HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 TOELATING

Gelet op de aanvraag d.d. 16 november 2012 (20121287 TNBWE) van

Arch Timber Protection Ltd.
Wheldon Road
WEST YORKSHIRE WF10 2JT
GROOT-BRITTANNIË

tot verkrijging van een toelating als bedoeld in artikel 19 van de Verordening (EU) 528/2012, op basis van de werkzame stoffen 3-jood-2-propynylbutylcarbamaat, propiconazool en tebuconazool,

ANTIBLU Select 3787

Mede gelet op artikel 89 lid 2 juncto artikel 91 van de Verordening (EU) 528/2012, juncto artikel 44, eerste lid, Wet gewasbeschermingsmiddelen en biociden zoals deze luidde voor de inwerkingtreding van Verordening (EU) 528/2012

BESLUIT HET COLLEGE als volgt:

1.1 Toelating

1. Het middel ANTIBLU Select 3787 is toegelaten voor de in bijlage I genoemde toepassingen onder nummer 14342 N met ingang van datum dezes. 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

Mede gelet op artikel 50 Wet gewasbeschermingsmiddelen en biociden worden voorschriften gegeven.

Dit leidt tot de volgende voorschriften:

aard van het preparaat: Met water mengbaar concentraat

werkzame stof:	*gehalte:*
3-jood-2-propynylbutylcarbamaat	79,15 g/kg
propiconazool	40 g/kg
tebuconazool	20 g/kg

letterlijk en zonder enige aanvulling:

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

Pack A: -
Pack B: propionzuur; aminen, kokosalkyldimethyl; tris-(2-hydroxyethyl)-N-talkvet-alykylamino-propaan; vetzuren, C8-10

gevaarsymbool:	*Aanduiding:*
Pack A and B:	
Xn	Schadelijk
N	Milieugevaarlijk

Waarschuwingszinnen:

Pack A:

R20	-Schadelijk bij inademing.
R36	-Irriterend voor de ogen.
R43	-Kan overgevoeligheid veroorzaken bij contact met de huid.
R50	-Zeer vergiftig voor in het water levende organismen.

Pack B:

R22	-Schadelijk bij opname door de mond.
R34	-Veroorzaakt brandwonden.
R51/53	-Vergiftig voor in het water levende organismen; kan in het aquatisch milieu op lange termijn schadelijke effecten veroorzaken.

Veiligheidsaanbevelingen:

Pack A:

S21	-Niet roken tijdens gebruik.
S23	- Gas/rook/damp/spuitnevel niet inademen (toepasselijke term(en) aan te geven door de fabrikant).
S36/37	-Draag geschikte handschoenen en beschermende kleding.
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.

Pack B:

S21	-Niet roken tijdens gebruik.
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 water.
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).
S61	-Voorkom lozing in het milieu. Vraag om speciale instructies / veiligheidsgegevenskaart.

Specifieke vermeldingen: -

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.

2 DETAILS VAN DE AANVRAAG

Het betreft een aanvraag tot verkrijging van een toelating van het middel ANTIBLU Select 3787 (14342 N), een middel op basis van de werkzame stoffen 3-jood-2-propynylbutylcarbamaat, propiconazool en tebuconazool. Het middel wordt aangevraagd als houtverduurzamingsmiddel voor het preventief behandelen van pas geveld hout tegen blauwschimmels en oppervlakteschimmels, met uitzondering van hout dat in permanent contact zal komen met grond en/of water (gebruiksklasse 2 en 3). Het middel is bestemd voor professioneel gebruik en mag alleen worden toegepast in industriële installaties.

ANTIBLU Select 3787 wordt geleverd als een twee componenten product, Pack A en Pack B, waarbij Pack A de actieve stoffen bevat en Pack B de hulpstoffen. Pack A mag niet zonder Pack B gebruikt worden.

2.2 Informatie met betrekking tot de stoffen

Er zijn in Nederland reeds andere middelen op basis van de werkzame stoffen 3-jood-2-propynylbutylcarbamaat, propiconazool en tebuconazool toegelaten.
De werkzame stof 3-jood-2-propynylbutylcarbamaat is bij Richtlijn 2008/79/EG, dd 28 juli 2008 van de Europese Commissie van de Europese Gemeenschappen opgenomen in Bijlage I van Richtlijn 98/8/EG.
De werkzame stof propiconazool is bij Richtlijn 2008/78/EG, dd 25 juli 2008 van de Europese Commissie van de Europese Gemeenschappen opgenomen in Bijlage I van Richtlijn 98/8/EG.
De werkzame stof tebuconazool is bij Richtlijn 2008/86/EG, dd 5 september 2008 van de Europese Commissie van de Europese Gemeenschappen opgenomen in Bijlage I van Richtlijn 98/8/EG.

2.3 Karakterisering van het middel

ANTIBLU SELECT 3787 is a water based product used as a temporary preventative wood preservative containing 3-jood-2-propynylbutylcarbamaat, propiconazool en tebuconazool as active ingredients. It is supplied as a two pack concentrate that is diluted with water before application. The active ingredients are in pack A and the co-formulants in pack B. The product is for industrial use only using the application methods of dipping and deluging.

2.4 Voorgeschiedenis

De aanvraag is op 16 november 2012 ontvangen; op 12 oktober 2012 zijn de verschuldigde aanvraagkosten ontvangen. De aanvraag is een aantal maanden geschorst ivm een discussie tussen MSCAs over werkzaamheidsaspecten.

2.5 Eindconclusie

Bij gebruik volgens het Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing is het middel ANTIBLU Select 3787 op basis van de werkzame stoffen propiconazool, tebuconazool en 3-jood-2-propynylbutylcarbamaat voldoende werkzaam en heeft het geen schadelijke uitwerking op de gezondheid van de mens en het milieu.

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, 10 januari 2014

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. 10 januari 2014 tot toelating van het middel ANTIBLU Select 3787, toelatingnummer 14342 N

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als houtverduurzamingsmiddel voor het preventief behandelen van pas geveld hout tegen blauwschimmels en oppervlakteschimmels (gebruiksklasse 2 en 3), met uitzondering van hout dat in permanent contact zal komen met grond en/of water . Het middel mag alleen worden toegepast in industriële installaties.

ANTIBLU Select 3787 wordt geleverd als een twee componenten product, Pack A en Pack B, waarbij Pack A de actieve stoffen bevat en Pack B de hulpstoffen. Pack A mag niet zonder Pack B gebruikt worden.

De dosering en gebruiksinstructies zoals aangegeven in de gebruiksaanwijzing moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

De toepassing van ANTIBLU Select 3787 vindt inpandig plaats door dompelen of door een bevloeiingsmethodiek ingekapseld in een industriële installatie.

