Vacuum pressure treatment was not tested individually in the leaching study of Willems (2010).

Extrapolation of results from surface treatment of wood to vacuum pressure is not acceptable as in the report of the leaching workshop in 2005 the following is stated: "A leaching test will be required for each general application method (penetration and superficial) by which the wood preservative is to be applied. In addition, a leaching test will also be required for each formulation type (water and solvent based) of the wood preservative". Furthermore the workshop participants mutually agreed that superficial treatment processes result in higher leaching rates. However, it should be considered that the leaching rate pattern for both processes is different over time: superficial treatment processes result in an initial high leaching rate while penetration treatment processes result in a more constant leaching rate over time.

Results from this study can only be used for the risk assessment of surface treated wood with Embalit P. From the currently available leaching data from this test it cannot be concluded that leaching will decrease after the period for which the test has been run as too little evidence is available yet.

The results from the leaching study used in the CAR for propiconazole were corrected with extrapolation factors as the retentions of propiconazole in the different treatments were lower than the maximum treatment rates supported by the participant. As in the study of Willems (2010) the tested retention rates were **higher** than the maximum rate proposed in the Product Authorisation Dossier of 1.35 g/m² it was justified to modify the values for TIME 1 and TIME 2 and for harmonisation sake in line with the TGD it is decided to use the leaching rates corrected for a yearly rainfall of 700 mm and for the maximum recommended retention of 1.35 g/m² for the risk assessment of surface treatments of wood with Embalit P.

The risk assessment of vacuum pressure treatments of wood with Embalit P is based on, the leaching rates from the leaching study in the CAR for propiconazole.

All PEC for vacuum pressure calculations are derived from the CAR and based on the highest intended retentions proposed by the participant during the evaluation (200 g a.i./m³ for vacuum-pressure and double vacuum pressure).

Effect of re-application

PECs in this section have been calculated for one application to obtain the a.i. uptake in wood as indicated in the section on intended use. Any number of re-application would increase PECs of propiconazole derived from the intended uses of Embalit P. Re-application is further discussed in section 2.8.3.

2.8.2.1 PEC in Sewage treatment plant (STP)

Noise barrier in service

The OECD scenario “noise barrier” assumes that 70% of the emissions from wood will reach the wastewater treatment plant. The dimensions of the wastewater treatment plant (2000 m³ per day) was taken from the Technical Guidance Document (TGD, Part II, 2003). PECs in STP are listed in Table 2.8.2.1.1.

Table 2.8.2.1-1. PECs in STP (input: 1.35 g a.i./m² for professional brushing and dipping/automated spraying, 200 g a.i./ m³ for vacuum-pressure/double-vacuum pressure).

Scenario Wood in service	Application rate 1.35 g/m ² and 200 g/m ³ propiconazole	
	TIME 1 (30 days)	TIME 2 (default service life)
	PEC in STP effluent (µg a.i./l)	
Noise barrier - treatment professional brushing	1.04	0.067
Noise barrier - treatment dipping / automated spraying	1.04	0.026
Noise barrier - treatment vacuum-pressure	1.10	0.02
Noise barrier - treatment double-vacuum pressure	0.51	0.03

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

2.8.2.2 PEC in surface water

In-situ treatment (brushing or spraying)

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

On the basis of the above, no further assessment of emissions to water from in-situ treatment processes using Embalit P has been undertaken. The appropriate instructions are included in the label for Embalit P.

Service-life of treated wood

The OECD scenario “bridge over a small pond” calculates concentrations in pond water after 30 days and a longer relevant time period based on the leaching. In the calculation the dissipation half-life of propiconazole in water (6.4 days) is taken into account. In fact, both degradation and adsorption is taken into account when using a dissipation half-life. PECs in surface water for wood in service at Time 1 (30 days after the application) and Time 2 (default service life) are summarized in Table 2.8.2.2-1. The OECD scenario “noise barrier” assumes that 70% of the emissions from wood will reach the sewage and - via STP - the surface water. The dimensions of the wastewater treatment plant (2000 m³ per day) and the dilution factor (10) to the surface water were taken from the Technical Guidance Document (TGD, Part II, 2003). In addition, knowing log K_{ow} of propiconazole = 3.7 and Henry's law constant of propiconazole = $9.2 \cdot 10^{-5} \text{ Pa} \cdot \text{m}^3 \cdot \text{mol}^{-1}$, a factor of 0.21 was taken into account as a default for adsorption of propiconazole on sewage sludge (TGD Part II Appendix II default for log K_{ow} = 4, log H = -4). Furthermore, in the light of the arithmetic mean K_{oc} of 944 the factor of 0.21 appears the most applicable proportion of adsorption from TGD Part II Appendix II. Resulting PECs in surface water are reported in Table 2.8.2.2-1.

Table 2.8.2.2-1: PECs for the aquatic environment (input: 1.35 g a.i./m² for professional brushing and dipping/automated spraying, 200 g a.i./m³ for vacuum-pressure/double-vacuum pressure).

Scenario Wood in service	Application rate 1.35 g/m ² and 200 g/m ³ propiconazole	
	TIME 1 (30 days)	TIME 2 (default service life)
	PEC for the aquatic environment (µg a.i./l)	
Noise barrier - treatment professional brushing	0.104	0.0065
Noise barrier - treatment dipping / automated spraying	0.104	0.0026
Noise barrier - treatment vacuum-pressure	0.11	0.002
Noise barrier - treatment double vacuum-pressure	0.051	0.003
Bridge over pond - treatment professional brushing	5.59	0.36
Bridge over pond - treatment dipping / automated spraying	5.59	0.14
Bridge over pond - treatment vacuum-pressure	32.2	3.47
Bridge over pond - treatment double vacuum-pressure	32.2	3.47

2.8.2.3 PEC in sediment

The transferred concentration in suspended sediment was calculated from mg a.i./l (water) to mg a.i./kg suspended sediment using formula 50 with the aid of formulas 23 and 24 from the TGD (2003), part II. The concentration in freshly deposited sediment was taken as the PEC for sediment, and therefore, the properties of suspended matter were used. The degradation half-life of propiconazole in the whole water-sediment system (DT50 of 1206 days at 12°C) was used in order to provide PECs in surface water for the calculation of PECs in suspended sediment. The propiconazole concentration in water as mg/l has to be multiplied by a factor of 21.3 to get the concentration in sediment as mg/kg wet weight. The PECs in sediment for the in-service scenarios described under PEC in surface water are listed in Table 2.8.2.3-1.

Table 2.8.2.3-1: PECs for the sediment (input: 1.35 g a.i./m² for professional brushing and dipping/automated spraying, 200 g a.i./ m³ for vacuum-pressure/double-vacuum pressure).

Scenario Wood in service	Application rate 1.35 g/m ² and 200 g/m ³ propiconazole	
	TIME 1 (30 days)	TIME 2 (default service life)
	PEC for the sediment (mg a.i./kg)	
Noise barrier - treatment professional brushing	0.00222	0.000139
Noise barrier - treatment dipping / automated spraying	0.00222	0.000055
Noise barrier - treatment vacuum-pressure	0.002	0.0001
Noise barrier - treatment double vacuum-pressure	0.001	0.0001
Bridge over pond - treatment professional brushing	0.40	0.95
Bridge over pond - treatment dipping / automated spraying	0.40	0.56
Bridge over pond - treatment vacuum-pressure	2.30	13.7
Bridge over pond – treatment double vacuum-pressure	2.30	13.7

2.8.2.4 PEC in marine water and sediment

PECs in marine water and sediment are 1/10 of PECs in freshwater and its sediment due to the difference of TGD defaults of dilution factors (freshwater 10 and marine water 100). However, marine assessment is not considered necessary based on the intended uses in wood preservatives and related Emission Scenario Documents.

2.8.2.5 PEC in air

Propiconazole has a very low vapour pressure (0.000056 Pa at 25 °C) and therefore emission to air is not considered relevant.

2.8.2.6 PEC in soil

The OECD ESD for wood in service assumes 10 cm horizontal and vertical distance in soil. However, it was decided by the 23rd Competent Authority Meeting to consider soil volumes representing 50 cm horizontal and vertical distances in the risk assessment, and it was confirmed by the 24th Competent Authority Meeting that the 50 cm horizontal and vertical distances should apply at product authorisation stage as well as the Annex 1 entry. All PEC calculations for in-situ and in-service scenarios listed in Table 3.3.8.1 were carried out based on 50 cm horizontal and vertical distance. In the scenario 'house' the horizontal distance is 50 cm symmetrically to all four directions around the house (see ESD page 75 figure 5-3).

In-situ treatment (brushing or spraying)

During outdoor in-situ brush treatment by a professional, an initial PEC can be calculated according to OECD scenarios of fence and timber house. Assuming that 3% (professionals) of the applied product is lost due to spills and drips to soil, initial PECs for Embalit P containing 9.7% w/w propiconazole are calculated.

For the in-situ spray-treatment of a house façade by a professional, an initial PEC can be calculated by adapting the Emission Scenario document for biocides used as masonry preservatives, PT10 (INERIS, 2002). In this document, the house has the same dimensions as in the PT08 Emission Scenario Document (OECD), but two distinct volumes of soil are considered as environmental compartments – soil adjacent to the house is considered to receive runoff and dripping from the spraying process, soil distant to the house is considered to receive spray drift. The ESD gives a

volume of 0.5 m³ for the adjacent soil, based on compartment dimensions of 10 cm x 10 cm, and a volume of 27.3 m³ for the distant soil, based on a soil depth of 10 cm. In the calculations presented here, however, these dimensions have been amended in line with the decision of the 23rd Competent Authority Meeting so that a compartment size of 50 cm x 50 cm is considered for the adjacent soil, and a soil depth of 50 cm is considered for the distant soil. This gives soil volumes of 13 m³ for the adjacent soil and 121.7 m³ for the distant soil.

Service-life of treated wood

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

Soil concentrations were calculated for 30 days (TIME 1) and a relevant longer period (TIME 2) after application taking into account the soil dissipation half-life of propiconazole (77 days). PECs in soil for wood in service at Time 1 (30 days after the application) and Time 2 (default service life) are summarized in Table 2.8.2.6-1.

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

PECs in soil after Time 1 (30 days) and Time 2 (default service life) after brushing application can be calculated with the OECD scenarios 1) fence and 2) timber house. Initial PEC in soil after the in-situ application is combined with the PEC in soil after Time 1(30 days). The same approach can be applied to the longer assessment period Time 2 (default service life). Combined PECs are reported in Table 2.8.2.6-1.

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

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

Initial PEC in soil after the in-situ application is combined with the PEC in soil after Time 1(30 days). The same approach can be applied to the longer assessment period Time 2 (default service life). Combined PECs are reported in Table 2.8.2.6-1.

