HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 HERREGISTRATIE TOELATING

Gelet op de aanvraag d.d. 26 september 2012 (20121186 THBWE) van

Dr. Wolman GmbH
Dr. Wolmanstraße 31 -33
76547 SINZHEIM
DUITSLAND

tot herregistratie van de toelating als bedoeld in artikel 19 van Verordening 528/2012/EU betreffend het op de markt aanbieden en het gebruik van biociden, op basis van de werkzame stof propiconazool

Wolsit KD 10

gelet op artikel 66, eerste lid, Wet gewasbeschermingsmiddelen en biocidenzoals deze luidde voor de inwerkingtreding van verordening 528/2012/EU,

BESLUIT HET COLLEGE als volgt:

1.1 Herregistratie toelating

1. De toelating van het gewasbeschermingsmiddel Wolsit KD 10, welke expireert op 1 december 2013 wordt voor de in bijlage I genoemde toepassingen verlengd onder nummer 11727. 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 69 van verordening 528/2012/EU ,

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

werkzame stof:	*gehalte:*
propiconazool	41 g/l

letterlijk en zonder enige aanvulling:

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

gevaarsymbool:	*aanduiding:*
C	Bijtend
N	Milieugevaarlijk

Waarschuwingszinnen:

R34	-Veroorzaakt brandwonden.
R50	-Zeer vergiftig voor in het water levende organismen.

Veiligheidsaanbevelingen:

S26	-Bij aanraking met de ogen onmiddellijk met overvloedig water afspoelen en deskundig medisch advies inwinnen.
S28	-Na aanraking met de huid onmiddellijk wassen met veel . . . (aan te geven door de fabrikant).
S36/37/39	-Draag geschikte beschermende kleding, handschoenen en een beschermingsmiddel voor de ogen/het gezicht.
S45	-Bij een ongeval of indien men zich onwel voelt onmiddellijk een arts raadplegen (indien mogelijk hem dit etiket tonen).
S60	-Deze stof en de verpakking als gevaarlijk afval afvoeren.
S61	-Voorkom lozing in het milieu. Vraag om speciale instructies / veiligheidsgegevenskaart.

Specifieke vermeldingen:

DPD11	-Bevat propiconazool. Kan een allergische reactie veroorzaken.

2. 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:

   a. letterlijk en zonder enige aanvulling:
   het wettelijk gebruiksvoorschrift
   De tekst van het wettelijk gebruiksvoorschrift is opgenomen in Bijlage I, onder A.

b. 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 52 van verordening 528/2012/EU, mag het middel Wolsit KD 10 in de oude verpakkingen:

1. tot 20 september 2014 nog worden gebruikt en in voorraad of voorhanden worden gehouden;
2. tot 20 maart 2014 nog op de markt worden gebracht.

2 DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraag

De toelating van het gewasbeschermingsmiddel Wolsit KD 10 is laatstelijk bij besluit d.d. 26 juli 2013 verlengd tot 1 december 2013. Het betreft een aanvraag tot herregistratie van de toelating van het middel Wolsit KD 10 (11727 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) in een industriële installatie tegen houtaantastende schimmels (houtrot) met uitzondering van hout dat in permanent contact zal komen met grond en/of water. Toepassing door middel van (dubbel) vacuüm druk in gesloten systemen;
2. voor het preventief behandelen van hout binnen- en buitenshuis (gebruiksklasse 2 en 3) in een industriële installatie tegen schimmels (houtrot, houtverkleurende- en blauwschimmels) met uitzondering van hout dat in permanent contact zal komen met grond en/of water. Toepassing door middel van industrieel dompelen of spuittunnel in gesloten systemen. Bij gebruiksklasse 3 alleen toepassen met een topcoat;
3. voor het preventief behandelen van hout binnenshuis tegen echte huiszwam (*Serpula lacrymans*). In situ binnenshuis toepassing door middel van spuiten of strijken;
4. voor het curatief behandelen van binnenmuren tegen echte huiszwam (*Serpula lacrymans*) ter voorkoming van besmetting van aangrenzend hout. In situ binnenshuis toepassing door middel van boorgatinjectie, boorgatdrenking, spuiten en strijken.

2.2 Informatie met betrekking tot de stof

De werkzame stof propiconazool is bij Richtlijn 2008/78/EG, d.d. 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

Wolsit KD 10 is een houtverduurzamingsmiddel op basis van de werkzame stof propiconazool. 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 26 september 2012 ontvangen; op 5 maart 2013 zijn de verschuldigde aanvraagkosten ontvangen.

2.5 Eindconclusie

Bij gebruik volgens het Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing is het middel Wolsit KD 10 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 19 Verordening 528/2012).

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht 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, 20 september 2013

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

ir. J.F. de Leeuw
voorzitter

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I bij het besluit d.d. 20 september 2013 tot herregistratie van de toelating van het middel Wolsit KD 10, toelatingnummer 11727 N

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als houtverduurzamingsmiddel:
1. voor het preventief behandelen van hout binnen- en buitenshuis (gebruiksklasse 2 en 3) in een industriële installatie tegen houtaantastende schimmels (houtrot) met uitzondering van hout dat in permanent contact zal komen met grond en/of water. Toepassing door middel van (dubbel) vacuüm druk in gesloten systemen;
2. voor het preventief behandelen van hout binnen- en buitenshuis (gebruiksklasse 2 en 3) in een industriële installatie tegen schimmels (houtrot, houtverkleurende- en blauwschimmels) met uitzondering van hout dat in permanent contact zal komen met grond en/of water. Toepassing door middel van industrieel dompelen of spuittunnel in gesloten systemen. Bij gebruiksklasse 3 alleen toepassen met een topcoat;
3. voor het preventief behandelen van hout binnenshuis tegen echte huiszwam (*Serpula lacrymans*). In situ binnenshuis toepassing door middel van spuiten of strijken;
4. voor het curatief behandelen van binnenmuren tegen echte huiszwam (*Serpula lacrymans*) ter voorkoming van besmetting van aangrenzend hout. In situ binnenshuis toepassing door middel van boorgatinjectie, boorgatdrenking, spuiten en strijken.

Bestrijding van houtaantastende schimmels op oppervlakken die niet van hout zijn, is enkel toegestaan indien noodzakelijk om aantasting van het naastliggende hout te voorkomen.