De twee componenten worden voor gebruik gemengd in concentraties van 0,2 - 1,5% w/w voor Pack A en 0,3 - 0,9% w/w voor Pack B. De gekozen concentratie hangt af van de aard van de installatie, de houtsoort en de verwachte duur van opslag van het hout. De laagste dosering is alleen geschikt voor sparrenhout dat niet langer dan 4 weken bescherming nodig heeft. Raadpleeg de fabrikant voor het vaststellen van de optimale dosering voor de specifieke condities ter plaatse.

Voor de aanmaak van ANTIBLU Select 3787 gebruiksoplossing van de gewenste concentratie wordt eerst een vooraf bepaalde hoeveelheid Pack A aan een bepaalde hoeveelheid water toegevoegd, waarna een bijpassende hoeveelheid Pack B wordt bijgemengd. Het hout wordt behandeld met een dosering van 15 l/m^3. Overtollig product dient te worden opgevangen en hergebruikt bij de aanmaak van nieuwe gebruiksvloeistof.

Bij het gebruik van dit product dienen geschikte persoonlijke beschermingsmiddelen te worden gedragen, zoals een beschermingsmiddel voor de ogen of het gezicht, een ondoorlaatbaar schort, laarzen en handschoenen.

Behandeling en opslag van hout dienen plaats te vinden onder dak en boven een vloeistofdichte vloer. Lozing op het riool van het middel is niet toegestaan. Gemorste hoeveelheden en resten die het middel bevatten, moeten worden verwijderd als chemisch afval.

Voorzorgsmaatregelen:
Resten van het middel, besmette materialen (inclusief zaagsel) en de verpakking als gevaarlijk afval afvoeren. Lege verpakking mag niet worden hergebruikt.

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 10 januari 2014 tot toelating van het middel ANTIBLU Select 3787, toelatingnummer 14342 N

Product Assessment Report Mutual Recognition

Antiblu Select 3787

03-01-2014

Internal registration/file no:	20121287
Authorisation/Registration no:	14342N
Granting date/entry into force of authorisation/ registration:	10-01-2014
Expiry date of authorisation/ registration:	31-03-2020
Active ingredient:	IPBC, Propiconazole en Tebuconazole
Product type:	8

Biocidal product assessment report related to product authorisation according to 528/2012/EC

Contents

1 General information about the product application

1.1 Applicant

Arch Timber Protection
Wheldon Road
Castleford
SF10 2JT
United Kingdom

1.2 Current authorisation holder[1]

Not applicable.

1.3 Proposed authorisation holder

Arch Timber Protection.

1.4 Information about the product application

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

1.5 Information about the biocidal product

Productname: Antiblu Select 3787
Productname in RMS: Antiblu Select 3787
PT: 8
Active substance: IPBC, Propiconazole en Tebuconazole

[1] Applies only to existing authorisations

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:	-

Based on Reg (EC) 1272/2008, no classification or labelling is required regarding physical and chemical properties.

Supported shelf life of the formulation: two years in HDPE

Packaging

Professional use

	Packaging authorised by RMS	Packaging applied for in NL	Packaging authorised in NL
Packaging size and type	Pack A: 25 L HDPE IBC Pack B: 25 L HDPE IBC	Pack A: 25 L HDPE IBC Pack B: 25 L HDPE IBC	Pack A: 25 L HDPE IBC Pack B: 25 L HDPE IBC
Packaging size and type	Pack A: 200 L HDPE IBC Pack B: 200 L HDPE IBC	Pack A: 200 L HDPE IBC Pack B: 200 L HDPE IBC	Pack A: 200 L HDPE IBC Pack B: 200 L HDPE IBC
Packaging size and type	Pack A: 1000 L HDPE IBC Pack B: 1000 L HDPE IBC	Pack A: 1000 L HDPE IBC Pack B: 1000 L HDPE IBC	Pack A: 1000 L HDPE IBC Pack B: 1000 L HDPE IBC

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

Pack A:

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:	Xn	Indication of danger:	Harmful
R phrases	R20	Harmful if inhaled.	
	R36	Irritating to eyes.	
	R43	May cause sensitization by skin contact.	
S phrases	S23	Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).	
	S36/37	Wear suitable protective clothing and gloves.	
	S46	If swallowed, seek medical advice immediately and show this container or label.	
Special provisions:	-	-	
DPD-phrases			
Child-resistant fastening obligatory?			Not applicable
Tactile warning of danger obligatory?			Not applicable

Explanation:	
Hazard symbol:	-
Risk phrases:	-
Safety phrases:	S23 is assigned by Ctgb based on R20.
Other:	-

Pack B:

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):			
Propionic acid; amines, coco alkyldimethyl; ethanol, 2,2'-[[3-[(2-hydroxyethyl)amino]propyl]imino]bis-, N-tallow alkyl derivs.; fatty acids, C8-C10			
Symbol:	Xn	Indication of danger:	Harmful
R phrases	R22	Harmful if swallowed.	
	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).	
	S36/37/39	Wear suitable protective clothing, gloves and eyes/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			
Child-resistant fastening obligatory?			Not applicable
Tactile warning of danger obligatory?			Not applicable

Explanation:	
Hazard symbol:	-
Risk phrases:	-
Safety phrases:	S24 and S25 are not assigned by CTGB, as personal protective equipment is prescribed.
Other:	-

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

Pack A

Symbol:	N	Indication of danger:	Dangerous for the environment.
R phrases	R50	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment	
S phrases	S60	This material and its container must be disposed of as hazardous waste. (Deze zin hoeft niet te worden vermeld op het etiket indien u deelneemt aan het verpakkingenconvenant, en op het etiket het STORL-vignet voert, en ingevolge dit convenant de toepasselijke zin uit de volgende verwijderingszinnen op het etiket vermeldt: 1) Deze verpakking is bedrijfsafval, mits deze is schoongespoeld, zoals wettelijk is voorgeschreven. 2) Deze verpakking is bedrijfsafval, nadat deze volledig is geleegd. 3) Deze verpakking dient nadat deze volledig is geleegd te worden ingeleverd bij een KCA-depot. Informeer bij uw gemeente.)	
	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 active substance and the triggers laid down in the Dangerous Preparation Directive 1999/45/EC and Directive 2008/6/EC
Risk phrases:	Classification based on toxicity of one active substance and the triggers laid down in the Dangerous Preparation Directive 1999/45/EC and Directive 2008/6/EC
Safety phrases:	S60 and S61 are assigned to biocidal products for professional use with N, R50
Other:	-

Pack B

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.
Special provisions (DPD-phrases) :	-	-

Explanation:	
Hazard symbol:	Classification based on toxicity of two co-formulants and the triggers laid down in the Dangerous Preparation Directive 1999/45/EC and Directive 2008/6/EC
Risk phrases:	Classification based on toxicity of two co-formulants and the triggers laid down in the Dangerous Preparation Directive 1999/45/EC and Directive 2008/6/EC
Safety phrases:	S61 is assigned to biocidal products for professional use with N, R51/53
Other:	-

The proposed classification and labelling of pack A (N, R50) differs from to that proposed in the Product Assessment Report by the competent authority UK (N, R50/53). The classification of pack A is determined by the concentration, aquatic ecotoxicity and classification and labelling of the active substance IPBC for which there is still an outstanding question about risk phrase R53. As no common agreement between Member States could be achieved this has been sent to the C+L group for clarification. However, UK has decided to assign the classification and labelling N, R50/53 to IPBC which clarifies the difference in classification and labelling of the product by UK and CMS NL.
The proposed classification and labelling of pack B is identical (N, R51/53) to that proposed in the Product Assessment Report by the competent authority UK.