Table 2.8.2.6-1: Wood in-situ and in-service: Summary of calculated PECs (input: 1.35 g a.i./m² for professional brushing and dipping/automated spraying, 200 g a.i./m³ for vacuum-pressure/double-vacuum pressure).

Scenario	Application rate 1.35 g/m ² and 200 g/m ³ propiconazole		
	Concentration in local soil at the end of the day of application	Time 1 (30 days)	Time 2 (default service life)
Scenarios related to professional brushing treatment – in-situ + in-service combined			
	PEC for soil (mg a.i./kg ww)		
Fence	0.000191	0.326	0.069
House	0.000229	0.392	0.083
Scenarios related to professional brushing treatment –in-service only			
	PEC for soil (mg a.i./kg ww)		
Fence	n/a	0.164	0.069
House	n/a	0.197	0.083
Noise Barrier	n/a	0.074	0.031
Scenarios related to professional spraying treatment – in-situ + in-service combined			
	PEC for soil (mg a.i./kg ww)		
Façade / House – adjacent soil	0.00153	1.50	0.033
Façade / House – distant soil	0.000082	0.069	0
Scenarios related to dipping / spraying – in-service only			
	PEC for soil (mg a.i./kg ww)		
Fence	n/a	0.164	0.027
House	n/a	0.197	0.033
Noise Barrier	n/a	0.074	0.012
Scenarios related to vacuum pressure– in-service only			
	PEC for soil (mg a.i./kg ww)		
Fence	n/a	0.173	0.026
House	n/a	0.217	0.033
Noise Barrier	n/a	0.078	0.012
Scenarios related to double vacuum pressure– in-service only			
	PEC for soil (mg a.i./kg ww)		
Fence	n/a	0.080	0.034
House	n/a	0.099	0.043
Noise Barrier	n/a	0.036	0.016

Application of STP sludge to agricultural soil and grassland

Local PECs in agricultural soil and grassland as a result of the application of STP sludge was calculated, where the STP sludge may become contaminated due to the emission to drain in the Noise Barrier scenario. The highest emission rate from the Noise Barrier scenario was used as the input value (0.0026 kg a.i./day, from the spraying/dipping Time 1 calculations). The resulting PECs are reported in Table 2.8.2.6-2.

Table 2.8.2.6-2: STP sludge to agricultural soil and grassland: Summary of calculated PECs in soil (input: 1.35 g a.i./ m² for dipping/spraying).

	Local PEC in agricultural soil averaged over 30 days (mg a.i./kg ww)	Local PEC in agricultural soil averaged over 180 days (mg a.i./kg ww)	Local PEC in grassland averaged over 30 days (mg a.i./kg ww)	Local PEC in grassland averaged over 180 days (mg a.i./kg ww)
Wood in service: noise barrier - highest emission to facility drain 0.0026 kg a.i./day	0.0011	0.0007	0.0004	0.0003

2.8.2.7 PEC in groundwater

TGD does not contain a detailed approach to calculate PEC in groundwater but only the equation 67 to calculate concentration in pore water. Because this is a worst-case assumption, neglecting transformation and dilution in deeper soil layers, FOCUS-PEARL 3.3.3 modelling was carried out. In the PEARL modelling the following assumptions were made for all nine FOCUS scenarios: Wood is treated with propiconazole at a rate of 1.35 g a.i./m². It is assumed that the total amount applied will be emitted during service-life and thus is a conservative approach.

The housing density is 35 houses per hectare with each house having a treated area of 125 m² which results in a total area of 5906 m² yielding an emission of 4375 g a.i./ha.

An annual loss is 20% because the shortest assumed service-life of treated wood is 5 years, i.e. $0.2 \cdot 5906 \text{ g a.i./ha} = 1181 \text{ g a.i./ha}$.

All the compound enters the soil compartment 10 equally spaced events per year, i.e. $1181/10 = 118.1 \text{ g a.i./ha}$.

Given the way in which propiconazole is likely to enter the soil by being washed off the timber surface and running down to the soil as a result of precipitation, limited interception by the grass cover is considered to occur, and therefore, the whole amount of 118.1 g a.i./ha/year was loaded directly to the soil surface.

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

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

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

i) median of 8 values from laboratory studies

ii) arithmetic mean of 3 values from a laboratory study

iii) median of 9 values

iv) arithmetic mean of 4 values

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

For wood preservation use the predicted environmental concentration in groundwater, as represented by the 80th percentile leachate concentration at 1 m soil depth, for propiconazole and 1,2,4-triazole was less than 0.1 µg/l in all nine FOCUS-PEARL scenarios.

Embalit P contains only one active substance (propiconazole and no substances of concern). Therefore aquatic effects of the product can be extrapolated from the environmental effect studies on propiconazole.

2.8.3 Risk Assessment

Risk to the environment is characterized quantitatively by comparing a Predicted Environmental Concentration (PEC) with a Predicted No-Effect Concentration (PNEC) in different environmental compartments and scenarios. In this part of Document II the PEC/PNEC ratios only are presented. Detailed PEC_{local} calculations according to the OECD ESD for wood preservatives and TGD, part II (2003) are included in Doc II-B Appendix 2. All the calculations are based on the recommended maximum retentions (200 g/m³ for vacuum pressure/double vacuum and dip treatment, 1.35 g/m² for brushing and spraying against decay and blue stain).

2.8.3.1 STP

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

Table 2.8.3.1-1: PEC/PNEC ratios for the STP (input: 1.35 g a.i./m² for professional brushing and dipping/automated spraying, 200 g a.i./ m³ for vacuum-pressure/double-vacuum pressure).

Scenario Wood in service	Application rate 1.35 g/m ² and 200 g/m ³ propiconazole	
	TIME 1 (30 days)	TIME 2 (default service life)
	PEC/PNEC for the STP	
Noise barrier - treatment professional brushing	0.00104	0.000067
Noise barrier - treatment dipping / automated spraying	0.00104	0.000026
Noise barrier - treatment vacuum-pressure	0.00110	0.00002
Noise barrier - treatment double-vacuum pressure	0.00051	0.00003

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

PEC/PNEC ratios for the STP are below 1 for all application methods, meaning that there is no unacceptable risk to STP microorganisms. (Table 2.8.3.1-1).

2.8.3.2 Surface water

$PNEC_{surfacewater} = 1.6 \text{ µg a.i./l}$

Table 2.8.3.1-2: PEC/PNEC ratios for the aquatic environment (input: 1.35 g a.i./m² for professional brushing and dipping/automated spraying, 200 g a.i./ m³ for vacuum-pressure/double-vacuum pressure).

Scenario	Application rate 1.35 g/m ² and 200 g/m ³ propiconazole	
	TIME 1 (30 days)	TIME 2 (default service life)
	PEC/PNEC for the aquatic environment	
Wood in service		
Noise barrier - treatment professional brushing	0.065	0.0041
Noise barrier - treatment dipping / automated spraying	0.065	0.0016
Noise barrier - treatment vacuum-pressure	0.069	0.0013
Noise barrier - treatment double vacuum-pressure	0.032	0.0019
Bridge over pond - treatment professional brushing	3.49	0.2250
Bridge over pond - treatment dipping / automated spraying	3.49	0.0875
Bridge over pond - treatment vacuum-pressure	20.1	2.17
Bridge over pond - treatment double vacuum-pressure	20.1	2.17

Treated wood in service

There is unacceptable risk to the aquatic environment from wood in service in the bridge over pond scenario after TIME 1 (30 days), representing treated wood with direct losses to (small) waters. The risk is acceptable after the longer assessment period TIME 2 (default service life) for surface treatments for wood in service in the bridge over pond scenario. However, the risk is unacceptable for vacuum-pressure treatments after TIME 2 (default service life).

Concerning (indirect) emission due to leaching from the noise barrier via the STP to surface water, risk is acceptable at TIME 1 (30 days). Risk is still acceptable after the longer assessment period (default service life).

Since an unacceptable risk is identified where direct losses to water may occur, there should be a labelling against applications where direct losses to water are possible, thereby preventing use in these situations.

2.8.3.3 Sediment

$PNEC_{\text{sediment}} = 0.054 \text{ mg a.i./kg wet sediment.}$

Table 2.8.3.1-3: PEC/PNEC ratios for the sediment (input: 1.35 g a.i./m² for professional brushing and dipping/automated spraying, 200 g a.i./ m³ for vacuum-pressure/double-vacuum pressure).

Scenario	Application rate 1.35 g/m ² and 200 g/m ³ propiconazole	
	TIME 1 (30 days)	TIME 2 (default service life)
	PEC/PNEC for the sediment	
Wood in service		
Noise barrier - treatment professional brushing	0.04111	0.00257
Noise barrier - treatment dipping / automated spraying	0.04111	0.00103
Noise barrier - treatment vacuum-pressure	0.03704	0.00185
Noise barrier - treatment double vacuum-pressure	0.01852	0.00185
Bridge over pond - treatment professional brushing	7.41	17.59
Bridge over pond - treatment dipping / automated spraying	7.41	10.37
Bridge over pond - treatment vacuum-pressure	42.59	253.70
Bridge over pond – treatment double vacuum-pressure	42.59	253.70

Treated wood in service

There is unacceptable risk to sediment dwelling organisms from wood in service in the bridge over pond scenario after TIME 1 (30 days). The risk is still unacceptable after the longer assessment period TIME 2 (default service life) for all treatments.

Concerning emission due to leaching from the noise barrier via the STP to surface water, risk is acceptable risk at TIME 1 (30 days). Risk is still acceptable after the longer assessment period (default service life).

Since an unacceptable risk is identified where direct losses to water may occur there should be a labelling against applications where direct losses to water are possible, thereby preventing use in these situations.

2.8.3.4 groundwater used as drinking water

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

None of the predicted environmental concentration in groundwater, as represented by the 80th percentile leachate concentration at 1 m soil depth, for propiconazole and 1,2,4-triazole exceeds the maximum permissible concentration of 0.1 µg/l given for groundwater in Directive 80/778/EEC (amended by 98/83/EC).

2.8.3.5 atmosphere

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

2.8.3.6 soil

$PNEC_{soil} = 0.0998 \text{ mg a.i./kg wet soil}$

Table 2.8.3.1-4: Wood in-situ and in-service: Summary of calculated PEC/PNEC ratios (input: 1.35 g a.i./m² for professional brushing and dipping/automated spraying, 200 g a.i./ m³ for vacuum pressure/double-vacuum pressure.