Hout dat geïmpregneerd is met Wolsit KD 10 mag niet gebruikt worden in situaties en op plaatsen waar directe uitloging vanuit het hout naar oppervlakte- en grondwater kan plaatsvinden. Aan elk stuk geïmpregneerd hout of elke bundel verpakt geïmpregneerd hout dient een duidelijk leesbare waarschuwing gehecht te worden waarop staat aangegeven dat het betreffende hout geïmpregneerd is met het product Wolsit KD 10 en dat het hout niet toegepast mag worden direct langs of boven oppervlaktewater.

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

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

Aquaria/vissenkommen/vijvers en wateropslagtanks vóór aanbrenging in situ binnenshuis verwijderen of afdekken.

Neem bij in situ binnenshuis toepassingen de nodige maatregelen om te voorkomen dat vleermuizen en andere beschermde dieren worden blootgesteld.

De retenties en toedieningswijzen zoals aangegeven in de gebruiksaanwijzing moeten worden aangehouden.

Na gebruik handen wassen.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

1. Het preventief behandelen van hout in een industriële installatie (vacuümdruk of dubbel vacuüm) tegen houtaantastende schimmels (houtrot)

Ter verduurzaming van hout binnen- en buitenshuis, zonder dat er sprake is van permanent grondcontact. Toepassen door middel van vacuümdruk of dubbel vacuüm (gebruiksklasse 2 en 3). Zie voor retentie de volgende tabel.

Gebruik	Toepassingstechniek	Concentratie (van product)	Retentie
Bescherming van hout binnen- en buitenshuis (gebruiksklasse 2 en 3) tegen houtaantastende schimmels (houtrot)	Vacuümdruk Dubbel vaccuüm	Afhankelijk van de omstandigheden 0,5% - 1,0% Wolsit KD-10 in water (max 1,0%)	0,5% - 1,0% verdund product: 1,8 kg Wolsit KD-10 /m^3

Het middel mag ook toegepast worden op hout, dat in direct contact kan komen met levensmiddelen, speciaal als hoge eisen aan de hygiënische omstandigheden worden gesteld zoals voor groentekisten, fruitkisten, pallets, enz..

Alvorens het hout te behandelen dienen alle benodigde bewerkingen, zoals boren en inkepen te zijn uitgevoerd.

2. Het preventief behandelen van hout in een industriële installatie (industrieel dompelen of spuittunnel) tegen houtaantastende schimmels

Ter verduurzaming van hout binnen- en buitenshuis, zonder dat er sprake is van permanent grondcontact. Toepassen door middel van industrieel dompelen of spuittunnel (gebruiksklasse 2 en gebruiksklasse 3). Zie voor retentie de volgende tabel.

Gebruik	Toepassingstechniek	Concentratie (van product)	Retentie
Bescherming van hout binnen- en buitenshuis (gebruiksklasse 2 en 3) tegen schimmels (houtrot, houtverkleurende- en blauwschimmels)	Industrieel dompelen	Afhankelijk van de omstandigheden 1,75% - 3,5% Wolsit KD-10 in water (max 3,5%)	1,75% - 3,5% verdund product: 3,5 g Wolsit KD-10 /m^2
Bescherming van hout binnen- en buitenshuis (gebruiksklasse 2 en 3) tegen schimmels (houtrot, houtverkleurende- en blauwschimmels)	Geautomatiseerd bespuiten (spuittunnel)	Afhankelijk van de omstandigheden met een maximum concentratie van 3,5% Wolsit KD-10 in water	3,5% verdund product: 3,5 g Wolsit KD-10 /m^2

Het middel mag ook toegepast worden op hout, dat in direct contact kan komen met levensmiddelen, speciaal als hoge eisen aan de hygiënische omstandigheden worden gesteld zoals voor groentekisten, fruitkisten, pallets, enz.

Alvorens het hout te behandelen dienen alle benodigde bewerkingen, zoals boren en inkepen te zijn uitgevoerd.

Bij gebruik ter bescherming tegen houtaantastende schimmels voor gebruiksklasse 3 mag Wolsit KD 10 alleen toegepast worden met een topcoat (verf of beits die uitloging van het houtverduurzamingsmiddel voorkomt).

.

3. In situ preventief behandelen van hout binnenshuis tegen de echte huiszwam (*Serpula lacrymans*)

Toepassen door middel van spuiten en strijken. Zie voor retentie de volgende tabel.

Gebruik	Toepassingstechniek	Concentratie (van product)	Retentie
Bescherming van hout binnenshuis tegen *Serpula lacrymans*	Spuiten Strijken	Afhankelijk van de omstandigheden 1,0% -2,5% Wolsit KD-10 in water (max 2,5%)	1,0% - 2,5% verdund product: 96,5 g Wolsit KD-10 /m^2

4. In situ curatief behandelen van muren (metselwerk) die zijn begroeid door de echte huiszwam (*Serpula lacrymans*) ter voorkoming van besmetting van aangrenzend hout

De op de muren aanwezige schimmelgroei zorgvuldig verwijderen. Het losse stucwerk moet worden verwijderd en uitgekrabd. De te behandelen oppervlakken dienen stofvrij gemaakt te worden alvorens het product toe te passen. Toepassing geschiedt onder lage druk, d.w.z. met grote druppel. Bij sterke schimmelaantasting dienen gaten (16-18 mm diameter) in de muur (schuin naar beneden) geboord te worden tot 2/3 van de muurdikte.
De onderlinge afstand tussen de gaten dient 30 cm (in horizontale richting) resp. 20 cm (in verticale richting) te bedragen. De gaten dienen verspringend aangebracht te worden.
De boorgaten enige malen vullen of injecteren (onder ca. 5 bar) met het product, en vervolgens de boorgaten afsluiten.

Toepassen door middel van boorgatinjectie, boorgatdrenking, spuiten en strijken. Zie voor retentie de volgende tabel.