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.

Persistent foaming of the product as determined using CIPAT MT 47.2 was more than 60 mL foam after 1 min. This is acceptable as the product is used for industrial dipping in an open tank. There is no mechanical application of the product and as such, the excess of foaming will not affect product use. The CIPAC foaming test requires 30 inverts of the test vessel to be carried out, which is not representative for normal use conditions.

The product is applied in the following ratio's: 0.2% - 1.5% Pack A and 0.3% - 0.9% Pack B.

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 Product Assessment Report of the original authorisation. The conclusions of the RMS are acceptable, considering the following:

- Efficacy of the lowest dose (0.2 % Pack A, equivalent to 158 ppm IPBC, 80 ppm propiconazole and 40 ppm tebuconazole) was not demonstrated. The UK CA considered that the test performed with another product 'Antiblu 3759' (dose 146 ppm IPBC and 94 ppm propiconazole) supported the minimum application rate. However, there is no evidence or justification that 80 ppm propiconazole and 40 ppm tebuconazole will give the same efficacy as 94 ppm propiconazole. The applicant provided a statement that the lowest dose will only be recommended for obtaining a protection of 4 weeks or less on spruce. This is a specific circumstance where the customer only requires a minimal level of protection.
For this use the lowest dose rate is acceptable and this will be stated on the label.
- The dosing of the product is not specified since pack A and pack B should be combined and for each pack a dose range is set, without a set ratio between pack A and B. The applicant provided a statement that for each new use at the treatment plant, the manufacturer will provide specific instructions for the product based on site specific conditions, also in NL. When this is stated on the label the dose range as proposed is acceptable.

2.5.1 The label claim

The applicant has provided a Dutch label (WG/GA). This has been adapted to our standards.
Note that this product contains two components: Pack A and Pack B. Information is added to the WG/GA's of Pack A and Pack B that the two components should not be used separately.

Use class
In the PAR, efficacy is restricted to use class 2 and 3. This information is added to the WG/GA.

Professional use
In the PAR, efficacy is restricted to industrial users. This information is added to the WG/GA.

Consult manufacturer
In the PAR it is mentioned that depending on the treatment plant and application method, the manufacturer will provide specific instructions for the product based on site specific conditions. This information is added to the WG/GA.

Lowest dose
The lowest dose will only be recommended for obtaining a protection of 4 weeks or less on spruce. This information is added to the WG/GA.

2.5.2 Resistance

In the PAR no information on resistance was given.
Propiconazole and tebuconazole are triazoles. Resistance of fungi to triazoles in plant protection products or biocides is well documented and leads to increasing problems with (cross) resistance against mycobiotics used in hospitals to control infections with *Aspergillus fumigatus*. This can be a possible risk for human health.
However, ANTIBLU Select 3787 contains besides two triazoles also another active substance, IBPC. Because of the combined action of the three active substances the development of resistance against ANTIBLU Select 3787 is not very likely. Therefore, it is not necessary to add a resistance management strategy to the label.

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.

2.6.2 Assessment of exposure to humans and the environment

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

Concerning the assessment of the exposure to environment: Antiblu Select 3787 is a product containing 88.6 g/L IPBC, 43.44 g/L propiconazole and 23.3 g/L tebuconazole for use as a wood preservative biocide on freshly sawn or felled wood and unseasoned timber as a protective treatment against wood staining fungi and surface moulds. The applicant has indicated that the proposed use is intended to provide a temporary, rather than a long term, protection until the treated wood is processed further. However, as discussed in more detail later in this assessment, no evidence was provided to show that the treatment is indeed temporary, and therefore the UK CA has performed the assessment for Use Classes 1-3. Label recommendations indicate that the product is to be diluted in water to a maximum concentration of 1.5 % product. The resulting treatment solution is proposed to be used in industrial surface treatment application methods (dip and deluge) at a maximum rate of 15 L/m^3 wood. The resulting active substance concentrations in the treatment solution (and application rates to wood in brackets) are therefore calculated by the UK CA to be 1.33 g IPBC/L (19.94 g IPBC/m^3 wood); 0.65 g propiconazole/L (9.78 g propiconazole/m^3 wood); and 0.35 g tebuconazole/L (5.24 g tebuconazole/m^3 wood). For details on the assessment of the exposure to the environment we refer to 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.

The formulation Antiblu Select 3787 contains three active substances: IPBC (7.915%), propiconazole (4.0%) and tebuconazole (2.00%). The RMS UK did not assess the combined toxicity from a concomitant exposure to all three substances. Therefore a separate assessment was made by the Ctgb.

According to the proposal for the assessment of combined toxicity prepared by France and discussed at the TM III 2012, as a first tier approach, toxicological effects are considered to be additive by default. This implies that if a sum of the risk indices for each substance per exposure scenario is below 1, no concern for adverse effects after combined exposure exists. If a sum of the risk indices exceeds 1, as a second tier approach, a more detailed assessment is necessary, including the analysis of the mode of action and target organs for each substance. If the substances have different modes of action and different target organs are affected, the additivity approach is not applicable and the effects of each substance should be regarded separately. In that case no concern for combined toxicological effects of the substances exists.

In the present case, the following sums of risk indices are calculated for three substances per each exposure scenario (see Table 6.1 of Product Assessment Report of the original authorisation):

For industrial flow coating (deluge): 0.65 + 0.0139[2] + 0.39 = 1.054
For industrial automated dipping: 0.97 + 0.02 + 0.57 = 1.74
For industrial handling of treated wet wood: 0.24 + 0.005 + 0.14 = 0.385
For industrial cleaning of a dipping tank after use: 0.24 + 0.005+ 0.08 = 0.321.
For a non-professional adult standing treated wooden posts (acute exposure) : 0.0072[3] + 0.00002 + 0.02 = 0.027
For an infant chewing wood cut-off (acute exposure): 0.0319 + 0.054 + 0.16 = 0.2459[4]
For a professional sanding treated wooden posts (chronic exposure): 0.001 + 0.0134[5] + 0.023[6] = 0.0374
For an infant playing on a (weathered) playground structure and mouthing: 0.061 + 0.083[7]+ 0.139[8] = 0.28

For the scenario of the inhalation of volatile residues indoors, only exposure to IPBC was considered based on low vapour pressure of propiconazole and tebuconazole (5.6 x 10^{-5} Pa at 25 ºC and 1.7 x 10^{-6} Pa at 20 ºC, respectively). Therefore no combined exposure needs to be assessed for this scenario.