Scenario	Application rate 1.35 g/m ² and 200 g/m ³ propiconazole		
	Concentration in local soil at the end of the day of application	Time 1 (30 days)	Time 2 (default service life)
Scenarios related to professional brushing treatment – in-situ + in-service combined			
PEC/PNEC for soil			
Fence	0.00191	3.267	0.691
House	0.00229	3.928	0.832
Scenarios related to professional brushing treatment –in-service only			
PEC/PNEC for soil			
Fence	n/a	1.643	0.691
House	n/a	1.974	0.832
Noise Barrier	n/a	0.741	0.311
Scenarios related to professional spraying treatment – in-situ + in-service combined			
PEC/PNEC for soil			
Façade / House – adjacent soil	0.0153	15.030	0.331
Façade / House – distant soil	0.00082	0.691	0.000
Scenarios related to dipping / spraying – in-service only			
PEC/PNEC for soil			
Fence	n/a	1.643	0.271
House	n/a	1.974	0.331
Noise Barrier	n/a	0.074	0.012
Scenarios related to vacuum pressure– in-service only			
PEC/PNEC for soil			
Fence	n/a	1.733	0.261
House	n/a	2.174	0.331
Noise Barrier	n/a	0.078	0.012
Scenarios related to double vacuum pressure– in-service only			
PEC/PNEC for soil			
Fence	n/a	0.802	0.341
House	n/a	0.992	0.431
Noise Barrier	n/a	0.361	0.160

Treated wood in service

The OECD ESD for wood in service assumes 10 cm horizontal and vertical distance in soil. However, it was decided by the 23rd Competent Authority Meeting to consider soil volumes representing 50 cm horizontal and vertical distances in the risk assessment. All PEC/PNEC calculations for in-service scenarios listed in Table 2.8.3.1-4 were carried out based on 50 cm horizontal and vertical distance. In the scenario 'house' the horizontal distance is 50 cm symmetrically to all four directions around the house (see ESD page 75 figure 5-3).

At an application level of 200 g/m³, there is unacceptable risk to the terrestrial environment in the in-service scenarios fence and house after TIME 1 (30 days) and for vacuum pressure treatment. Risk is acceptable in all in-service scenarios after TIME 2 (default service life).

At an application level of 1.35 g/m² (dip/spray/brush treatment), there is unacceptable risk to the terrestrial environment after TIME 1 (30 days) for the in-service scenarios fence and house. For the noise barrier scenario, risk is acceptable. After TIME 2 (default service life), risk is acceptable in all in-service scenarios.

In-situ treatment combined with treated wood in service

When in-situ treatments by brush or spray are considered, at an application level of 1.35 g/m², there is an acceptable risk to the terrestrial environment adjacent to the treated structure immediately after treatment but an unacceptable risk after TIME 1. After TIME 2 (default service life), however, risk is acceptable. For the distant soil compartment in the façade/house scenario, risk is acceptable immediately after application and, with degradation processes, PEC/PNEC approaches zero at TIME 2.

Application of sewage treatment plant sludge to agricultural soil and grassland

$$PNEC_{\text{soil}} = 0.1 \text{ mg a.i./kg wet soil}$$

Table 2.8.3.1-5: STP sludge to agricultural soil and grassland: Summary of calculated PEC/PNEC ratios

	Local PEC in agricultural soil averaged over 30 days (mg a.i./kg ww)	Local PEC in agricultural soil averaged over 180 days (mg a.i./kg ww)	Local PEC in grassland averaged over 30 days (mg a.i./kg ww)	Local PEC in grassland averaged over 180 days (mg a.i./kg ww)
Wood in service: noise barrier - highest emission to facility drain 0.0026 kg a.i./day	0.011	0.007	0.004	0.003

The highest emission to the drain due to leaching from treated noise barrier, is from wood treated by spraying/dipping at a retention of 1.35 g/m².

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

2.8.3.7 Effect of reapplication

For those intended uses for which re-application is possible (i.e. spraying or brushing), PEC/PNEC values for the soil compartment at TIME 2 are low (0 – 0.832), indicating that re-application would not give rise to any unacceptable risk.

All environmental risk assessments presented are based on the application of Embalit P without any topcoat (worst case). In practice, the state of the art for UC 3 applications is for a topcoat to be applied to provide protection against UV degradation of the wood surface. Whilst this topcoat may be renewed during the service life of the wood preservative, without any negative effect on the environmental risk assessment, it is not considered necessary for the Embalit P treatment to be re-applied.

For Use Class 2 applications, the parts of the wood or wall treated are protected against direct wetting by rain. Re-application in this situation has no effect on the environmental risk assessment.

2.8.3.8 Endocrine disruption

When Member States are authorising Embalit P the potential of propiconazole to cause endocrine disruption must be considered. This is because propiconazole may have the potential to cause

endocrine disruption based on suspected properties for the azole group and that there is not sufficient data. However, in the submitted studies there were no effects in the test animals which could be related to possible endocrine disruption.

Propiconazole has undergone a comprehensive battery of in vivo mammalian toxicology and ecotoxicology testing that cover a broad spectrum of endocrine endpoints that are sufficient to detect endocrine disruption. This testing included a tiered battery of acute, sub-chronic, chronic/carcinogenicity and reproductive mammalian toxicology tests. In addition to acute, chronic and lifecycle ecotoxicology tests. Furthermore, these studies have robust experimental designs, follow internationally accepted protocols, have a high level of replication and a long history of use in hazard identification and risk assessment. The results from these studies show no evidence of endocrine-mediated adverse effects on endocrine organs, reproduction or development with propiconazole. Therefore, there is no concern for potential adverse effects via endocrine toxicity.

2.9 Measures to protect man, animals and the environment

On the label it should be indicated:

- For professional use only
- To be used as wood preservative

Based on the risk assessment for the professional operator and the sensitising properties gloves and coveralls are prescribed on the label.

In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, the label and safety-data sheets of Embalit P shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

In view of the unacceptable risk identified for in service treated timber over or near water, appropriate risk mitigation measures must be taken to protect the aquatic environment. In particular, the label and safety-data sheets of Embalit P shall indicate that wood treated with this product may not be used over or near water bodies.

3 Proposal for decision

No further information is required.

The RMS NL considers that sufficient data have been provided to verify the outcome and conclusions, and permit the authorisation of Embalit P.

Proposed classification based on Directive 1999/45/EC

Symbol:	Xi, N	
Indication of danger:	Irritant, Dangerous for the environment	
R-phrases:	R43	May cause sensitization by skin contact.
	R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
S-phrases:	S21	When using, do not smoke.
	S36/37	Wear suitable protective clothing and gloves.
	S61	Avoid release to the environment. Refer to special instructions/Safety data sheets.

Proposed classification based on Regulation EC 1272/2008

Signal word:	Warning		
Pictogram:	GHS07, GHS09		
	Hazard class-and-Category	Code	Hazard statement
Hazard statements:	Skin Sens. 1	H317	May cause an allergic skin reaction.
	Aquat.chron.2	H411	Toxic to aquatic life with long lasting effects.
Precautionary statements:		P280	Wear protective gloves/protective clothing.
		P273 P391 P501	Avoid release to the environment. Collect spillage. Dispose of contents/container ... (in accordance with local/regional/national/international regulation (to be specified)).

4 Annex:

- **Summary of product characteristics**
- **List of studies reviewed (including study summaries)**
- **Analytical methods residues – active substance**
- **Toxicology and metabolism –active substance**
- **Toxicology – biocidal product**
- **Safety for professional operators**
- **Safety for non-professional operators and the general public**
- **Residue behaviour**

Annex 1: Summary of product characteristics

(a) Product trade name: Embalit P

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

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

Active substance(s)				Contents				
Common name	IUPAC name	CAS number	EC number	Concentration	Unit	w/w (%)	Minimum purity (% w/w)	Same source as for Annex I inclusion
propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole	60207-90-1	262-104-4	100x(100/u*) (TGAI) 100 (PAI)	g/l	9.7x(100/u*) (TGAI) 9.7 (PAI)	93	yes

* u= purity of Wocosen technical in % w/w (min. 93 %)

Co-formulants					Contents				
Common name	IUPAC name	Function	CAS number	EC number	Concentration	Unit	w/w (%)	Classification	Substance of concern
ethoxylated castor oil	-	Emulsifier	61791-12-6	500-151-7	400	g/l	38.8	not classified	no
dipropyleenglycol monomethylether	(2-methoxymethylethoxy)propanol	Solvent	34590-94-8	252-104-2	1000L x density** – 500 kg – (100x(100/u*))	g/l	concentration in g/l : density **	not classified	no
Water	Water	Solvent	7732-18-5	231-791-2	100	g/l	9.7	not	no

								classified	
**density = 1.031 g/ml (25 °C)									
						Sum	1031	g/l	100

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

Yes, the product is identical to the representative product evaluated for annex I inclusion of propiconazole.

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

No, the product does not contain GMOs in the sense of Directive 2001/18/EC.

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

CONFIDENTIAL INFORMATION, Not in Public Version

Name of the active substance: propiconazole

Manufacturer

Company Name: Syngenta Crop Protection AG

Address: CH - 4002

City: Basle Postal Code: - Country: Switzerland

Telephone: +41 61 323 9242 Fax: +41 61 323 4366 E-Mail: -

Intra-Community VAT number or, for non EU companies, company registration number: 501558

Manufacturing site(s) (if different)

Company Name: Syngenta Crop Protection AG

Address: CH - 1870

City: Monthey Postal Code: - Country: Switzerland

Telephone: +41 61 323 9242 Fax: +41 61 323 4366 E-Mail: -

Intra-Community VAT number or, for non EU companies, company registration number: 501558

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

CONFIDENTIAL INFORMATION, Not in Public Version

Formulator

Company Name: Hoetmer B.V.

Address: Singel 271-D

City: Dordrecht Postal Code: NL-3311 KS Country: The Netherlands

Telephone: +31 78 6350720 Fax: +31 78 6133029

E-Mail: hoetmerbv@hoetmer.com

Intra-Community VAT number or, for non EU companies, company registration number: NL00.30.00.680.B01

Physical state and nature of the biocidal product:

(e) Type of formulation: SL

(f) Ready-to-use product: no

Classification and labelling statements of the biocidal product:

(g) Product classification: Xi, Irritant; N, Dangerous for the environment

(h) Risk and Safety Phrases: R43, R51/53; S21, S36/37, S61

(i) Product classification according to GHS: GHS07, Warning, Skin Sens. 1; GHS09, Aquat. Chron. 2

(j) Hazard and Precautionary statement according to GHS: H317, H411; P273, P280, P391, P501

Intended uses and efficacy:

(k)	PT: 8
(l)	Target harmful organisms: 1) sap stain fungi, 2) moulds, blue stain, 3) blue stain, 4) wood destroying Basidiomycetes
(m)	Development stage of target organisms: n.a.
(n)	Function/mode of action: 1) fungicide, 2) demethylation inhibition of ergosterol synthesis
(o)	Field of use: 1) timber in service life, Use Class 2 & 3, 2) fresh cut logs and green timber
(p)	Application aim: preventive
(q)	User category: professional / industrial
(r)	Application method: 1) dipping, 2) spraying, 3) brushing, 4) injection, 5) penetrative processes

Directions for use:

(s) Manner and area of use:

Organisms to be controlled are wood attacking fungi: sap stain fungi, moulds, wood destroying Basidiomycetes (decay), blue stain fungi.