Gebruik	Toepassingstechniek	Concentratie (van product)	Retentie
Bescherming van hout binnenshuis tegen *Serpula lacrymans* door curatieve behandeling van muren (metselwerk)	Boorgatinjectie Boorgatdrenking Spuiten Strijken	Afhankelijk van de omstandigheden met een maximum concentratie van 1,0% Wolsit KD-10 in water	1,0% verdund product: 96,5 g Wolsit KD-10 /m^2

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 20 september 2013 tot herregistratie van de toelating van het middel Wolsit KD 10, toelatingnummer 11727 N

Product Assessment Report
Mutual Recognition

Wolsit KD 10

20 September 2013

Internal registration/file no:	20121186 THBWE
Authorisation/Registration no:	11727N
Granting date/entry into force of authorisation/ registration:	20 September 2013
Expiry date of authorisation/ registration:	31 March 2020
Active ingredient:	Propiconazole
Product type:	PT8

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

Contents

1 General information about the product application

1.1 Applicant

Dr. Wolman GmbH
Dr. Wolman Straße 31-33
D-76547 Sinzheim
Germany

1.2 Current authorisation holder

Dr. Wolman GmbH
Dr. Wolman Straße 31-33
D-76547 Sinzheim
Germany

1.3 Proposed authorisation holder

Dr. Wolman GmbH
Dr. Wolman Straße 31-33
D-76547 Sinzheim
Germany

1.4 Information about the product application

Application for re-registration based on mutual recognition. The primary assessment has been carried out by reference member state UK.

1.5 Information about the biocidal product

Productname: Wolsit KD 10
Productname in RMS: Wolsit KD 10
PT: 8
Active substance: Propiconazole

2 Summary of the product assessment

2.1 Identity related issues

For the assessment of the identity related issues we refer to Product Assessment Report of the original authorisation.

2.2 Classification, labelling and packaging

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

Professional use

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):			
-			
Symbol:	-	Indication of danger:	-
R phrases	-	-	
S phrases	S21	When using do not smoke	
Special provisions:	-	-	
DPD-phrases			
Child-resistant fastening obligatory?			Not applicable
Tactile warning of danger obligatory?			Not applicable

Explanation:	
Hazard symbol:	-
Risk phrases:	-
Safety phrases:	-
Other:	-

Supported shelf life of the formulation: two years in HDPE

The proposed classification and labelling of the preparation is not identical to that proposed in the Product Assessment Report by the competent authority UK. S2 is not assigned as the product is solely to be used by professionals.

Packaging

Professional use

	Packaging authorised by RMS	Packaging applied for in NL	Packaging authorised in NL
Packaging size and type	5 litre plastic jerrycan	5 litre HDPE jerrycan	5 litre HDPE jerrycan
Packaging size and type	30 litre plastic jerrycan	30 litre HDPE jerrycan	30 litre HDPE jerrycan
Packaging size and type	60 litre plastic drum	60 litre HDPE drum	60 litre HDPE drum
Packaging size and type	1000 litre Intermediate Bulk Container (IBC)	1000 litre Intermediate Bulk Container (IBC, HDPE)	1000 litre Intermediate Bulk Container (IBC, HDPE)

2.2.2 Proposal for the classification and labelling of the formulation concerning health

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):			
-			
Symbol:	C	Indication of danger:	Corrosive
R phrases	R34	Causes burns	
S phrases	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.	
	S28	After contact with skin, wash immediately with plenty of ... (to be specified by the manufacturer).	
	S35	This material and its container must be disposed of in a safe way.	
	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection	
	S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).	
Special provisions: DPD-phrases	DPD11	Contains propiconazole. May produce an allergic reaction.	
Child-resistant fastening obligatory?			Not applicable
Tactile warning of danger obligatory?			Not applicable

Explanation:	
Hazard symbol:	-
Risk phrases:	R21 is previously assigned by CTGB. However, as the formulation is corrosive, no acute toxicity testing is required, and acute dermal toxicity is likely to be caused by the corrosive properties. Therefore R21 is considered to be not necessary.
Safety phrases:	S1/2 is not indicated, as the formulation is intended for professional use only. S20 and S25 are not compulsory with the assigned R-phrase. S24 is not compulsory, as S36 is assigned.
Other:	-

2.2.3 Proposal for the classification and labelling of the formulation concerning the environment

Symbol:	N	Indication of danger:	Dangerous for the environment.
R phrases	R50	Very toxic to aquatic organisms.	
S phrases	S60	This material and its container must be disposed of as hazardous waste.	
	S61	Avoid release to the environment. Refer to special instructions/safety data sheets.	
Special provisions (DPD-phrases) :	-	-	

Explanation:	
Hazard symbol:	Classification based on toxicity of one co-formulant and the triggers laid down in the Dangerous Preparation

Risk phrases:	Directive 1999/45/EC and Directive 2008/6/EC Classification based on toxicity of one co-formulant and the triggers laid down in the Dangerous Preparation
Safety phrases:	Directive 1999/45/EC and Directive 2008/6/EC S60 and S61 are assigned to biocidal products for professional use with N, R50.

The NL classification of the preparation is based on the lowest acute toxicity endpoint for daphnia (0.0058 mg/L) for co-formulant dimethyl alkyl (C12-C14) amine from the EU BPD first draft CAR of BKC (June 2010) and the draft final CAR for ADBAC (September 2011) (PT8). Endpoints from these CARs were used as read across of co-formulant dimethyl alkyl (C12-C14) amine, responsible for the classification of the preparation, with BKC and ADBAC is possible.
The proposed classification and labelling of the preparation (N, R50) differs from that proposed in the Product Assessment Report by the competent authority UK (N, R50/53). The endpoints and concentrations used for classification and labelling of the preparation are not elaborated in the PAR so it is not clear where the RMS has based its classification of the preparation upon.

2.3 Physico/chemical properties and analytical methods

For the assessment of the physical and chemical properties we refer to Product Assessment Report of the original authorisation.

2.4 Risk assessment for Physico-chemical properties

For the risk assessment for physico-chemical properties we refer to Product Assessment Report of the original authorisation.

2.5 Effectiveness against target organisms

For the assessment of the effectiveness against target organisms we refer to the Product Assessment Report of the original authorization by the RMS UK (Wolsit KD-10, September 2012). The conclusions of the RMS are acceptable.

In the Product Assessment Report by the RMS UK it is stated that ‘As a condition of the authorisation, in the absence of supporting efficacy data on the use of the product as a superficial treatment against wood rotting fungi on use class 3 wood, without a topcoat suitable data, generated to CEN 839, will need to be provided within 18 months from the date of authorisation’. Since the applicant only requested authorisation of this product in NL for superficial treatment of use class 2 wood and use class 3 wood with a topcoat, this condition of authorisation is not relevant for this assessment.