As can be seen from these calculations, the sum of risk indices per exposure scenario marginally exceeds 1 for industrial flow coating (deluge) and significantly exceeds 1 for industrial automated dipping. Therefore, as a second tier, toxicological profiles of each substance will be assessed.

For tebuconazole, in the available repeated dose toxicity studies the effects were mostly observed in the liver (increased weights, enzyme induction, decreased plasma glyceride levels) and the adrenals (vacuolization of the *zona fasciculalta* cells). Tebuconazole was also a developmental toxicant in the available developmental toxicity studies (classification as R63: possible risk of harm to the unborn child). The AEL of 0.03 mg/kg bw/day is based on the histopathological alterations in the adrenal cortex and non-specific liver effects (slightly increased weight, enzyme induction and decreased plasma glyceride levels) in a one-year study in dogs.

For propiconazole, the most critical effect is liver toxicity. Increased liver weights and slight histopathological changes in the liver were seen already in short-term studies. Propiconazole is a strong inducer of xenobiotic metabolism and tumor promoter in rodents. In rat teratogenicity studies a slight increase in the incidence of cleft palate was observed; however, due to low incidences and the fact that these changes occurred only in the

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[2] The reported risk index value in the PAR in table 6.1 is wrong for automated flow coating (deluge) for propiconazole; dermal exposure was not taken into account. The correct value of 0.0139 was calculated by the Ctgb.
[3] The reported risk index value in the PAR in table 6.2 is incorrect for an adult sanding treated posts for IPBC; no correction for 60 kg operator body weight was applied for dermal exposure. The correct value of 0.0072 was calculated by the Ctgb.
[4] All three risk indices for propiconazole, tebuconazole and IPBC have been calculated incorrectly by the RMS. Instead of correcting for 10 kg infant weight, the correction for 60 kg body weight was applied. The correct risk indices were calculated by the Ctgb.
[5] The reported risk index in Table 6.6 of the PAR is wrong; the exposure was compared with the acute (instead of chronic) AEL, although the RMS states that this is a long-term scenario. The correct risk index of 0.0134 was calculated by the Ctgb.
[6] The reported risk index in Table 6.6 of the PAR is incorrect; the exposure was compared with the AEL of 0.2 mg/kg bw/day, while for tebuconazole the AEL is 0.03 mg/kg bw/day. The correct risk index of 0.023 was calculated by the Ctgb.
[7] The reported risk index in Table 6.7 of the PAR is wrong; the exposure was compared with the acute (instead of chronic) AEL, although the RMS states that this is a long-term scenario. The correct risk index of 0.083 was calculated by the Ctgb.
[8] The reported risk index in Table 6.7 of the PAR is incorrect; the exposure was compared with the AEL of 0.2 mg/kg bw/day, while for tebuconazole the AEL is 0.03 mg/kg bw/day. The correct risk index of 0.139 was calculated by the Ctgb.

presence of marked maternal toxicity they were considered to be incidental. In a two-generation study wit rats slight reproductive effects (reduced litter sizes and pup weights, reduction in testes/epididymides weights) were observed at high doses. The long-term systemic AEL of 0.08 mg/kg bw/day was based on the liver toxicity in parental animals in the 2-generation study with rats. The short-term systemic AEL of 0.3 mg/kg bw/day was based on the developmental changes (slight increases in cleft palate, increased visceral and skeletal variations) in a teratology study with rats.

For IPBC, the observed changes in the repeated dose oral toxicity studies included local effects in the stomach (erosions, ulceration and/or inflammation), liver (increased weights, sometimes accompanied by hepatocellular changes), kidneys (increased weights, females only) and thyroids (enlarged thyroids accompanied by foci of small vacuolated cells and general follicular enlargement in 78-week mice study). In the repeated dose inhalation toxicity studies decreased RBC cholinesterase activity in females and decreased brain cholinesterase activity in both sexes were observed. However, the relevance of these findings was not clear, as no dose-response was observed and the normal variation seemed to be wide. In addition, local effects in the larynx were observed the repeated dose inhalation toxicity studies. IPBC did not affect fertility and did not cause developmental toxicity. The long-term systemic AEL of 0.2 mg/kg bw/day was based on non-specific effects (reduced body weights and body weight gains) and histopathological changes in stomach, forestomach and salivary glands in the chronic toxicity study with rats. The short-term systemic AEL of 0.35 mg/kg bw/day was based on the non-specific effects (reduced body weight and body weight gain) and increased absolute and relative kidney and liver weights in the 90-day study with rats.

As can be seen from these data, all three substances cause liver toxicity. Furthermore, both tebuconazole and propiconazole cause developmental effects. Therefore concern for combined toxicological effects of the three substances exists. Regarding developmental effects, using the additivity approach as a first tier, the sum of risk indices of tebuconazole and propiconazole needs to be calculated for two scenarios for which the sums of risk indices exceeded 1. As IPBC is not a developmental toxicant, it does not need to be considered. This leads to the following results:

For industrial flow coating (deluge): 0.65 + 0.0139 = 0.6639
For industrial automated dipping: 0.97 + 0.02 = 0.99

As in both cases the sum of risk indices per exposure scenario does not exceed 1, no concern for adverse developmental effects from concomitant exposure to tebuconazole and propiconazole exists.

Regarding the liver effects caused by the three substances, it should be noted that these effects were minor in case of tebuconazole and IPBC, and it cannot be excluded that they were in fact adaptive in nature. For tebuconazole, the observed effects were limited to the increased liver weight and enzyme induction in the absence of histopathological changes, which is considered to be typical for an adaptive response according to ECETOC Technical Report No. 85 (2002).[9] For IPBC, the effects were also mostly limited to increased liver weights, sometimes accompanied by minor histopathological changes (hepatocyte enlargement). In a chronic toxicity rat study, absolute liver weights were increased at the interim kill in females at 40 mg/kg bw/day and 80 mg/kg bw/day and in males at 80 mg/kg bw/day, but this effect was not noted at the terminal kill. The transient nature of the effect also suggests an adaptive response. In two available 90-day toxicity studies with rats, increased absolute and relevant liver weights were also observed. Hepatocyte enlargement was evident in one of the two studies; however, this effect was not noted anymore after a 28-day recovery period and considered to be reversible. According to ECETOC Technical

[9] ECETOC Technical Report No. 85. Recognition of, and Differentiation between, Adverse and Non-adverse Effects in Toxicology Studies. Brussels, December 2002.