The product is used to

- control of wood destroying (decay) and wood discolouring fungi (blue stain) in Use Class 2 and 3.

- control of discolouration in fresh felled logs and green timber (sap stain and moulds).

The product is to be used by professional and industrial users only.

(t) Conditions of use:

Description	Application	Application method	Mid Toxic Value (MTV)	Test range active substance	Retention of undiluted product
Sapstain and moulds	Fresh felled logs and green timber	Dipping and spraying	0.3 g a.s./m ²	0.23 – 0.38 g a.s./m ²	3.8 g/m ²
Blue stain (1)	UC 2 en 3 in service	Dipping, brushing and spraying	1.35 g a.s./m ²	0.7 – 2.7 g a.s./m ²	13.5 g/m ²
Blue stain (2)	UC 2 en 3 in	Vacuum	483 g a.s./m ³	-	5 kg/m ³

	service				
Wood destroying Basidiomycetes	UC 2 en 3 in service	Penetrative methods	430 g a.s./m ³	250 - 600 g a.s./m ³	2.5 - 6 kg/m ³

(u) Instructions for safe use of the product:

For professional use only.

Based on the risk assessment for the professional operator and the sensitising properties gloves and coverall are prescribed on the label.

In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, the label and safety-data sheet of Embalit P shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

In view of the unacceptable risk identified for in service treated timber over or near water, appropriate risk mitigation measures must be taken to protect the aquatic environment. In particular, the label and safety-data sheets of Embalit P shall indicate that wood treated with this product may not be used over or near water bodies.

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

In case of skin contact wash off immediately with plenty of water (based on the sensitising properties of the product).

(w) Instructions for safe disposal of the product and its packaging

Soak up spilled material with absorptive material such as sand, soil, diatomaceous earth, etc. Prevent product from spreading e.g. by damming in with absorptive material. Clean contaminated area thoroughly with carbonated or soapy water. Do not allow the wash water to run off into any sewer, stream, well or pond, and if necessary soak it up with more absorbent material. Collect spillage and washing waters in specially marked, tightly closing containers. Dispose of in a manner approved by Local Authority. Spilled product cannot be used further and must be disposed of. Dispose of empty containers in an incinerator approved for chemicals. Damaged containers should be placed in specially marked larger ones. Check possibilities of recycling large empty containers, drums and barrels.

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

The product is considered stable in the original HDPE container at room temperature for up to 3 years..

(y) Additional information: -

Annex 2A: List of studies reviewed

List of new data submitted in support of the evaluation of the active substance

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
A7.4.1.3	7.4.1.3	Höger S.	2011	Propiconazole – Toxicity to <i>Pseudokirchneriella subcapitata</i> in a 96-hour algal growth inhibition test, Harlan Laboratories Ltd., 4452 Itingen, Switzerland, D06766 Syngenta Study reference CGA064250/10713	Syngenta	X		X	
A7.5.1.3	7.5.1.3	Porch J.R., Martin K.H., Krueger H.O	2009	Propiconazole formulation (Lag 2008 045) – Chronic Toxicity in Higher Plants, Wildlife International Ltd, Report no: 528-284 GLP, Unpublished	Syngenta	X		X	

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

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
B3.4 Autoflammability	AGR 4457	Mak, W.A.	2011	Self-ignition temperature of WOCOSEN 100 SL	Janssen PMP		X	X	-

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
							X	X	-
B3.8 Persistent foaming	AGR 4458	de Ryckel, B	2010	Persistent foaming of WOCOSSEN 100 SL, batch 2629-101109	Janssen PMP		X	X	-
B7.1	B7.1	Willems, W.	2010	Leaching of WOCOSSEN® 100 SL from treated timber Janssen Pharmaceutica N.V. Report no. 09054 Not GLP, Unpublished	Janssen		X	X	

Annex 2B: Study summaries

Study Summary B7.1

Section 7.1/01
Annex Point IIB VII.

Foreseeable routes of entry into the environment

		Official use only
	1 REFERENCE	
1.1 Reference	Willems, W. (2010) : Leaching of WOCOSEN 100 SL from treated timber. Janssen PMP, unpublished report No. 09054	
1.2 Data protection	Yes	
1.2.1 Data owner	Janssen Pharmaceutica NV	
1.2.2 Companies with letter of access		
1.2.3 Criteria for data protection	Unpublished data	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	No harmonised guideline available	
2.2 GLP	No	
	3 MATERIALS AND METHODS	
Wood	Scots pine sapwood (<i>Pinus sylvestris</i>)	
Product tested	Size of the panels: 50 x 12.5 x 2.5 cm, planed and sanded WOCOSEN 100 SL, containing 10% w/v propiconazole Diluted before use 3% WOCOSEN 100 SL in tap water.	
Superficial treatment	The diluted product was applied to achieve 500 ml/m ² (propiconazole uptake 1.46 g/m ²). No topcoat applied. The specimens were dried/conditioned for 2 months.	
Leaching test	A set of four treated panels (total surface area = [0.5 m x 0.125 m] x 4 = 0.25 m ²) was exposed vertically on a south-facing test rack with a backing to prevent exposure to rain from behind. Rainfall run-off from the panel was diverted by PVC guttering into a laboratory dark glass flask. The collected water was taken for analysis periodically after 1-3 litres had been collected in the flask. Rainfall was recorded throughout the exposure period, and the accumulated rainfall at each sampling interval was recorded. Exposure continued for approximately twenty one months, with water being taken for analysis at twenty nine intervals during this period.	
	4 RESULTS AND DISCUSSION	
Analysis of leachates	Analysis of the leachates was carried out by the following method : Janssen PMP HPLC method Appendix 2	

Analysis results for the leachates are given in Tables 1 and 2.

Calculation of flux rate

A graph of cumulative leaching (mg/m²) vs. time (after exposure days were corrected for average EU rainfall of 720mm) was plotted for each application, and a trendline was fitted using the functionality within Microsoft Excel in the form $Q_c = a + b * \ln(T)$, where

Q_c = cumulative quantity leached (mg/m²)

T = time (days).

Using the derived terms a and b, the trendline was extrapolated to cover the maximum service life proposed (20 years, for vacuum-pressure/double-vacuum treated timber items). From the cumulative quantity leached at the appropriate time point, the average daily emission from treated wood, in mg propiconazole/m², was calculated

for :

30 days	-	Time 1
1825 days	-	default service life for brush treated wood
5475 days	-	default service life for automated spray/dip treated wood
7300 days	-	default service life for vacuum-pressure/double-vacuum treated wood

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

Superficial application (1.46 g/m²): 1.40E-03 g/m²/day

Vac-pressure application (730 g/m³):1.40E-03 g/m²/day

The following long term daily leaching value were determined :

1825 days

Brush application (1.46 g/m²): 8.75E-05 g/m²/day

5475 days

Dip application (1.46 g/m²): 3.49E-05 g/m²/day

7300 days

VP/DV application (730 g/m³): 2.73E-05 g/m²/day

Applicant's Summary and conclusion

Section 7.1/01
Annex Point IIB VII.

Foreseeable routes of entry into the environment

Results and discussion	<p>The flux rates calculated are based on application rates (1.46 g/m² for superficial treatment, 730 g/m³ for impregnation) in excess of the maximum recommended rates (1.35 g/m² for superficial treatment, 600 g/m³ for impregnation)</p> <p>The following adjusted short term (30 day) daily leaching values was determined :</p> <p>Superficial application (1.35 g/m²): 1.29E-03 g/m²/day Vac-pressure application (600 g/m³): 1.15E-03 g/m²/day</p> <p>The following long term daily leaching value were determined :</p> <p>1825 days Brush application (1.35 g/m²): 8.09E-05 g/m²/day 5475 days Dip application (1.35 g/m²): 3.17E-05 g/m²/day 7300 days VP/DV application (600 g/m³): 2.24E-05 g/m²/day</p>
Conclusion	<p>Daily leaching rates to be used for risk assessment purposes, based on application rate of 1.35 g/m² (superficial application) and 600 g/m³ (impregnation) are :</p> <p>30 days : 1.29 mg/m²/day (superficial application), 1.15 mg/m²/day (impregnation) 1825 days : 0.081 mg/m²/day 5475 days : 0.032 mg/m²/day 7300 days : 0.022 mg/m²/day</p>
Reliability	1
Deficiencies	None

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date	EVALUATION BY RAPPORTEUR MEMBER STATE 13 May 2011
Materials and methods	<i>Applicant's version is acceptable</i>

Section 7.1/01

Foreseeable routes of entry into the environment

Annex Point IIB VII.

Results and discussion	<p><i>Applicant's version is partially acceptable</i></p> <p><i>Vacuum pressure treatment was not tested individually. Extrapolation of results from surface treatment of wood to vacuum pressure is not acceptable as in the report of the leaching workshop in 2005 the following is stated: "A leaching test will be required for each general application method (penetration and superficial) by which the wood preservative is to be applied. In addition, a leaching test will also be required for each formulation type (water and solvent based) of the wood preservative". Furthermore the workshop participants mutually agreed that superficial treatment processes result in higher leaching rates. It should be considered that the leaching rate pattern for both processes is different over time: superficial treatment processes result in an initial high leaching rate while penetration treatment processes result in a more constant leaching rate over time.</i></p> <p><i>Results from this study can only be used for the risk assessment of surface treated wood with Wocosen 100 SL although from the currently available leaching data from this test it cannot be concluded that leaching will decrease after the period for which the test has been run as too limited evidence is available yet.</i></p>
Conclusion	<p><i>Daily leaching rates to be used for risk assessment purposes, based on application rate of 1.35 g/m² (superficial application)</i></p> <p><i>1825 days (brush application): 0.081 mg/m²/day</i></p> <p><i>5475 days (dip application): 0.032 mg/m²/day</i></p>
Reliability	<p><i>2</i></p>
Acceptability	<p><i>Partially acceptable</i></p>
Remarks	<p><i>No data on the Quality Assurance (QA) standard of the testing laboratory at the testing time. According to TNsG on data requirements (p. 142) exposure studies (e.g. leaching study) should be done to an appropriate protocol and suitable QA standards.</i></p>
COMMENTS FROM ...	
Date	<p><i>Give date of comments submitted</i></p>
Results and discussion	<p><i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p>
Conclusion	<p><i>Discuss if deviating from view of rapporteur member state</i></p>
Reliability	<p><i>Discuss if deviating from view of rapporteur member state</i></p>
Acceptability	<p><i>Discuss if deviating from view of rapporteur member state</i></p>
Remarks	

Table 1: Concentration of propiconazole in the leachate (mg/L).