2.5.1 The label claim

The applicant has provided a Dutch label (WG/GA). This has been adapted to our standards.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

For the description of the intended use(s) we refer to Product Assessment Report of the original authorisation.

Use class
In the PAR, efficacy for superficial treatment is claimed for use class 2 and 3. However, authorisation of this product in NL for superficial treatment was only requested for use class 2 and use class 3 with topcoat. The WG/GA has been adapted accordingly.

Industrial use: softwood/hardwood
There is a discrepancy between the PAR and SPC with respect to the authorisation of the industrial application of this product in hardwood. In the PAR (Chapter 8, Decision) only application of this product in softwood is authorised and only the retention/application rates in softwood are mentioned. On the SPC, retention/application rates in both hardwood and softwood are mentioned. We assumed that the PAR is correct, particularly since in the environmental assessment in the PAR it is concluded that the proposed rates of 'Wolsit KD-10' as a vacuum pressure treatment on hardwood are not supported for authorisation. Since the applicant only requested authorisation of this product in NL for industrial application in soft wood (by only mentioning the retention/application rates in softwood on the WG/GA and PGB PUB), application of this product in hardwood is not authorised in NL and has not been added to the WG/GA.

Curative treatment of wood
Curative treatment of wood as described on the WG/GA proposed by the applicant, has not been authorized by the RMS UK. This use has therefore been removed from the WG/GA.

2.6.2 Assessment of exposure to humans and the environment

2.6.2.1 Human toxicology

For the assessment of the exposure to humans we refer to Product Assessment Report of the original authorisation.

Vacuum pressure treatment

For the estimation of the exposure of professional users during vacuum pressure treatment, the RMS UK used Handling Model 1 (User Guidance v.1, 2002, p. 26) considering 2 treatment cycles of 180 minutes duration per cycle. However, according to User Guidance v.1, 2002, p.41, the default scenario for vacuum pressure treatment is 3 cycles of 180 minutes per day. Therefore the exposure for this scenario was recalculated by the Ctgb.

The indicative exposure values given by Handling Model 1 for water-based formulations are 1080 mg/cycle for hands exposure (actual exposure inside gloves), 8570 mg/cycle for body exposure and 1.9 mg/m^3 for inhalation exposure. Actual exposure without gloves was estimated from actual exposure inside gloves, using the assessment factor 100 according to HEEG opinion on default protection factors for protective clothing and gloves (agreed in TM I 2010), and is equal to 108000 mg/cycle.

Considering the propiconazole concentration of 0.045%, dermal absorption of 2% and 60 kg operator body weight, this results in the following exposure estimates:

For body exposure (100% clothing penetration): 8570 x 3 x 0.045% x 2% / 60 = 3.86 x 10^{-3} mg/kg bw/day

For hands exposure (actual exposure without gloves): 108000 x 3 x 0.045% x 2% / 60 = 4.86 x 10^{-2} mg/kg bw/day

Due to very low vapour pressure of propiconazole (5.6×10^{-5} Pa at 25°C) inhalation exposure during vacuum pressure treatment is considered to be negligible.

Total dermal exposure (body + hands): $0.0486 + 3.86 \times 10^{-3} = 0.052$ mg/kg bw/day. Considering the AEL of 0.08 mg/kg bw/day, this corresponds to (0.052/0.08 =) 65.6% of the AEL.

Based on this, no adverse effects are expected for unprotected professional user from exposure to propiconazole due to the application of Wolsit KD 10 by vacuum pressure.

Double-vacuum pressure treatment

For the estimation of the exposure of professional users during double-vacuum pressure treatment, the RMS UK used Handling Model 1 (User Guidance v.1, 2002, p. 26) considering 4 treatment cycles of 60 minutes duration per cycle. However, according to User Guidance v.1, 2002, p.41, the default scenario for double-vacuum pressure treatment is 6 cycles of 60 minutes per day. Therefore the exposure for this exposure scenario was recalculated by the Ctgb.

The indicative exposure values given by Handling Model 1 for water-based formulations are 1080 mg/cycle for hands exposure (actual exposure inside gloves), 8570 mg/cycle for body exposure and 1.9 mg/m^3 for inhalation exposure. Actual exposure without gloves was estimated from actual exposure inside gloves, using the assessment factor 100 according to HEEG opinion on default protection factors for protective clothing and gloves (agreed in TM I 2010), and is equal to 108000 mg/cycle.

Considering the propiconazole concentration of 0.045%, dermal absorption of 2% and 60 kg operator body weight, this results in the following exposure estimates:

For body exposure (100% clothing penetration): $8570 \times 6 \times 0.045\% \times 2\% / 60 = 7.71 \times 10^{-3}$ mg/kg bw/day

For hands exposure (actual exposure without gloves): $108000 \times 6 \times 0.045\% \times 2\% / 60 =$ 0.0972 mg/kg bw/day

Due to very low vapour pressure of propiconazole (5.6×10^{-5} Pa at 25°C) inhalation exposure during double-vacuum pressure treatment is considered to be negligible.

Total dermal exposure (body + hands): $0.0972 + 7.71 \times 10^{-3} = 0.105$ mg/kg bw/day. Considering the AEL of 0.08 mg/kg bw/day, this corresponds to (0.105/0.08 =) 131.1% of the AEL. Therefore adverse effects from exposure to propiconazole during application of Wolsit KD 10 by double-vacuum pressure cannot be excluded for unprotected professional users.

If the use of personal protective equipment is considered (100% clothing penetration, actual exposure inside gloves), the following exposure estimates are derived:

For body exposure (100% clothing penetration): $8570 \times 6 \times 0.\ 045\% \times 2\% / 60 = 7.71 \times 10^{-3}$ mg/kg bw/day

For hands exposure (actual exposure inside gloves): $1080 \times 6 \times 0.045\% \times 2\% / 60 = 9.72 \times 10^{-4}$ mg/kg bw/day

Total dermal exposure (body + hands) with PPE: $9.72 \times 10^{-4} + 7.71 \times 10^{-3} = 8.68 \times 10^{-3}$ mg/kg bw/day. Considering the AEL of 0.08 mg/kg bw/day, this corresponds to (8.68×10^{-3}/0.08 =) 11% of the AEL.

Based on this, no adverse effects are expected for protected (gloves) professional user from exposure to propiconazole due to the application of Wolsit KD 10 by double-vacuum pressure.