Report No. 85 (2002)[8], zonal hepatocyte hypertrophy is generally regarded as an adaptive change associated with enzyme induction or smooth endoplasmic reticulum proliferation. In the 90-day study with rabbits, increased absolute and relative liver weights were observed at high dose levels (75 and 150 mg/kg bw/day) in females only, while no effects on the organ weights were noted in males. Slight to moderate hepatocyte enlargement with brown pigment in the cytoplasm was observed in both sexes at 75 and 150 mg/kg bw/day. In the absence of a recovery period it is not clear whether this effects was reversible. No other histopathological changes were noted. No clear histopathological changes in the liver were noted in a chronic toxicity study with rats.

In summary, although liver effects were observed in the repeated dose toxicity studies with all three substances, for IPBC and tebuconazole they are minor in nature and are likely to be adaptive. Therefore it is not to be expected that the combined exposure to three substances will lead to severe effects in the liver. Besides the developmental effects and liver effects, the three substances do not have common target organs, and the AELs are based on different critical effects. Therefore it is assumed that no adverse effects are expected from concomitant exposure to IPBC, propiconazole and tebuconazole due to combined toxicity.

Based on the risk assessment, no adverse effects from the exposure to IBPC, propiconazole and tebuconazole due to the application of Antiblu Select 3787 are expected for protected (gloves, coverall) professional user.

Based on the risk assessment, no adverse effects from indirect exposure to IPBC, propiconazole and tebuconazole due to the application of Antiblu Select 3787 are expected for unprotected professional users and general public.

2.8 Risk assessment for the environment

For the risk assessment for the environment we refer to Product Assessment Report of the original authorisation.
Antiblu Select 3787 contains three active substances, IPBC, propiconazole and tebuconazole.

Substances of concern
Pack A contains the three active ingredients

IPBC	7.9%w/w	R50
Propiconazole	4 %w/w	R50/53
Tebuconazole	2 %w/w	R51/53

The other components of this pack have no environmental classification.

Pack B contains the following components with an environmental classification

Ethoduomeen T/13	14 %w/w	R50/53
Ethoduomeen T/25	6 %w/w	R51/53
Barlene 12C	7.5 %w/w	R50
Cocoalkyl-N,N-dimethylamine N-oxide	1.5%w/w	R50

Antiblu Select 3787 contains Ethoduomeen T/13, Ethoduomeen T/25 and Barlene 12C as coformulants which have environmental classifications contributing to the pack B classification. They are deemed substances of concern in the concentrate, however once diluted the concentrations are low and would not lead to any environmental classification in the ready to use solution.
The ready to use treatment solution is not classified as hazardous and no component would be deemed a substance of concern. Coformulants will therefore not need to be considered further in the environmental assessment.

Preliminary conclusion NL CA: According to the classification of both products proposed by CMS NL, IPBC and propiconazole contribute to the classification of product A and Ethoduomeen T/13 and Ethoduomeen T/25 contribute to the classification of the product B. We therefore do not agree with the UK CA that assessment of substances of concern is not required in the PAR and kindly ask the UK CA why substances with similar classifications as the active substances and at similar % in the product as the active substances are not taken into account in the risk assessment.

Response UK CA: Whilst we note the comments raised by the NL CA regarding the presence of "*Substances of Concern*" within the formulation, we should emphasise that this wood preservative product was assessed in line with internal guidance that was developed by the UK at the time of its evaluation. Such guidance is now being discussed at EU level through the PAMRFG and TM, with additional collaborative work expected between UK and DK. We accept that not all MS are in agreement with the UK proposals but until there is an agreed EU approach for assessing SoCs, the UK CA can see no reason to change our assessment which we currently consider is appropriate.

Final conclusion NL CA: We consider the current risk assessment complete as no agreed EU approach for assessing SoCs is available up till now and thus we can accept the motivation of the UK CA.

IPBC and Iodine

IPBC releases iodine into the environment. Iodine has not been assessed by the RMS as a relevant metabolite. Iodine is a naturally occurring element. Background levels of iodine in soil are 0.5 – 20 mg/kg dw with a mean value of 5 mg/kg dw. Recent national risk assessments of IPBC for products in PT07 and PT03 applications have shown that the emission of iodine to soil did not significantly increase the background concentrations and thus a risk is also not expected from IPBC in Antiblu Select 3787.
Current PAR does not address the leaching of iodine to groundwater. It is known from other risk assessment that iodine does leach to groundwater above levels of 0.1 µg/L. However, iodine is an essential nutrient which is needed in relatively high concentration, and for this reason the limit concentration of 0.1 µg/L for pesticides is not considered applicable. The concentration in groundwater is not expected to reach concentrations larger than natural background concentration. Furthermore the contribution of iodine to the summed risk of the active substances and metabolites is not clear.

The PEC/PNEC ratios result in a value <1 at both time 1 and 2 for sediment and the risk is considered acceptable. For surface water the PEC/PNEC value is > 1 at Time 1, and < 1 at Time 2. However, the UK CA considered that, due to the very rapid degradation of IPBC, the secondary exposure of surface waters and sediments via an STP following application to a noise barrier will not occur, and therefore IPBC PEC values should not be considered in a combined risk assessment. Removal of the IPBC PECsw values from the combined risk assessment results in PEC/ PNEC values of < 1 for both Time 1 and Time 2 risk assessments. The UK CA therefore consider that the combined risk to surface waters and sediments is acceptable.

Preliminary conclusion NL CA: The current risk assessment is incomplete as an environmental risk assessment for all active substances and their major metabolites (including iodine) in water and sediment is missing and thus we can not accept the conclusions made by the RMS.

Response UK CA: As the NL CA will be aware, the DK CA presented a paper at TM-II-2012 (June 2012) looking at emissions and risks posed by a hypothetical PT 8 substance breaking down to form either 100 % iodine or 100% iodide or 100% iodate. This was in response to issues raised at mutual recognition regarding 2 x DK product authorisations. It is our understanding that this paper plus revised calculations tabled at the meeting

demonstrated some potential risks but essentially only for iodine and water bodies when using the "bridge over a pond" scenario (20 m^3 volume).

Several sensible refinements were highlighted by DK in their assessment of risk to aquatic and soil compartments and supported by UK CA, namely :-

- Comparison of predicted emissions with natural background levels in soil to demonstrate acceptable risk ;
- Use of refinements for surface water emissions which take account of removal by adsorption onto suspended matter and into sediment (as this is essentially the same approach adopted in several other PT's when considering exposure to surface water).