Date	Rain mm	Water sampled g	Propi mg/L	Analysis
09.02.09-24.03.09	0 - 81	2131	5.9	HPLC-UV*
25.03.09-27.03.09	81 - 99	1833	3.2	HPLC-UV*
28.03.09-20.05.09	99 - 154	998	0.6	HPLC-MS**

Date	Rain mm	Water sampled g	Propi mg/L	Analysis
21.05.09-11.06.09	154 - 210	1392	0.57	HPLC-MS**
12.06.09-10.07.09	210 - 257	1019	0.82	HPLC-MS**
11.07.09-23.07.09	257 - 307	1206	0.23	HPLC-MS**
24.07.09-26.08.09	307 - 358	1128	0.29	HPLC-MS**
27.08.09-06.10.09	358 – 400.5	700	0.31	HPLC-MS**
07.10.09-03.11.09	400.5 – 479.5	1251	0.37	HPLC-MS**
04.11.09-10.11.09	479.5 – 507.5	1396	0.76	HPLC-MS**
11.11.09-23.11.09	507.5 – 604.6	2868	0.39	HPLC-MS**
24.11.09-24.11.09	604.6 – 618.6	2494	0.33	HPLC-MS**
25.11.09-27.11.09	618.6 – 633.6	1193	0.75	HPLC-MS**
28.11.09-30.11.09	633.6 – 654.6	1956	0.83	HPLC-MS**
01.12.09-07.12.09	654.6 – 682.7	2066	0.59	HPLC-MS**
08.12.09-14.12.09	682.7 – 698.7	533	0.62	HPLC-MS**
15.12.09-04.01.10	698.7 – 719.7	961	0.33	HPLC-MS**
05.01.10-02.02.10	719.7 – 763.7	1744	0.40	HPLC-MS**
03.02.10-23.02.10	763.7 – 797.7	1863	0.30	HPLC-MS**
24.02.10-01.03.10	797.7 – 842.7	2867	0.40	HPLC-MS**
02.03.10-01.04.10	842.7 – 902.7	1173	0.19	HPLC-MS**
02.04.10-21.06.10	902.7 – 994.7	922	0.11	HPLC-MS**
22.06.10-15.07.10	994.7 – 1050.7	2285	0.10	HPLC-MS**
16.07.10-17.08.10	1050.7 – 1149.7	899	0.08	HPLC-MS**
18.08.10-27.08.10	1149.7 – 1207.7	1172	0.18	HPLC-MS**
28.08.10-16.09.10	1207.7 – 1287.7	993	0.13	HPLC-MS**

Date	Rain mm	Water sampled g	Propi mg/L	Analysis
17.09.10-22.10.10	1287.7 – 1384.2	1748	0.09	HPLC-MS**
23.10.10-10.11.10	1384.2 – 1450.2	1431	0.30	HPLC-MS**
11.11.10-14.11.10	1450.2 – 1510.2	2857	0.30	HPLC-MS**

Table 2: Leaching from 1 m² of exposed wood (mg/m²). Wood area exposed:0.25 m²

Date	Rain mm	Water sampled g	Propi mg/m ²
09.02.09-24.03.09	0 - 81	2131	50.29
25.03.09-27.03.09	81 - 99	1833	23.46
28.03.09-20.05.09	99 - 154	998	2.39
21.05.09-11.06.09	154 - 210	1392	3.17
12.06.09-10.07.09	210 - 257	1019	3.34
11.07.09-23.07.09	257 - 307	1206	1.11
24.07.09-26.08.09	307 - 358	1128	1.31
27.08.09-06.10.09	358 – 400.5	700	0.87
07.10.09-03.11.09	400.5 – 479.5	1251	1.85
04.11.09-10.11.09	479.5 – 507.5	1396	4.24
11.11.09-23.11.09	507.5 – 604.6	2868	4.59
24.11.09-24.11.09	604.6 – 618.6	2494	3.29
25.11.09-27.11.09	618.6 – 633.6	1193	3.58
28.11.09-30.11.09	633.6 – 654.6	1956	6.49
01.12.09-07.12.09	654.6 – 682.7	2066	4.87
08.12.09-14.12.09	682.7 – 698.7	533	1.32
15.12.09-04.01.10	698.7 – 719.7	961	1.27
05.01.10-02.02.10	719.7 – 763.7	1744	2.76

Date	Rain mm	Water sampled g	Propi mg/m ²
03.02.10-23.02.10	763.7 – 797.7	1863	2.24
24.02.10-01.03.10	797.7 – 842.7	2867	4.58
02.03.10-01.04.10	842.7 – 902.7	1173	0.89
02.04.10-21.06.10	902.7 – 994.7	922	0.41
22.06.10-15.07.10	994.7 – 1050.7	2285	0.91
16.07.10-17.08.10	1050.7 – 1149.7	899	0.29
18.08.10-27.08.10	1149.7 – 1207.7	1172	0.84
28.08.10-16.09.10	1207.7 – 1287.7	993	0.52
17.09.10-22.10.10	1287.7 – 1384.2	1748	0.63
23.10.10-10.11.10	1384.2 – 1450.2	1431	1.72
11.11.10-14.11.10	1450.2 – 1510.2	2857	3.43

Study Summary A7.4.1.3

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3

1 REFERENCE	
1.1 Reference	Höger S, 2011, Propiconazole – Toxicity to <i>Pseudokirchneriella subcapitata</i> in a 96-hour algal growth inhibition test, Harlan Laboratories Ltd., 4452 Itingen, Switzerland, D06766, 11 January 2011 Syngenta Study reference CGA064250/10713
1.2 Data protection	Yes
1.2.1 Data owner	Syngenta Crop Protection AG.
1.2.2	
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I
2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD 201 (2006) OPPTS 850.5400 (1996, Public Draft) 761/2009/EC, C.3 (2009) JMAFF 2-7-7 (2005)
2.2 GLP	Yes
2.3 Deviations	No
3 MATERIALS AND METHODS	
3.1 Test material	CGA64250 tech.
3.1.1 Lot/Batch number	P.802028
3.1.2 Specification	As given in section 2
3.1.3 Purity	95.2%
3.1.4 Composition of Product	n.a.
3.1.5 Further relevant properties	
3.1.6 Method of analysis	HPLC with UV/VIS detection.
3.2 Preparation of TS solution for poorly soluble or volatile test substances	50.17 mg CGA64250 dispersed in 500 mL test medium, using 15 minutes of ultrasonication followed by 72 hours of intense stirring on a magnetic stirrer (in the dark). Membrane filtration (0.45 µ pore size).

Official
use
only

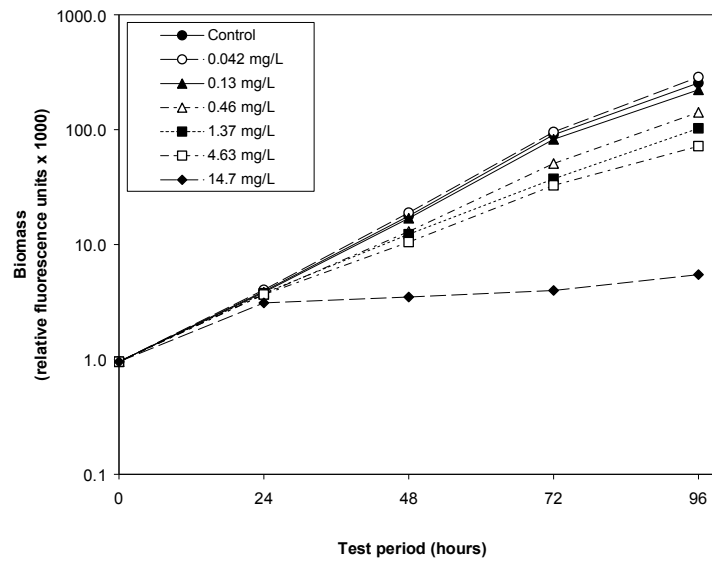
Section A7.4.1.3

Growth inhibition test on algae

Annex Point IIA7.3

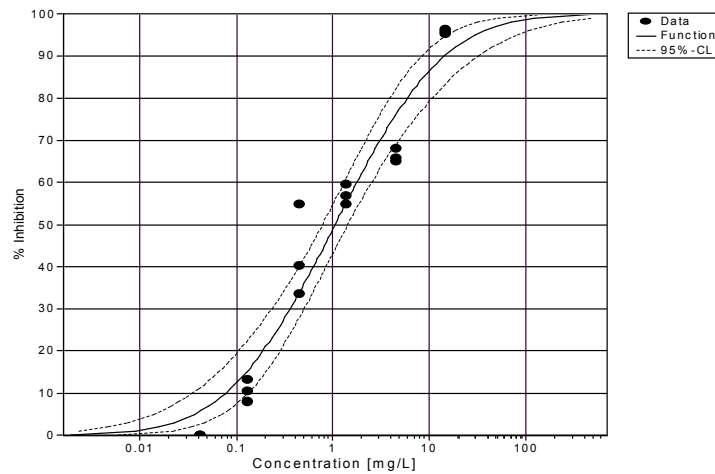
3.3 Reference substance	Yes. Potassium dichromate, twice a year.
3.3.1 Method of analysis for reference substance	Not described
3.4 Testing procedure	
3.4.1 Culture medium	OECD algal test medium. Hardness 24 mg/L as CaCO ₃ Na ₂ EDTA . 2H ₂ O 100 µg/L, pH 8.1.
3.4.2 Test organisms	<i>Pseudokirchneriella subcapitata</i> , Strain No. 61.81 SAG.
3.4.3 Test system	Test vessels – 50 mL Erlenmeyer flasks, containing 15 mL test volumes, with continuous magnetic stirring
3.4.4 Test conditions	Static test Temperature – 22 °C pH start – 8.2 pH end 8.2 – 8.8 Illumination – mean 5000 lux (range 4520 – 5400 lux)
3.4.5 Duration of the test	96-h
3.4.6 Test parameter	Inhibition of growth (biomass, growth rate and yield), determined from measurements of fluorescence
3.4.7 Sampling	Fluorescence of algal cells measured at 24, 48, 72 and 96-h Analytical samples for deretmination of propiconazole concentrations taken at start of test (0-h) and at end of test (96-h)
3.4.8 Monitoring of TS concentration	Yes, start of test (0-h) and at end of test (96-h)
3.4.9 Statistics	72 and 96-h EC50s, with 95% confidence intervals, determined using Probit analysis. LOEC/NOEC identified using Williams t-test (one-sided, $\alpha = 0.05$) or Welch t-test (one-sided, $\alpha = 0.05$)
4 RESULTS	
4.1 Limit Test	Not performed
4.1.1 Concentration	n.a.
4.1.2 Number/percentage of animals showing adverse effects	n.a.
4.2 Results test substance	
4.2.1 Initial concentrations of test substance	Test start - 0 (control), 0.052, 0.152, 0.527, 1.56, 5.16, 15.4 mg ai/L
4.2.2 Actual concentrations of test substance	Test end - 0 (control), 0.0337, 0.113, 0.393, 1.21, 4.15, 14.0 mg ai/L