Maintenance/cleaning of the dipping tank

To estimate the exposure of professional users during maintenance/cleaning of the dipping tank, the RMS UK used Handling Model 1, considering 1 cycle of 120 minutes per day, and clothing penetration of 4%. It was assumed by the RMS that the cleaning of the treatment plant will only occur with adequate personal protective equipment (chemical resistant coverall). However, this type of PPE cannot be prescribed for professional users according to Dutch national specific policy. Therefore the recalculation was made by the Ctgb, considering as a first tier no PPE being used.

The indicative exposure values given by Handling Model 1 for water-based formulations are 1080 mg/cycle for hands exposure (actual exposure inside gloves), 8570 mg/cycle for body exposure and 1.9 mg/m^3 for inhalation exposure. Actual exposure without gloves was estimated from actual exposure inside gloves, using the assessment factor 100 according to HEEG opinion on default protection factors for protective clothing and gloves (agreed in TM I 2010), and is equal to 108000 mg/cycle.

Considering the propiconazole concentration of 0.045%, dermal absorption of 2% and 60 kg operator body weight, this results in the following exposure estimates:

For body exposure (100% clothing penetration): 8570 x 1 x 0.045% x 2% / 60 = 1.29 x 10^{-3} mg/kg bw/day

For hands exposure (actual exposure without gloves): 108000 x 1 x 0.045% x 2% / 60 = 0.0162 mg/kg bw/day

Due to very low vapour pressure of propiconazole (5.6 x 10^{-5} Pa at 25℃) inhalation exposure during vacuum pressure treatment is considered to be negligible.

Total dermal exposure (body + hands): 1.62 x 10^{-3} + 1.29 x 10^{-3} = 2.91 x 10^{-3} mg/kg bw/day. Considering the AEL of 0.08 mg/kg bw/day, this corresponds to (2.91 x 10^{-3}/0.08 =) 3.6% of the AEL.

Based on this, no adverse effects are expected for unprotected professional user from exposure to propiconazole due to the cleaning/maintenance operations.

Automated dipping

For the exposure of professional users during automated dipping the RMS UK used Dipping Model 1 (TNsG part 2, p. 167). However, this is not with agreement with HEEG Opinion 2009 (discussed at TM III 2009), according to which Handling Model 1 should be used to assess the exposure during automated dipping, considering 4 cycles of 1 hour per day. Therefore the exposure assessment using Handling Model 1 was performed by the Ctgb.

The indicative exposure values given by Handling Model 1 for water-based formulations are 1080 mg/cycle for hands exposure (actual exposure inside gloves), 8570 mg/cycle for body exposure and 1.9 mg/m^3 for inhalation exposure. Actual exposure without gloves was estimated from actual exposure inside gloves, using the assessment factor 100 according to HEEG opinion on default protection factors for protective clothing and gloves (agreed in TM I 2010), and is equal to 108000 mg/cycle.

Considering the propiconazole concentration of 0.1575%, dermal absorption of 2% and 60 kg operator body weight, this results in the following exposure estimates:

For body exposure (100% clothing penetration): 8570 x 4 x 0.1575% x 2% / 60 = 0.018 mg/kg bw/day

For hands exposure (actual exposure without gloves): 108000 x 4 x 0.1575% x 2% / 60 = 0.227 mg/kg bw/day

Due to very low vapour pressure of propiconazole (5.6×10^{-5} Pa at 25°C) inhalation exposure during vacuum pressure treatment is considered to be negligible.

Total dermal exposure (body + hands): 0.018 + 0.227 = 0.245 mg/kg bw/day. Considering the AEL of 0.08 mg/kg bw/day, this corresponds to (0.245/0.08 =) 306% of the AEL. Therefore adverse effects from exposure to propiconazole during application of Wolsit KD 10 by automated dipping cannot be excluded for unprotected professional users.

If the use of personal protective equipment is considered (100% clothing penetration, actual exposure inside gloves), the following exposure estimates are derived:

For body exposure (100% clothing penetration): 8570 x 4 x 0.1575% x 2% / 60 = 0.018 mg/kg bw/day

For hands exposure (actual exposure inside gloves): 1080 x 4 x 0.1575% x 2% / 60 = 0.023 mg/kg bw/day

Total dermal exposure (body + hands) with PPE: 0.018 + 0.023 = 0.041 mg/kg bw/day. Considering the AEL of 0.08 mg/kg bw/day, this corresponds to (0.041/0.08 =) 51% of the AEL.

Based on this, no adverse effects are expected for protected (gloves) professional user from exposure to propiconazole due to the application of Wolsit KD 10 by automated dipping.

Spray-tunnel application

The calculation performed by the RMS UK and the used defaults are considered acceptable. Based on it, no adverse effects are expected for unprotected professional user from exposure to propiconazole due to the spray-tunnel application of Wolsit KD 10.

In situ spraying of masonry and wood inside the houses

The calculation performed by the RMS UK and the used defaults are considered acceptable. Based on it, no adverse effects are expected for unprotected professional user from exposure to propiconazole due to the application of Wolsit KD 10 by spraying. This exposure scenario is also considered to represent the worst-case scenario for the application of Wolsit KD 10 by brushing.

Indirect exposure to propiconazole as a result of application of Wolsit KD 10

For all indirect exposure scenarios the calculations performed by the RMS are considered to be acceptable.

2.6.2.2 Environment

In the PAR the environmental risk assessment is performed for industrial and professional use of the product Wolsit KD 10.

The product contains 4.74% w/w propiconazole. Wolsit KD 10 is proposed for use on softwood, with application to give a minimum retention of 1.8 kg product/m^3 (penetrative treatment) and a minimum application rate of 3.5 g product /m^2 (superficial treatment).

Wolsit KD 10 is also proposed for use on hardwood, with application to give a minimum retention of 6.6 kg product/m^3 (penetrative treatment only).

The intended industrial uses of Wolsit KD 10 include protection of structural timber for interior and exterior use without ground contact e.g. cladding, boarding at balconies, pergolas and fruit boxes, (Use Classes 1-3). It is considered possible by the UK CA that the vertical posts of pergolas could in some cases be in direct contact with ground, so should perhaps be covered by the Use Class 4 fence post scenario. However, the house Use Class 3 scenario is more critical for soil exposure due to assumptions of treated wood area, so should cover this risk whether the pergola is in ground contact or not.
Wolsit KD 10 is also proposed to be applied professionally indoors by spray or brush as a preventative/curative treatment of wood in houses and by injection (borehole injection/flooding) as a curative treatment (Use Class 1).