Agreement was reached that assessment should concentrate on the iodide and iodate species so any potential concerns arising from iodine emissions could be disregarded (as it is not likely to exist in this form in the environment). Furthermore, modelling of emissions to the aquatic compartment demonstrated acceptable risks for iodide and iodate when the new pond volume (1000 m^3) was used in calculations so COM agreed to investigate whether this revised model could be used ahead of OECD TFB ratification of the amended ESD.

Further discussion took place at the July 2012 PA&MRFG meeting where DK presented a general paper on iodine release from IPBC based wood protection products.

Based upon the PAR for ANTIBLU SELECT 3787, the maximum in-use concentration applied to timber will be a 1.5% working solution of product. With an IPBC content of 88.6 g/L, this equates to an in-use concentration for IPBC of 1.33 g/L (0.133%). This is applied industrially by dip / deluge to a retention rate of 15 L of diluted product per m^3 of wood (so 19.95 g m^{-3} of IPBC : broadly equivalent to 199.5 mg m^{-2}).

Bunding of industrial treatment sites is required as appropriate RMM for this product so there should be no emissions of IPBC or iodine/iodate/iodide during application & storage. Emissions would only be likely due to in-service leaching following placement of wood originally treated with ANTIBLU 3787 in UC 3 scenarios. Therefore, use of modelling proposed by DK in their TM-II-2012 presentation would seem appropriate.

This DK model assesses in-service risks posed by a 0.6% IPBC product whose leaching losses equate to 6.16 mg m^{-2} d^{-1} at Time 1 and 0.178 mg m^{-2} d^{-1} at Time 2. If it is assumed that all applied IPBC will leach from wood after 30 d following application of ANTIBLU 3787, then a T1 flux rate of 199.5 /30 = 6.65 mg m^{-2} d^{-1} can be calculated which is similar to that assessed by DK.
Furthermore, a worst case T2 flux rate for ANTIBLU 3787 can be derived assuming a much reduced 10-yr service life equating to 199.5/365 x 10 = 0.055 mg m^{-2} d^{-1} (significantly lower than that used by DK).

At this point, it should be noted that UK CA used flux rates almost 3 times greater in emissions assessment (T1 of 17.5 mg m^{-2} d^{-1} and T2 of 0.143 mg m^{-2} d^{-1}) based on proposals by the Applicant that 15 L of treatment solution per m^3 was equivalent to 0.394 L per m^2 (when it is widely accepted that the application rate would be 0.15 L per m^2).

Values presented by DK for the national product represent significantly higher emissions than those likely to be manifested by wood originally treated for sapstain control with ANTIBLU 3787 but whilst PEC/PNECs may be unacceptable, emissions to soil are likely to be acceptable when compared to background levels. Although predicted concentrations in water might exceed background levels based on the "bridge over a pond" scenario, DK state that they used the existing 20 m^3 pond model rather than the proposed 1000 m^3 pond volume so PECs could be decreased by a factor of 50.

Another factor that has not been taken into account during the UK assessment is that ANTIBLU 3787 will be applied as an anti-sapstain during seasoning of partially processed timber. Therefore, before any treated wood will reach the marketplace where it could be used in UC 3 locations, it will likely undergo significant processing in order to cut, shape, sand or plane the wood. Any such processing would remove a large fraction of the wood initially treated with anti-sapstain and it is possible that ≥50% of applied IPBC could be lost before wood has been converted into exterior panelling, boarding, cladding etc.

As a consequence of these factors particularly DK proposals that appear to have been adopted as being a sensible approach by MS, the UK CA considers that emissions of iodine (likely to be present as either iodide or iodate) would not give rise to unacceptable environmental risk.

Final conclusion NL CA: Despite not taking iodine into account in the risk assessment for the water and sediment compartments, the above motivation of the UK CA not to take emissions of iodine, iodide or iodate into account is considered to be acceptable.

Removal of anti-sapstain product during processing of wood

Preliminary conclusion NL CA: We question the statement of the UK CA that treated wood will likely undergo significant processing in order to cut, shape, sand or plane the wood as these processes will highly decrease the efficacy of the wood preservation. Wood preservation is a process that is carried out at the end of the wood processing process.

Response UK CA: This product is intended solely for sapstain control during the period when cut logs are transported to sawmills for seasoning / processing and before finished wood is placed on the market. Any discolouration radically reduces the value of timber so these products are applied as soon as possible to minimise financial losses. Various sawing, cutting, planing and shaping processes will be applied to treated wood and each process will remove preservative from the outer treated layers.

Such niche uses were discussed briefly at the recent 2nd leaching workshop (led by the German CA) and there seemed to be agreement that there is potential for significant removal of preservative. The only problem raised by several attendees was how to actually quantify such losses as no models exist at the moment and whether it was worth devoting resource to this area as there would only be a small number of products sold for this use. Ideally, the product should be applied when logs arrive at sawmills / industrial joinery plants and finished wood leaving those sites should contain little or no sapstain product.

Final conclusion NL CA: We consider the current risk assessment complete as no agreed EU models for assessing anti-sapstain products is available up till now and thus we can accept the motivation of the UK CA.

Emission scenarios

The worst-case exposure scenario for surface water and sediment from the revised ESD for PT8 is the bridge over pond scenario, the worst-case exposure scenario for soil is the wooden house scenario. However, The UK CA has not included calculations in the PAR for the bridge over pond scenario as for unclear reasons they consider it to be unrealistic. In the frame of the ESD review project, the default value for the size of the receiving water body (V_{water}) was set to 1000 m³. This value is based on an evaluation made by the German Federal Environment Agency (UBA) showing that a ratio of bridge surface to water volume of 1 : 100 is realistic. Taking into account a bridge surface of 10 m², this results in a default value for V_{water} of 1000 m³ which is thus more realistic than the pond size of 20 m^3 from the previous version of the ESD for PT8.

Preliminary conclusion NL CA: The current risk assessment is incomplete as an environmental risk assessment for all active substances and their major metabolites (including iodine) in water and sediment using the bridge over pond scenario according to the revised ESD for PT8 is missing and thus we can not accept the conclusions made by the RMS.

Response UK CA: The UK CA notes the comments raised by NL with regard to the "bridge over a pond" scenario but there seems to be some confusion over the UK position outlined in the PAR document. When this evaluation was performed (i.e. >15 months ago), the revised ESD for PT 8 was only in draft form and on general circulation for discussion. Although the "bridge" scenario was updated to include a larger pond volume of 1000 m^3, advice given to UK CA by the Commission was to continue using models specified in the existing 2003 ESD until such time as the revised ESD had been formally ratified by OECD TFB (which we understand has yet to take place).