4.2.3 Growth curves

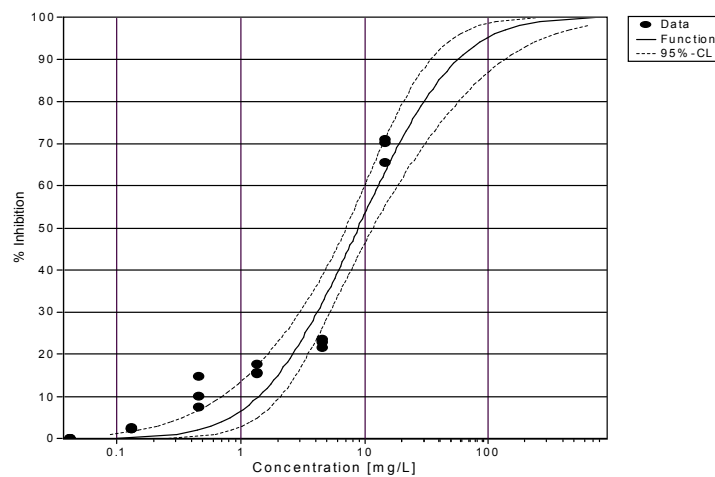


4.2.4 Concentration / response curve

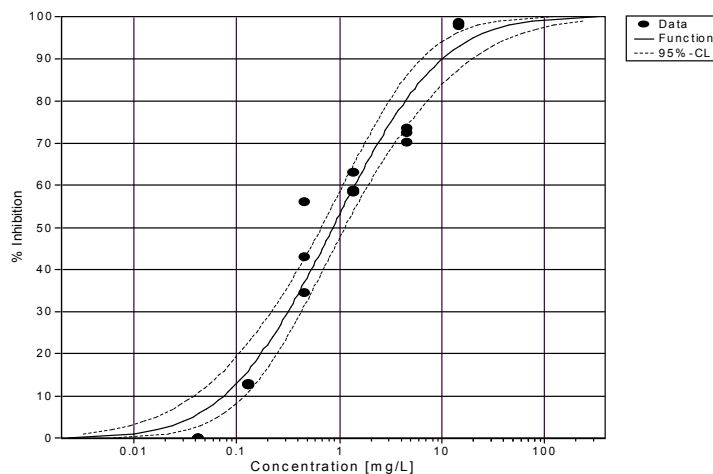
Biomass



Growth rate



Yield



4.2.5 Cell concentration data

Treatment / dilution	Mean measured concentration (mg/L)	Rep. no.	Biomass of algae*			
			24 hours	48 hours	72 hours	96 hours
Control	---	1	4.0	19.1	94.3	291.8
		2	4.1	19.5	97.9	272.6
		3	3.4	15.1	91.7	265.9
		4	3.8	17.4	86.2	251.7
		5	3.8	14.8	69.0	224.7
		6	4.4	20.6	102.1	222.1
		Mean SD	3.9 0.3	17.7 2.4	90.2 11.7	254.8 27.6
1:1600	0.042	1	3.9	18.8	96.2	270.9
		2	4.1	19.1	95.7	291.2
		3	4.1	18.9	94.2	298.5
		Mean SD	4.0 0.1	18.9 0.2	95.4 1.0	286.8 14.3
		1:500	0.13	1	3.9	17.1
2	3.8			16.8	75.9	222.8
3	3.8			16.9	82.7	222.7
Mean SD	3.8 0.0			16.9 0.1	82.3 6.2	222.5 0.4
1:160	0.46			1	3.8	13.8
		2	3.7	11.1	38.9	112.1
		3	3.5	14.1	54.3	145.6
		Mean	3.7	13.0	50.7	141.6

Section A7.4.1.3

Growth inhibition test on algae

Annex Point IIA7.3

		n	0.2	1.6	10.5	27.7
1:50	1.37	SD	0.2	1.6	10.5	27.7
		1	3.8	12.2	36.1	105.8
		2	3.9	12.7	40.1	106.7
		3	3.6	12.0	35.6	95.1
		Mean	3.8	12.3	37.3	102.5
		SD	0.2	0.3	2.5	6.4
1:16	4.63	1	3.7	11.1	35.3	71.1
		2	3.7	10.5	31.6	76.3
		3	3.6	9.9	31.4	68.1
		Mean	3.7	10.5	32.7	71.8
		SD	0.1	0.6	2.2	4.2
1:5	14.7	1	3.2	3.6	4.4	6.6
		2	3.1	3.2	3.4	4.8
		3	3.0	3.7	4.1	5.1
		Mean	3.1	3.5	4.0	5.5
		SD	0.1	0.3	0.5	0.9

*Biomass derived from fluorescence measurements

4.2.6 Effect data
(cell multiplication inhibition)

72-h

Parameter	AUC	Growth rate	Yield
EC ₅₀ (mg/L)	1.6	8.95	1.03
95% CI	1.1-2.3	6.6-13	0.72-1.5
NOEC (mg/L)	0.13	0.46	0.13
LOEC (mg/L)	0.46	1.37	0.46

96-h

Parameter	AUC	Growth rate	Yield
EC ₅₀ (mg/L)	1.05	8.9	0.87
95% CI	0.78-1.4	7.1-11.7	0.67-1.13
NOEC (mg/L)	0.19	2.6	0.17
LOEC (mg/L)	0.11-0.28	1.7-3.5	0.11-0.25

4.2.7 Other observed effects

None seen

4.3 Results of controls

Rep. no.	Biomass of algae			
	24 hours	48 hours	72 hours	96 hours
1	4.0	19.1	94.3	291.8
2	4.1	19.5	97.9	272.6

Section A7.4.1.3

Growth inhibition test on algae

Annex Point IIA7.3

3	3.4	15.1	91.7	265.9
4	3.8	17.4	86.2	251.7
5	3.8	14.8	69.0	224.7
6	4.4	20.6	102.1	222.1
Mean	3.9	17.7	90.2	254.8
SD	0.3	2.4	11.7	27.6

4.4 Test with reference substance Yes

4.4.1 Concentrations Not stated

4.4.2 Results 72-h EC₅₀ (growth rate) 0.99 mg/L

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The influence of the test item Propiconazole on the growth of the freshwater green algal species *Pseudokirchneriella subcapitata* was investigated in a 96-hour static test according to the OECD Guideline 201 (2006) and the Commission Regulation (EC) No 761/2009, C.3, as well as according to the OPPTS Guideline No. 850.5400 (Public Draft, April 1996) and JMAFF Test Guidelines, 2-7-7 (2005).

Due to the low solubility of the test item in test medium, a dispersion of the test item with the loading rate of 100 mg/L was continuously stirred at room temperature in the dark over 72 hours. Subsequently, the dispersion was filtered. The dilutions 1:5, 1:1.6, 1:50, 1:160, 1:500 and 1:1600 of the undiluted filtrate with the loading rate of 100 mg/L were used as test media. Additionally, a control was tested in parallel. The preparation of the test media was based on the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, 2000.

Annex Point IIA7.3

5.2 Results and discussion

At the start of the test, the analytically determined concentrations of Propiconazole in the test media (dilutions 1:1600, 1:500, 1:160, 1:50, 1:16 and 1:5) were 0.052, 0.152, 0.527, 1.56, 5.16 and 15.4 mg/L, respectively. During the test period of 96 hours, a decrease of test item concentration in the test media occurred. At the end of the test, 65 to 91% of the initially measured concentrations were found.

The biological results of the study are based on the mean measured concentrations of the test item (calculated as geometric mean):

Parameter	after 72 h		
	AUC	Growth rate	Yield
EC ₅₀ (mg/L)	1.6	8.95	1.03
95% CI	1.1-2.3	6.6-13	0.72-1.5
NOEC (mg/L)	0.13	0.46	0.13
LOEC (mg/L)	0.46	1.37	0.46

Parameter	after 96 h		
	AUC	Growth rate	Yield
EC ₅₀ (mg/L)	1.05	8.9	0.87
95% CI	0.78-1.4	7.1-11.7	0.67-1.13
NOEC (mg/L)	0.19	2.6	0.17
LOEC (mg/L)	0.11-0.28	1.7-3.5	0.11-0.25

5.3 Conclusion

The OECD test validity criteria were met:

Control biomass increase 0 – 72-h = 94 x (required at least 16 x)

Mean coefficient of variation for control section-by-section specific growth rate (0 – 72-h) = 7.6% (required < 35%)

Coefficient of variation for control average specific growth rate over whole test period = 2.0% (required < 7%).

Consequently, the test is considered valid.

5.3.1 Reliability

1

5.3.2 Deficiencies

None

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Section A7.4.1.3

Growth inhibition test on algae

Annex Point IIA7.3

Date *13 May 2011*
 Materials and Methods *Applicant's version is acceptable*
 Results and discussion *Applicant's version is acceptable with correction of the endpoints stated for an exposure duration of 96 hour as these endpoints were wrongly copied from the original study report. The correct endpoints are stated in the tables below.*
The biological results of the study are based on the mean measured concentrations of the test item (calculated as geometric mean):

<i>after 72 h</i>			
<i>Parameter</i>	<i>AUC</i>	<i>Growth rate</i>	<i>Yield</i>
<i>EC50 (mg/L)</i>	<i>1.6</i>	<i>8.95</i>	<i>1.03</i>
<i>95% CI</i>	<i>1.1-2.3</i>	<i>6.6-13</i>	<i>0.72-1.5</i>
<i>NOEC (mg/L)</i>	<i>0.13</i>	<i>0.46</i>	<i>0.13</i>
<i>LOEC (mg/L)</i>	<i>0.46</i>	<i>1.37</i>	<i>0.46</i>

<i>after 96 h</i>			
<i>Parameter</i>	<i>AUC</i>	<i>Growth rate</i>	<i>Yield</i>
<i>EC50 (mg/L)</i>	<i>1.05</i>	<i>8.9</i>	<i>0.87</i>
<i>95% CI</i>	<i>0.78-1.4</i>	<i>7.1-11.7</i>	<i>0.67-1.13</i>
<i>NOEC (mg/L)</i>	<i>0.042</i>	<i>0.13</i>	<i>0.042</i>
<i>LOEC (mg/L)</i>	<i>0.13</i>	<i>0.46</i>	<i>0.13</i>

4.2 Conclusion *The 72 h EC50 for growth rate was determined to be 8.95 mg/L
 The 72 h NOEC for growth rate was determined to be 0.46 mg/L
 The 96 h EC50 for growth rate was determined to be 8.9 mg/L
 The 96 h NOEC for growth rate was determined to be 0.13 mg/L*

4.3 Reliability *1*

4.4 Acceptability *Acceptable*

4.5 Remarks *None*

COMMENTS FROM ...