For details on the assessment of the exposure to the environment we refer to the Product Assessment Report of the original authorisation.

2.7 Risk assessment for human health

For the risk assessment for human health we refer to Product Assessment Report of the original authorisation.

Based on the risk assessment, no adverse effects are expected for protected (gloves) professional user from exposure to propiconazole due to application of Wolsit KD 10.

Based on the risk assessment, no adverse effects are expected for unprotected professional and non-professional users and general public from indirect exposure to propiconazole as a result of application of Wolsit KD 10.

2.8 Risk assessment for the environment

For the risk assessment for the environment we refer to Product Assessment Report of the original authorisation.

Substances of concern
The product contains a number of components which, by virtue of their acute aquatic toxicity, are required to carry the N symbol plus appropriate R50 or R50-53 or R51-53 or R52-53 risk phrases. As such, they must be considered as “substances of concern (SoC)”.

For industrial PT8 uses the UK CA have taken the approach of considering that the relevant levels would be those in the diluted treatment solution, not those in the undiluted formulation. Hence, because the SoC in the concentrate formulation are not a SoC in the treatment solution, UK CA concludes that the substance is not an SoC for environmental risk assessment. Dutch CA agrees with this approach.

Propiconazole
The RMS has assessed the risk for the STP, surface water, sediment, soil and groundwater exposed to propiconazole but not for its metabolite 1,2,4-triazole. The RMS considers 1,2,4-triazole to be a soil metabolite. However, in the UK PAR of the wood preservative product Embadecor which also contains propiconazole it was concluded that due to its high water solubility (700 g l^{-1} at 20 ℃), low molecular weight (69.1 g mol^{-1}) plus low Koc (89 l kg^{-1}), the compound is not expected to bind to soil/sludge/sediment and therefore be highly mobile. On this basis, only risk of 1,2,4-triazole to surface water and groundwater was considered relevant.

We do not agree with this assumption as the risk for the soil compartment can be calculated with data available from the PPP dossier on triazole metabolites agreed endpoints for numerous aquatic and terrestrial organisms. Also in the DAR on propiconazole PECs are calculated for this metabolite and thus its potential presence in soil is not neglected. Considering the PPP ecotoxicology profile of 1,2,4-triazole a relatively low toxicity is indicated showing a potentially low risk. Therefore we can in this case accept the lack of calculations for the metabolite in sewage sludge, sediment and soil.

The effect of potential reapplications

The assessment report of propiconazole for PT08 states: *" The effects of possible re-applications on risk need to be evaluated at product authorisation stage. Re-applications in-situ (remedial treatment) are only possible according to conditions to be set in the product authorisation procedure"*.

Re-application of Wolsit KD 10 is not applicable as the product is not intended for in situ treatments. We can therefore accept that the RMS has not addressed re-application in its Product Assessment Report.

Endocrine disruption

Propiconazole is a potential endocrine disruptor. The assessment report for Annex I placement states therefore: "*When Member States are authorising products containing propiconazole 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."* The RMS has addressed potential endocrine disruption of propiconazole in this PAR as follows:

Propiconazole has undergone a comprehensive battery of in vivo mammalian toxicology and ecotoxicology testing that cover a broad spectrum of endocrine sensitive endpoints that are sufficient to detect potential endocrine disruption. This testing included a tiered battery of acute, sub-acute, sub-chronic, chronic/carcinogenicity and reproductive mammalian toxicology tests, in addition to acute, chronic and lifecycle ecotoxicology tests. For example a marine fish life-cycle test with sheepshead minnow,(*Cyprinodon variegatus*) is available for which further evaluation of raw data has been made in terms of sex ratio of F0 generation in order to detect endocrine disruption potential of propiconazole. 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 clear and unambiguous evidence of endocrine-mediated adverse effects on endocrine organs, reproduction or development with propiconazole. It is possible that the changes in adrenal, testis and epididymis weights observed in the rat are secondary to generalised toxicity and that the low incidence of cleft palate identified in the rat is due to a non-endocrine disruptive mechanism. Therefore, although the evidence suggests no obvious
concern for endocrine disruption, there remains an uncertainty as to whether further investigation would be appropriate.

However, at present, there are no clear criteria agreed at EU level to identify endocrine disrupters for regulatory purposes. In addition, currently, the BPD does not specify any regulatory implications of identifying a substance as an endocrine disrupter. Therefore, it is proposed that this assessment is revisited once EU-agreed criteria for endocrine disrupters are established and the new Biocidal Product Regulation which stipulates regulatory consequences for substances identified as endocrine disrupters is implemented.''

We can accept the discussion on endocrine disruptive properties of propiconazole in the PAR.

Summary risk assessment

Professional indoor uses (Use Class 1-2):

The indoor uses were considered at Annex I to result in negligible environmental exposure. No further fate assessment was conducted for product authorisation. Conclusion: Indoor uses (UC 1-2) are acceptable based on exposure being negligible.

Industrial uses (Use Class 3): Application and Storage
Risk from manufacture, application and storage are addressed for UC3 uses, provided risk mitigation measures are applied. In view of the risks identified for the soil and aquatic compartments, appropriate mitigation measures must be taken to protect those compartments. In particular, the label and safety data sheets of 'Wolsit KD-10' shall indicate that freshly treated timber must be stored after treatment under shelter, or on impermeable hard standing, to prevent direct loss to soil or water and that any losses must be collected for reuse or disposal. The label must indicate: that losses during industrial application by the dripping, spray tunnel and vacuum impregnation process must be contained (no drain connection to storm drains or STPs) and recycled, or collected and treated as waste in accordance with the national regulations.
The label must specify that industrial wood treatment sites must comply with the following requirements:
- application processes must be carried out within a contained area;
- situated on impermeable hard standing;
- with bunding to prevent run-off and
- a recovery system in place (e.g. sump).

The label must specify that storage of treated wood must be either:
- undercover with a recovery system in place (e.g. sump) or;
- on impermeable hard standing and bunded to prevent run-off with a recovery system in place (e.g. sump).

Industrial uses (Use Class 3): Treated Wood In Service
For product authorisation it has to be demonstrated that treated wood in service does not pose unacceptable risk to the environment, as a safe use for UC 3 has not been demonstrated at Annex I. Therefore, further assessment was needed for environmental exposure from 'wood in service' stage.