However, the UK CA has long argued that the 20 m^3 "bridge" model is grossly over-predictive and therefore continued to base regulatory decisions upon the more relevant "noise barrier" model (a position agreed at TM for several active substances reviews). We must point out that we do not object to the new 1000 m^3 volume but actively support this change but, unfortunately, we believed we could not use this updated model when the assessment was initially performed.

Similar comments were raised by DE CA and so revised bridge models have been performed by the Applicant which demonstrates acceptable PEC/PNEC values when degradation has been taken into account :

Table 1 – PEC/PNEC values for bridge over pond

	Tier 1 – no degradation		**Tier 2- with degradation**	
Water	**30 days**	**10 years**	**30 days**	**10 years**
IPBC	10.5	10.44	0.075	0.0006
Tebuconazole	1.38	1.387	0.597	0.0247
Propiconazole	1.599	1.596	0.791	0.302
Cumulative (addition)	13.479	13.42	1.46	0.328
Sediment				
IPBC	-*	-*	-*	-*
Tebuconazole	-	0.0242	0.0564	0.001
Propiconazole	-	0.0912	1.876	0.0349
Cumulative (addition)	-	0.1155	1.932	0.0359

* IPBC calculations not included as risk assessment in the AR was based on EPM so will give the same results as surface water.

As Tier 1 Time 1 calculations are based on 100% loss, they are included for interest but should not form a basis for making decisions. A 100% loss of product in 30 days is totally unrealistic as if all a.s. were lost during the test period, the product would not prove efficacious. Similarly, it has been concluded in many of the active substance reviews / product authorisations that a risk at Time 1 can be tolerated when risk at Time 2 is acceptable.

Final conclusion NL CA: With the submission of additional calculations taking into account the new revised draft PT08, the RMS considers the PAR to be complete.

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 UK CA included the following on endocrine disruption in the PAR:

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. 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 that there is some evidence of adverse effects that raise a concern for potential endocrine disruption (histopathological changes of the adrenal gland in rats and dogs and a low incidence of malformations in developmental toxicity studies in rats, rabbits and mice in the presence of maternal toxicity). To establish whether or not these effects are mediated by a specific endocrine mechanism or whether they are secondary to generalised toxicity, further investigations would be required and this has been included as a condition of the authorisation.
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 and this has been included as a condition of the authorisation.

Conclusion NL CA: We agree with the UK CA not to assess endocrine disruption of propiconazole in the PAR until criteria for identification of endocrine disruptors is agreed upon at EU level.

Leaching rates, TIME 1 and risk assessment

Preliminary conclusion NL CA: The applicant has not supplied a leaching study. Therefore the UK CA assumed 100% leaching in 1 year and over 10 years (=service life). However, the product is intended as a short term wood protection product and only offers protection for up to 12 weeks. The assumption that a wood protection product remains in the wood for its service life could only be valid for a wood protection product that is intended to last the full service life of the wood. Therefore we cannot accept the current assumption made that TIME 2 is taken as the service life of the wood.

RMS concludes that at TIME 1 there is a risk, but at TIME 2 all risks are acceptable and thus the intended uses are acceptable. We can not accept this as it is likely that a short term wood protection will leach 100% from the wood well within the woods full service life. We think the risks should have been calculated assuming 100% leaching in 1 year. Regarding the proposal of the UK CA to reduce service life by 33% (10 years service life instead of 15 years) this deviates from agreed approaches at TM. An adaptation of the service life is acceptable only if there is further scientific justification which is now missing in the PAR.

For similar reasons as stated above, we cannot accept the refinement of the groundwater calculations to use leaching rates of 10 years service life. Also the reduction of application rate is poorly supported and we as yet cannot accept this. We cannot accept the reduction in amount of houses per hectare as in NL, we do have holiday resorts with this high amount of houses per hectare. But most importantly, currently the 35 houses per hectare is a harmonised amount of houses in the MOTA version 5. We do accept the refinement that actual maximum % of metabolite formation is used, but effects of individual refinements have not been reported, only the groundwater concentration estimations including all refinements.

Response UK CA: Whilst we agree that the lack of leaching data makes it difficult to predict losses from timber over time, this product does not differ greatly in composition from that of other formulations which are marketed with long-term biocidal activity. Although ANTIBLU 3787 is not needed to remain in wood at efficacious levels beyond several months, this is no guarantee that there would be anything approaching 100% loss. Furthermore, where leaching data are not available or suggest more rapid loss then expected, risk assessments are still performed assuming flux rates where 100% loss occurs during service life.

The idea that service life may be reduced has some merit and that is why, in this instance, the UK CA has proposed a reduction of 33% (10 years service life instead of 15 years) to offer suitable protection to environmental compartments. Furthermore, the assessment has not taken account of significant losses that would occur at sawmills and joineries where timber treated with ANTIBLU 3787 would be re-cut, planed, sanded, shaped and processed (thus removing a.s. in the form of contaminated sawdust and off-cuts). As this anti-sapstain will have been largely removed, the processed timber will need further treatment with long-term preservative and there is no reason to believe that any remaining propiconazole and IPBC from ANTIBLU 3787 would leach rapidly whilst actives in the overlying preservative would leach out during a 5 -20 year surface life (depending upon treatment method).

The UK is aware that the current ESD recommends use of 15 yr service life for most superficial application methods apart from coarse spray and brush. However, as explained within the PAR and further correspondence, we have supported a suggestion by the applicant to use 10 years as a more extreme worst case assessment as the product is intended only as an interim short-term treatment at sawmills / joineries. Whilst its in-use formulation (once made up to a working solution) is likely to be similar to other long term treatments, it is marketed specifically for use against sapstaining fungi whilst cut wood is being seasoned and processed and no claims for long term efficacy are made. In order to guarantee service lives of up to 15 years it is expected that additional treatments with other more standard PT8 products would need to be applied. For this very specific use pattern, the UK CA considered it appropriate to deviate from the current ESD defaults which are intended to be appropriate for more typical products with the usual long service lives.

Final conclusion NL CA: We can accept the motivation of the UK CA to set TIME 2 to 10 years instead of the default 15 years for this specific intended use of the wood protection product.

Use of FOCUS modelling of groundwater

Preliminary conclusion NL CA: The use of the FOCUSgw model for the exposure assessment of biocides in groundwater is agreed upon at TMs . Please notice our e-consultations for the use of the model in PT6 to PT10 products, which is also relevant for PT8. We would welcome it if the RMS takes notice of these e-consultations and seeks harmonisation.