Date *Give date of comments submitted*

Section A7.4.1.3

Growth inhibition test on algae

Annex Point IIA7.3

Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Study Summary A7.5.1.3

Section 7.5.1.3
Annex Point IIIA XIII
3.4

Terrestrial plant toxicity

Official
use only

1 REFERENCE

- 4.6 Reference** Porch J.R., Martin K.H., Krueger H.O., 2009, Propiconazole formulation (Lag 2008 045) – Chronic Toxicity in Higher Plants, Wildlife International Ltd, Report no: 528-284, February 12, 2009
- 4.7 Data protection** Yes
- 4.7.1 Data owner Syngenta Crop Protection AG
- 4.7.2**
- 4.7.3 1.2.2 Criteria for data protection Data submitted to the MS after 14 May 2000 on an existing active substance for the purpose of its entry into Annex I.

2 GUIDELINES AND QUALITY ASSURANCE

- 4.8 2.1 Guideline study** Yes
DIN ISO 22030
- 4.9 2.2 GLP** Yes
- 2.3 Deviations** No

3 METHOD

See Dossier Guidance for level of detail required in summarizing test and study reports

- 3.1 Test material** Propiconazole Formulation (LAg 2008 045)
- 4.9.1 3.1.1 Lot/Batch number Batch number: 2556-220708
- 3.1.2 Specification As given in section 2
Deviating from specification given in section 2 as follows
(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):
- 3.1.3 Purity Nominal content: 1.30% Propiconazole (w/w)
Analysed content: 1.19% Propiconazole (w/w)
- 3.1.4 Composition of Product *Only if investigation with biocidal product, give percentage of any ingredients*
- 3.1.5 Further relevant properties *If appropriate; give any substance specific properties affecting test performance/applicability of the method (substance stability, vapour pressure, water solubility).*

Section 7.5.1.3
Annex Point IIIA XIII
3.4

Terrestrial plant toxicity

4.9.2	3.1.6	Method of analysis	Treated soil analysis - HPLC with MS detection
4.10	3.2	Preparation of TS solution for poorly soluble or volatile test substances	<i>Only applicable, if mechanical dispersion or solubilizing agents are applied for test substances of low aqueous solubility or if special procedures are applied for testing volatile test substances (tabular form; see table A7_5_1_3-1)</i>
3.2	Reference substance		Yes Analytical Standard, Sigma Aldrich, Propiconazole mixture of stereo isomers A.S. batch: 2556-220708
3.3.1	Method of analysis for reference substance		HPLC with MS detection
4.11	3.4	Testing procedure	
4.11.1	3.4.1	Dilution water	n/a – test item dissolved in acetone, added to sand and incorporated into soil
3.4.2	Test plants		Brassica rapa CrGC syn Rbr (rapid-cycling variety)
3.4.3	Test system		Test type: chronic toxicity in higher plants Test concentrations: 5, 10, 15, 20, 30, 40, and 81 mg formulation/kg Controls: solvent control and a negative control Test Soils: amounts of test substance were weighed out, acetone added to dissolve and added to sand by mixing. The spiked sand was then added to known amounts of soil and mixed to produce the test concentrations. Planting: test soil added to plastic pots (16cm in diameter, 12cm deep) and 10 seeds added to each pot at approximate depth of 6mm Replicates: 10 replicate pots for each treatment group and control groups Observations: Day 1 and 2 after test initiation, 7 days after test initiation, Day 16, regularly throughout flowering and at Day 40 Sampling : Day 16 - shoot fresh weight, Day 40 – shoot fresh weight, shoot dry weight, pod fresh weight, pod dry weight
4.11.2	3.4.4	Test conditions	Temperature: 13.41 – 33.80°C Humidity: 9.87 – 84.70% 16 hour photoperiod

**Section 7.5.1.3
Annex Point IIIA XIII
3.4**

Terrestrial plant toxicity

4.11.3	3.4.5 Test duration	40 days
4.11.4	3.4.6 Test parameter	none
3.4.7	Sampling	Day 16: shoot fresh weight, Day 40: shoot fresh weight, shoot dry weight, pod fresh weight, pod dry weight
3.4.8	Method of analysis of the plant material	Oven dried to obtain dry weights
4.11.5	3.4.9 Quality control	
4.11.6	3.4.10 Statistics	Dunnett's t-test used to help define the NOEC and LOEC

4 RESULTS

4.12 4.1 Results test substance

4.12.1 4.1.1 Day 16 plant measurements

Proportion of Live Plants, Shoot Fresh Weight, Number of Open Flowers, and Number of Damaged Plants at Day 16 |

Treatment Group (mg/kg)	Proportion of Live Plants (Number Living out of Total)	Shoot Fresh Weight (g) Mean ± SD (% reduction)	Flowers Per Plant (n) Mean ± SD (% reduction)	Proportion of Damaged Plants (Number Damaged out of Total)
Pooled Control	100% (40 of 40) ¹	6.79 ± 1.513	0.65 ± 0.353	2.5% (1 of 40)
5.0	100% (19 of 19)	7.85 ± 1.142 (-16%)	0.36 ± 0.568 (45%)	5.3% (1 of 19)
10	100% (20 of 20)	8.16 ± 1.094 (-20%)	0.78 ± 0.396 (-18%)	0% (0 of 20)
15	100% (20 of 20)	6.22 ± 2.139 (8%)	0.56 ± 0.770 (15%)	0% (0 of 20)
20	100% (19 of 19)	7.14 ± 2.143 (-5%)	0.32 ± 0.409 (52%)	0% (0 of 19)
30	95% (19 of 20)	7.67 ± 1.496 (-13%)	0.36 ± 0.416 (45%)	0% (0 of 19)
40	100% (20 of 20)	6.73 ± 1.716 (1%)	0.42 ± 0.295 (36%)	0% (0 of 20)
81	100% (20 of 20)	5.75 ± 1.422 (15%)	0.42 ± 0.370 (36%)	10% (2 of 20)

No treatment group mean is significantly different from the control mean (Dunnett's test, $p < 0.05$). Mean ± SD = Mean plus or minus one standard deviation.

¹ Survival was 20 of 20 in both control groups.

Section 7.5.1.3
Annex Point IIIA XIII
3.4

Terrestrial plant toxicity

4.12.2 4.1.2 Day 40
plant
measurements

Proportion of Live Plants, Shoot Fresh Weight, Shoot Dry Weight, and Shoot Water Content at Day 40

Treatment Group (mg/kg)	Proportion of Live Plants (Number Living out of Total)	Shoot Fresh Weight (g) Mean ± SD (% reduction)	Shoot Dry Weight (g) Mean ± SD (% reduction)	Shoot Water Content (%) Mean ± SD (% reduction)
Pooled Control	98% (38 of 39) ¹	5.56 ± 1.692	0.791 ± 0.2000	85.5 ± 0.17
5.0	100% (20 of 20)	6.45 ± 1.791 (-16%)	0.910 ± 0.2501 (-15%)	85.9 ± 0.87 (0%)
10	100% (20 of 20)	4.70 ± 0.712 (16%)	0.718 ± 0.1009 (9%)	84.7 ± 0.52 (1%)
15	100% (20 of 20)	5.23 ± 2.236 (6%)	0.738 ± 0.3084 (7%)	85.7 ± 1.57 (0%)
20	100% (20 of 20)	5.10 ± 0.971 (8%)	0.726 ± 0.1553 (8%)	85.8 ± 1.00 (0%)
30	94% (17 of 18)	6.08 ± 2.219 (-9%)	0.872 ± 0.3489 (-10%)	85.7 ± 0.97 (0%)
40	100% (20 of 20)	5.20 ± 1.367 (7%)	0.714 ± 0.1523 (10%)	86.1 ± 1.30 (-1%)
81	100% (20 of 20)	8.15 ± 1.636 (-46%)	1.004 ± 0.1541 (-27%)	87.5 ± 1.17 (-2%)

No treatment group mean is significantly different from the control mean (Dunnett's test, $p < 0.05$).
Mean ± SD = Mean plus or minus one standard deviation.

¹ Survival was 18 of 19 in the Negative Control and 20 of 20 in the Solvent Control.

4.12.3 4.1.3 Day 40
pod measurements

Pod Number, Pod Fresh Weight, Pod Dry Weight, and Pod Water Content at Day 40

Treatment Group (mg/kg)	Pods Per Plant (n) Mean ± SD (% reduction)	Pod Fresh Weight (g) Mean ± SD (% reduction)	Pod Dry Weight (g) Mean ± SD (% reduction)	Pod Water Content (%) Mean ± SD (% reduction)
Pooled Control	19.6 ± 3.75	3.52 ± 0.972	0.650 ± 0.1759	81.5 ± 2.04
5.0	20.4 ± 5.02 (-4%)	3.68 ± 1.240 (-5%)	0.688 ± 0.2392 (-6%)	81.4 ± 0.32 (0%)
10	18.7 ± 8.56 (5%)	3.58 ± 1.798 (-2%)	0.715 ± 0.3505 (-10%)	80.0 ± 0.35 (2%)
15	17.0 ± 7.49 (14%)	3.13 ± 1.591 (11%)	0.572 ± 0.2589 (12%)	81.3 ± 2.23 (0%)
20	20.9 ± 6.24 (-7%)	3.85 ± 1.044 (-10%)	0.751 ± 0.2424 (-16%)	80.7 ± 1.28 (1%)
30	18.5 ± 4.16 (6%)	3.62 ± 1.141 (-3%)	0.711 ± 0.2230 (-9%)	80.3 ± 0.80 (1%)
40	18.3 ± 1.80 (6%)	3.37 ± 0.602 (4%)	0.638 ± 0.1607 (2%)	81.2 ± 2.21 (0%)
81	16.3 ± 3.85 (17%)	3.31 ± 0.707 (6%)	0.574 ± 0.1477 (12%)	82.6 ± 2.75 (-1%)

No treatment group mean is significantly different from the control mean (Dunnett's test, $p < 0.05$).
Mean ± SD = Mean plus or minus one standard deviation.