In situ treatment
According to the Applicant, 'in situ treatments' for Wolsit KD-10 are proposed only for indoor applications on and in walls and wood. It needs to be clearly put on the label that the product is not intended for outdoor in situ treatments, as this is not part of the environmental risk assessment.

Leaching data
Two semi-field leaching studies (with vacuum pressure treated softwood) and PEC calculations were submitted by the Applicant. The UK CA has decided not rely on these studies individually to derive a leaching rate for use in the PEC calculations. This was due to the lack of replicate or control test set-ups reducing the robustness of the data and there being no evidence that emissions were stable and did not undergo degradation during storage prior to analysis. However, the UK CA has considered that the combined data may be used as supporting information in a qualitative case.
The only application method tested was vacuum pressure, so these data cannot be extrapolated to the proposed surface treatments (dipping and spray-tunnel, spraying, brushing, borehole injection and borehole flooding). As the leaching data are performed on softwood, the results can't be extrapolated to hardwood, as agreed in the Arona leaching workshop guidance.

PEC calculations

Soil

The UK CA carried out a first tier worst case assessment based on the assumption 100% of active substance is lost to the environment due to leaching over the service life of the treated wood.

For all the proposed UC3 uses to softwood, when degradation is taken into account the Time 1 PEC:PNEC ratios are acceptable (i.e. <1) for surface water, sediment and STP compartments. For soil, the Time 1 PEC:PNEC ratios are greater than 1, taking into account degradation. However, all the longer term Time 2 PEC:PNEC ratios taking into account degradation are acceptable, except for the vacuum pressure treatment with House scenario where the Soil PEC:PNEC is 1.14.

Groundwater

For groundwater, assuming 100% leaching loss, predicted concentrations of propiconazole are well below the maximum acceptable concentration of 0.1 µg/L at all scenarios for both vacuum pressure and superficial treatments. For the metabolite, 1,2,4-triazole, a longer DT50 in soil of 60.5 days (accepted for use under the Plant Protection Products legislation) has been used in FOCUS PEARL 4.4.4. modelling. This gives acceptable PECgw concentrations of <0.1 µg/L for 1,2,4-triazole for superficial treatments, but for vacuum pressure treatments, at the Hamburg and Okehampton scenarios, PECgw exceeded 0.1 µg/L (max. 0.126 µg/L). Use of the proposed UC3 surface treatments are acceptable, even assuming this worst case leaching loss. The two areas where the vacuum pressure treatments result in unacceptable predicted exposure (propiconazole in soil and 1,2,4-triazole in groundwater) only slightly exceed the trigger values in each case i.e. a soil PEC:PNEC ratio of 1.14 (where <1 is acceptable) and a PECgw value of 0.126 µg/L (<0.1 µg/L being acceptable). The UK CA considered whether the 2 leaching studies could be used to crudely support each other in lieu of replicate test-set ups. The difference in orientation of the test set-up made direct comparison difficult, but the amount of rainfall was broadly similar in both studies. After normalisation of leaching loss for annual rainfall of 700 mm and correction for test versus proposed retention, the UK CA obtained significantly higher Time 1 emissions for the horizontal orientation compared to vertical orientation. However, the Time 2 emissions appeared to be similar at 94.52 mg/m^2 and 90.9 mg/m^2 (i.e. ca 11-12% of 810 mg/m^2). The UK CA concluded that these leaching studies could be taken together as supporting information.

Given the small margin by which the vacuum pressure treatments are not passing and the very conservative nature of the calculations in assuming 100% leaching loss (810 mg/m^2), it is reasonable to assume that this leaching loss will not need to be reduced by much to result in an acceptable risk assessment for softwood. In practice leaching loss will be much less than 100%. Although, it is considered that the leaching data provided cannot be relied on to derive a quantitative value for leaching loss, these two leaching trials may be considered as supporting evidence in making a reasoned qualitative case. The maximum Time 2 emission values of ca 90 and 95 mg/m^2 from these leaching studies, when compared to 100% loss of 810 mg/m^2 is equivalent to about only 11-12% loss. This provides reassurance that leaching loss in practice will be of a sufficient order of magnitude lower than 100%, that an acceptable soil PEC:PNEC ratio and PECgw value would result, given they only very slightly exceed acceptable limits, assuming 100% leaching loss.

On balance, the UK CA expects that the risk from the proposed UC3 vacuum pressure treatments for softwood will be acceptable in practice and considers that authorisation may be given. It is not possible to make the same qualitative arguments for the higher rates proposed for vacuum pressure use on hardwood. In the absence of information on an appropriate leaching rate for hardwood, the UK CA performed worst case first tier PEC calculations, based on 100% leaching loss. These resulted in unacceptable PEC:PNEC ratios for soil, surface water and sediment. PECgroundwater concentrations are acceptable for propiconazole, but exceed 0.1 µg/l for the metabolite 1,2,4-triazole. Therefore, the

proposed rates of 'Wolsit KD-10' as a vacuum pressure treatment on hardwood are not supported for authorisation. The UK CA experts did not assess in-situ outdoor superficial treatment of wood (preventive and curative). Considering that this type of use is assessed with a shorter service life (5 years) with the same retention, this may result in a higher risk and therefore is excluded from the label.

Overall conclusion for the aspect environment:
We agree with the RMS to remove the industrial vacuum treatment of hard wood from the proposed label. With the risk mitigations included in the WG/GA, the use of the wood protection product Wolsit KD 10 for requested Use Classes 1-3 (with the exception of industrial vacuum treatment of hard wood) will not cause unacceptable risks to the environment.

2.9 Measures to protect man, animals and the environment

In the Product Assessment Report of the original authorisation measures to protect man, animals and environment were proposed. In the table below the measures are listed and evaluated whether the measures are appropriate for the Dutch legal instructions and directions for use (WG/GA).