Response UK CA: With regard to use of the FOCUSgw model for biocidal products, it must be remembered that this was specifically designed for assessment of pesticides and is used in the absence of another other more relevant model. The model assumes the active substance is applied every year, or at least every 3 years and cannot really simulate a rapid loss through leaching following by no further inputs over service life within the FOCUS framework - output from the models is an 80th percentile annual average over a 20 year simulation. It is probable that if it were possible to fully replicate the release of ANTIBLU SELECT 3787 with a single short term exposure event followed by years of in-service life with no releases, then the 80th percentile PECgw would be zero. Whilst the UK CA accepts that it is probably not technically correct to model release over the whole service life, there will likely be negligible risk.
The UK CA performed the FOCUS groundwater assessment in line with Appendix 4 of the revised ESD for PT 8, where the issue of leaching of groundwater has been updated and agreed at TM and OECD. This was considered this to be the most up-to-date method that has been agreed for this type of assessment. We agree that issues need to be clarified for PT 6, 7, 9 and 10 but do not consider that this means opening up discussion for PT 8 yet again or altering our current position. For your information, the UK CA is hoping to contribute further to the ongoing e-consultations from NL on methods for assessing groundwater leaching potential for other PTs and, until any alternative method is agreed, we consider the methods based on the PT8 ESD to be the most appropriate to use in this case.

With regard to the UK CA choice of 16 houses per hectare instead of 35 houses, this reduction has long been a refinement in our FOCUS modelling to represent a more realistic density of timber or timber clad housing rather than simply base assessment upon UK urban housing density. As you may be aware, this lower value reflects the average percentage of wooden houses in Scandinavia (around 45%) since such buildings are more common there than in the rest of the EU (including the UK) and has been included within the supplement to Appendix 4 of the revised draft ESD for PT 18.

When combined with use of the new longer soil degradation DT50 value for 1,2,4-triazole (metabolite of both propiconazole and tebuconazole), we consider that this assessment offers suitable protection measures for groundwater.

Final conclusion NL CA: We consider the current risk assessment complete as the revised version of the PT8 ESD has been used for groundwater modelling thus we can accept the motivation of the UK CA.

Overall conclusion for the aspect environment:
The conclusions in the risk assessment of the RMS are valid and with the risk mitigations included in the WG/GA, the use of Antiblu Select 3787 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).

Measure	in WG/GA	comment
PROFESSIONAL LABEL:		
For professional use only	yes	Het middel is uitsluitend bestemd voor professioneel

		gebruik
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	Toegestaan is uitsluitend het gebruik als houtverduurzamingsmiddel voor het preventief behandelen van pas geveld hout (gebruiksklasse 2 en 3) tegen blauwschimmels en oppervlakteschimmels, met uitzondering van hout dat in permanent contact zal komen met grond en/of water. Het middel mag alleen worden toegepast in industriële installaties.
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 salt water. This phrase should be included on the label of Pack A only.	Yes	
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	Behandeling en opslag van hout dienen plaats te vinden onder dak en boven een vloeistofdichte vloer. Lozing op het riool van het middel is niet toegestaan. Gemorste hoeveelheden en resten die het middel bevatten, moeten worden verwijderd als chemisch afval.
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)	Yes	
The COSHH (Control of Substances Hazardous to Health) Regulations 2002 (as amended) apply to the use of this product at work	Not applicable	
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	Not applicable	
Do not contaminate ground, waterbodies or watercourses with chemicals or used container	Yes	Lozing op het riool van het middel is niet toegestaan. Gemorste hoeveelheden en resten die het middel bevatten, moeten worden verwijderd als chemisch afval. Resten van het middel, besmette materialen (inclusief zaagsel) en de verpakking als gevaarlijk afval afvoeren. Lege verpakking mag niet worden hergebruikt.
Dispose of surplus chemical, contaminated materials (including sawdust) and the empty container safely using a method approved by the waste diposal authority	Yes	
Wash hands and exposed skin before meals and after use	yes	Na gebruik handen wassen.
3-iodo-2-propynyl-N-butyl carbamate is a carbamate compound which has weak anticholinesterase activity. Do not use if under medical advice not to	No	The AEL derivation includes a safety factor for the whole population, including more sensitive individuals. This

work with anticholinesterase compounds.		specific restriction is also not included in Section 3.3 of Doc I of the CAR of IPBC nor in the inclusion Directive..
Additional		
		De laagste dosering is alleen geschikt voor sparhout dat niet langer dan 4 weken bescherming nodig heeft
		Raadpleeg de fabrikant voor het vaststellen van de optimale dosering voor de specifieke condities ter plaatse.
		De toepassing van ANTIBLU Select 3787 vindt inpandig plaats door dompelen of door een bevloeiingsmethodiek ingekapseld in een industriële installatie. Het hout wordt behandeld met een dosering van 15 l/m3.

3 Proposal for decision

The authorisation of ANTIBLU Select 3787 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 ANTIBLU Select 3787 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:

Pack A:

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:	Xn	Indication of danger:	Harmful
	N		Dangerous for the environment
R phrases	R20	Harmful if inhaled.	
	R36	Irritating to eyes.	
	R43	May cause sensitization by skin contact.	
	R50	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment	
S phrases	S21	When using do not smoke	
	S23	Do not breathe gas/fumes/vapour/spray (appropriate	

		wording to be specified by the manufacturer).	
	S36/37	Wear suitable protective clothing and gloves.	
	S46	If swallowed, seek medical advice immediately and show this container or label.	
	S60	This material and its container must be disposed of as hazardous waste. (Deze zin hoeft niet te worden vermeld op het etiket indien u deelneemt aan het verpakkingenconvenant, en op het etiket het STORL-vignet voert, en ingevolge dit convenant de toepasselijke zin uit de volgende verwijderingszinnen op het etiket vermeldt: 1) Deze verpakking is bedrijfsafval, mits deze is schoongespoeld, zoals wettelijk is voorgeschreven. 2) Deze verpakking is bedrijfsafval, nadat deze volledig is geleegd. 3) Deze verpakking dient nadat deze volledig is geleegd te worden ingeleverd bij een KCA-depot. Informeer bij uw gemeente.)	
	S61	Avoid release to the environment. Refer to special instructions/safety data sheets.	
Special provisions: DPD-phrases	-	-	
Child-resistant fastening obligatory?			Not applicable
Tactile warning of danger obligatory?			Not applicable

Pack B:

Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances):			
Propionic acid; amines, coco alkyldimethyl; ethanol, 2,2'-[[3-[(2-hydroxyethyl)amino]propyl]imino]bis-, N-tallow alkyl derivs.; fatty acids, C8-C10			
Symbol:	Xn	Indication of danger:	Harmful
	N		Dangerous for the environment
R phrases	R22	Harmful if swallowed.	
	R34	Causes burns.	
	R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	
S phrases	S21	When using do not smoke.	
	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 eyes/face protection.	
	S45	In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).	
	S61	Avoid release to the environment. Refer to special instructions/safety data sheets.	
Special provisions: DPD-phrases	-	-	
Child-resistant fastening obligatory?			Not applicable
Tactile warning of danger obligatory?			Not applicable