4.13

4.2
Results of
controls

**Section 7.5.1.3
Annex Point IIIA XIII
3.4**

Terrestrial plant toxicity

4.13.1 4.2.1 2.5%
Number/
percentage of plants
showing adverse
effects

4.2.2 Nature of adverse effects Leaf curl/necrosis

4.3 Test with reference substance Not performed
(If performed, fill in 4.3.1 and 4.3.2)

4.3.1 Concentrations

4.3.2 Results *Give information according to 4.1.1 to 4.1.8*

5 APPLICANT'S SUMMARY AND CONCLUSION

4.14 5.1 Materials and methods

Guideline: DIN ISO 22030

A rapid-cycling variant of rape (*Brassica rapa* CrGC syn Rbr) was tested for effects on seedling growth and reproductive capability. Seeds were planted in soil containing LAg 2008 045, a formulation containing nominally 1.22% w/w propiconazole. A negative control group and a solvent control group were maintained concurrently. The test and control groups consisted of ten replicate test pots, with each pot containing ten planted seeds of one species. Half of the replicates were harvested on Day 16 of the test in order to assess potential effects on early seedling growth. The remaining replicates were harvested on Day 40 in order to assess potential effects on reproductive capability. The number of seed pods with fertile seeds, fresh and dry weights of plant shoots and seed pods, and number surviving seedlings were determined at test termination.

5.2 Results and discussion

Emergence of the control groups exceeded 50% by two days after planting. At days 16 and 40, there were no observed effects resulting from the use of the solvent, so the negative and solvent groups were pooled for comparison to the treatment groups for all parameters.

On day 16 the number of live plants was 100% except at 30 mg/kg where one plant had died. Damage, consisting of chlorosis, leaf curl, or necrosis, was observed in five seedlings (one each in the Solvent Control, 5.0 mg/kg, and 30 mg/kg groups, and two in the 81 mg/kg group). Since there was only incidental mortality and plant damage, mean survival and the proportion of damaged plants in the treatment groups were not evaluated using a statistical test. There was no apparent dose-response, and no treatment group mean was significantly different from the control mean ($p > 0.05$) for any parameter tested.

At test termination on Day 40, the proportion of live plants to the number of plants present after day 7 thinning was 100% in all

groups except the Negative Control, in which 18 of 19 plants were living, and in the 30 mg/kg group, in which 17 of 18 plants were living. Mean shoot fresh weight was 5.56 g in the pooled controls, and ranged from 4.70 g in the 10 mg/kg group to 8.15 g in the 81 mg/kg group. Mean shoot dry weight was 0.791 g in the pooled controls and ranged from 0.714 g in the 40 mg/kg group to 1.004 g in the 81 mg/kg group. The mean number of pods containing fertile seeds was 19.6 in the pooled controls, and ranged from 16.3 in the 81 mg/kg group to 20.9 in the 20 mg/kg group. Mean pod fresh weight was 3.51 g in the pooled controls, and ranged from 3.13 g in the 15 mg/kg group to 3.85 g in the 20 mg/kg group. Mean pod dry weight was 0.649 g in the pooled controls and ranged from 0.572 g in the 15 mg/kg group to 0.751 g in the 20 mg/kg group. There was no apparent dose-response, and no treatment group mean was significantly different from the control mean ($p > 0.05$) for any parameter.

5.3 Conclusion

Soil-incorporation of LAg 2008 045 at nominal concentrations of up to 81 mg formulation/kg (corresponding nominally to 0.96 mg propiconazole/kg) resulted in no effects on any test parameter. Therefore, the NOEC was determined to be 81 mg formulation/kg, and the EC₅₀ was determined to be greater than 81 mg formulation/kg.

5.3.1 Reliability

1

5.3.2 Deficiencies

No

(If yes, discuss the impact of of deficiencies and implications on results. If relevant, justify acceptability of study)

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>13 May 2011</i>
Materials and Methods	<i>Applicant's version is acceptable</i>
Results and discussion	<i>Applicant's version is acceptable</i>

<p>Conclusion</p> <p>Reliability</p> <p>Acceptability</p> <p>Remarks</p>	<p><i>The NOEC was determined to be 81 mg formulation/kg dw (corresponding nominally to 0.96 mg propiconazole/kg dw), and the EC50 was determined to be greater than 81 mg formulation/kg dw (corresponding nominally to 0.96 mg propiconazole/kg dw). These endpoints were determined in soils containing 1.7% organic matter. According to the TGD (equation 71), results from tests with experimental soils should be converted to standard soils, which is defined as soils with an organic matter content of 3.4%. As the sorption of propiconazole to soil is related to organic matter content this conversion is justified. The conversion of the NOEC of 0.96 mg propiconazole/kg dw and the EC50 > 0.96 mg propiconazole/kg dw result in a NOEC of 1.92 mg propiconazole/kg dw and an EC50 > 1.92 mg propiconazole/kg dw. The corresponding endpoints based on wet soil are NOEC of 1.69 mg propiconazole/kg ww and an EC50 > 1.69 mg propiconazole/kg ww using the conversion factor of 0.88 as stated in the TGD.</i></p> <p><i>1</i></p> <p><i>Acceptable</i></p> <p><i>None</i></p>
<p>Date</p> <p>Materials and Methods</p> <p>Results and discussion</p> <p>Conclusion</p> <p>Reliability</p> <p>Acceptability</p> <p>Remarks</p>	<p>COMMENTS FROM ... (SPECIFY)</p> <p><i>Give date of comments submitted</i></p> <p><i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p>

Annex 3: Analytical methods residues – active substance

Propiconazole

Date: 27.05.2011

Matrix, action levels, relevant residue and reference

matrix	limit	relevant residue	reference or comment
plant products	not applicable		
food of animal origin	not applicable		
soil	0.05 mg/kg	parent compound and its degradation products CGA 21795, CGA 91305, CGA 118244, CGA 118245, CGA 136735 and CGA 71019 (1,2,4-triazole), 2,4-DCBA	-
drinking water	0.1 µg/l	parent compound	-
surface water	0.1 µg/l	parent compound	-
air	0.024 mg/m ³	parent compound	-
body fluids / tissues	not applicable		

Methods suitable for the determination of residues (monitoring methods)

Methods for products of plant origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
not applicable					

Methods for foodstuffs of animal origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
not applicable					

Methods for soil

reference	matrix	LOQ (mg/kg)	principle	comment	owner
A4.2 / 01		0.02	GLC-NPD	parent compound	Syngenta
A4.2 / 02					RCC

reference	LOQ (mg/kg)	principle	comment	owner
A4.2 / 04	0.05	GLC-ECD	total; 2,4-DCBA	Syngenta
A4.2 / 05	0.01	HPLC-UV	as 1,2,4-triazole	Syngenta
A4.2 / 06			(total; 1,2,4-triazole)	Syngenta
4.2 / 08	0.005	LC-LC-ESI/MS/MS	CGA 118 244	Syngenta
A4.2 / 17A	0.005	HPLC-LC/MS/MS	as parent compound and its degradation products CGA 21795, CGA 91305, CGA 118244, CGA 118245, CGA 136735 and CGA 71019 (1,2,4-triazole)	Syngenta
A4.2 / 17B				Syngenta

Methods for drinking water and surface water

reference	matrix	LOQ (µg/l)	principle	comment	owner
A4.2 / 09	drinking water	0.05	GLC-ECD	parent compound in potable water	Syngenta
A4.2 / 10B	drinking water and surface water	0.05	GC-MS	parent compound in potable water and surface water	Syngenta
A4.2 / 18	sediment	0.010 mg/kg	HPLC-LC/MS/MS	parent compound and its degradation products CGA 217495, CGA 91305 and CGA 136735)	Syngenta

Methods for air

reference	LOQ (µg/m ³)	principle	comment	owner
A4.2 / 11	10	GLC-NPD	parent compound	Syngenta
A4.2 / 11B	10	GC-MS	parent compound	Syngenta

Methods for body fluids/tissue

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Not applicable (not toxic or very toxic substance)					

Annex 4: Toxicology and metabolism –active substance

Propiconazole

Threshold Limits and other Values for Human Health Risk Assessment

Date: 17.05.2011

Summary			
	Value	Study	SF
AEL medium and long-term	0.08	2-generation rat study	100
AEL acute	0.3	developmental toxicity study in rat	100
Inhalative absorption		100% (default)	
Oral absorption		86% within 48 h *	
		* Correction for bioavailability in deriving the limit values is therefore not considered necessary.	
Dermal absorption		The estimated dermal absorption in humans is 1% for the Wocosen 100 SL product (10% propiconazole) and 2% for the 1% Wocosen 100 SL dilution and the Wocosen 12 OL product, based on an in vivo study in rat and a comparative in vitro dermal penetration study using rat and human skin	
Classification			
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)		Xn R22 R43; S(2), S36/37, S46	
with regard to toxicological data (according to the criteria in Reg. 1272/2008)		GHS07, warning H302, H317	

Embalit P

Date: 27.05.2011

General information

Formulation Type	SL
Active substance(s) (incl. content)	9.7% w/w propiconazole
Category	PT08

Acute toxicity and irritation studies are conducted with the product Wocosen 100 SL-C, which contains 100 g/l propiconazole and 5 g/l cypermethrin and is considered worst-case for Embalit P. Data were copied from the CAR.

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)

Rat LD50 oral (OECD 401)	> 2000 mg/kg
Rat LD50 dermal (OECD 402)	> 2000 mg/kg
Rat LC50 inhalation (OECD 403)	> 5.64 mg/liter air/4 h
Skin irritation (EPA 81-5 ¹)	Not irritating to skin, not corrosive
Eye irritation (EPA 81-4 ¹)	Not irritating
Skin sensitisation (OECD 406; Buehler)	Not sensitising ²

¹ the study was performed essentially according to the OECD guideline 404, resp. 405 valid at the time.

² the NL CA does not accept the Buehler study with Wocosen 100 SL and proposes to label the biocidal product Embalit P with R43 based on the amount of propiconazole.

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)

Short-term toxicity studies	Not determined
Toxicological data on active substance(s) (not tested with the preparation)	See CAR
Toxicological data on non-active substance(s) (not tested with the preparation)	Not determined, information from MSDS
Further toxicological information	Not necessary

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)

Directive 1999/45/EC	Xi, R43, S36/37
Regulation 1272/2008/EC	GHS07, warning, H317

Embalit P

Date: 27.05.2011

Exposure assessment

For the exposure assessment we refer to the CAR.

Risk assessment

The risk assessment for Embalit P is presented in paragraph 2.7.3. All values were taken from the CAR, but are presented in order to show what type of personal protective equipment is necessary for which application. It was concluded (paragraph 2.7.3) that gloves and coverall are prescribed when handling Embalit P.

Annex 7: Safety for non-professional operators and the general public

Embalit P

Date:27.01.2011

Embalit P is not intended for non-professional use. For the exposure assessment and the risk assessment for secondary exposure to Embalit P we refer to the CAR.

Propiconazole

Date: 27.05.2011

Not relevant for the intended use of Embalit P.