Industrial use (use 1 and 2 on the WG/GA)

Measure	**In WG/GA**	**WG/GA (in Dutch)**
The product is for use on timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting.	Yes	1. voor het preventief behandelen van hout binnen- en buitenshuis (gebruiksklasse 2 en 3) in een industriële installatie tegen houtaantastende schimmels (houtrot) met uitzondering van hout dat in permanent contact zal komen met grond en/of water; Toepassing door middel van (dubbel) vacuüm druk in gesloten systemen; 2. voor het preventief behandelen van hout binnen- en buitenshuis (gebruiksklasse 2 en 3) in een industriële installatie tegen schimmels (houtrot, houtverkleurende- en blauwschimmels) met uitzondering van hout dat in permanent contact zal komen met grond en/of water. Toepassing door middel van industrieel dompelen of spuittunnel in gesloten systemen. Bij gebruiksklasse 3 alleen toepassen met een topcoat
Treated timber must not be used in external situations where it is in contact with the ground and permanently exposed to wetting, or in permanent contact with fresh or salt water.		
Application processes must be carried out within a contained area, situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).	Yes but needs to be replaced by standard sentences	Behandeling en opslag van hout dient plaats te vinden onder dak of boven een vloeistofdichte vloer.
Storage of freshly treated wood must be either undercover with a		

recovery system in place (e.g. sump) or on impermeable hard standing and bunded to prevent run-off with a recovery system in place (e.g. sump).		
The COSHH (Control of Substances Hazardous to Health) Regulations 2002 (as amended) apply to the use of this product at work.	No	
Guidance on the safe use of wood preservatives is provided in leaflet WIS 29 ("Occupational hygiene and health surveillance at industrial treatment plants") at www.hse.gsi.gov.uk.	No	
Do not contaminate ground, waterbodies or watercourses with chemicals or used container.	Yes but needs to be replaced by standard sentences	Hout dat geïmpregneerd is met Wolsit KD 10 mag niet gebruikt worden in situaties en op plaatsen waar directe uitloging vanuit het hout naar oppervlakte- en grondwater kan plaatsvinden
DISPOSE OF SURPLUS CHEMICAL, CONTAMINATED MATERIALS (INCLUDING SAWDUST) AND THE EMPTY CONTAINER SAFELY using a method approved by the WASTE DISPOSAL AUTHORITY.	Yes but needs to be replaced by standard sentences	Lozing op het riool van het middel is niet toegestaan. Resten die het middel bevatten, dienen te worden hergebruikt of verwijderd als chemisch afval.
WASH HANDS AND EXPOSED SKIN before meals and after use.	Yes	The following sentence should be included in WG/GA: “Na gebruik handen wassen”.

Professional use (use 3 and 4 on the WG/GA)

Measure	**In WG/GA**	**WG/GA (in Dutch)**
For indoor use only. The product is for use on timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting.	Yes, it is explicitly mentioned that this is an indoor application (no ground contact, no exposure to weather)	3. voor het preventief behandelen van hout binnenshuis tegen echte huiszwam (Serpula lacrymans). In situ binnenshuis toepassing door middel van spuiten of strijken. 4. voor het curatief behandelen van binnenmuren tegen echte huiszwam (Serpula lacrymans) ter voorkoming van besmetting van aangrenzend hout. In situ binnenshuis toepassing door middel van boorgatinjectie, boorgatdrenking, spuiten en strijken.
The COSHH (Control of Substances Hazardous to Health) Regulations 2002 (as amended) apply to the use of this product at work.	No	
DO NOT CONTAMINATE FOODSTUFFS, EATING	No	The RMS has performed the calculations for an infant chewing a

UTENSILS OR FOOD CONTACT SURFACES.		piece of treated wood, and for contact with food and feeding stuff (impregnation of fruit boxes). In both cases the exposure is significantly below the AEL -> the sentence is not indicated by the risk assessment.
WASH HANDS AND EXPOSED SKIN before meals and after use.	Yes	The following sentence should be added to WG/GA: “Na gebruik handen wassen”
Do not contaminate ground, waterbodies or watercourses with chemicals or used container.	Yes but needs to be replaced by standard sentences	Hout dat geïmpregneerd is met Wolsit KD 10 mag niet gebruikt worden in situaties en op plaatsen waar directe uitloging vanuit het hout naar oppervlakte- en grondwater kan plaatsvinden
Do not contaminate plant life and remove or cover aquariums/fish bowls before application.	Yes but needs to be replaced by standard sentences	Aquaria/vissenkommen vóór aanbrenging in situ binnenshuis verwijderen of afdekken.
This material and its container must be disposed of in a safe way.	No	This is covered by S60.
UNPROTECTED PERSONS AND ANIMALS SHOULD BE KEPT AWAY FROM TREATED AREAS FOR 48 HOURS OR UNTIL SURFACES ARE DRY.	Yes	The following sentence should be included in WG/GA: Behandeld hout 48 uur, of totdat hout gedroogd is, buiten bereik van personen en dieren houden.
Dangerous to Bats. All bats are protected under the Wildlife and Countryside Act 1981. Before treating any structure used by bats, consult Natural England, Scottish Natural Heritage or the Countryside Council for Wales.	Yes but needs to be replaced by standard sentences	Neem bij in situ binnenshuis toepassingen de nodige maatregelen om te voorkomen dat vleermuizen en andere beschermde dieren worden blootgesteld.

3 Proposal for decision

The authorisation of Wolsit KD 10 is based on mutual recognition of the authorisation of RMS UK. For the evaluation we refer to the product assessment report which has been composed by the RMS conform the Common Principles.

It is expected that the application of Wolsit KD 10 according to the use instructions, will be effective and that there will be no harm for the health of humans, for those who use the product, and for the environment.

Proposal for the classification and labelling of the formulation
Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment, the following labelling of the formulation is proposed:

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):			
-			
Symbol:	C N	Indication of danger:	Corrosive Dangerous for the

		environment.
R phrases	R34	Causes burns
	R50	Very toxic to aquatic organisms.
S phrases	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	S28	After contact with skin, wash immediately with plenty of ... (to be specified by the manufacturer).
	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection
	S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
	S60	This material and its container must be disposed of as hazardous waste.
	S61	Avoid release to the environment. Refer to special instructions/safety data sheets.
Special provisions: DPD-phrases	DPD11	Contains propiconazole. May produce an allergic reaction.
Child-resistant fastening obligatory?		Not applicable
Tactile warning of danger obligatory?		Not applicable

Explanation:	
Hazard symbol:	-
Risk phrases:	-
Safety phrases:	Initially more than six S-phrases were assigned, therefore: S21 is not assigned because the product is only intended for professional use and smoking on the workfloor is not permitted in the Netherlands. S35 is not assigned because it is already covered by the assignment of S60.