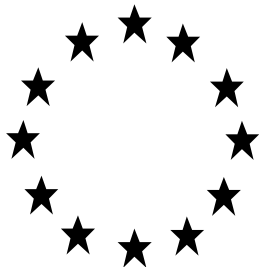
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(Applicant: KRS ApS, Denmark)



Boracol 10_3Bd

Product type 8

Boric acid, DDAC and disodium tetraborate as included in the Union list of approved active substances

Case Number in R4BP: [BC-TF035619-29]

Evaluating Competent Authority: DK

Date: 02.12.2019

OVERVIEW OF APPLICATIONS FOR BORACOL 10_3BD

Application type	RMS	Case number in the RMS	Decision date	Assessment carried out (i.e. first authorisation/ amendment/renewal)
NA-APP	DK	BC-TF035619-29	20.12.2019	First authorisation
NA-MAC	DK	BC-GG0069449-31	27.06.2022	Amendment, major change

Table of Contents

1 CONCLUSION

The Applicant, KRS (Denmark) submitted on 06.12.2017 an application (R4BP-3 Case nr. BC-TF035619-29) under Regulation (EU) No 528/2012 (BPR), application type NA-MRP (RMS Danmark), for authorisation of Boracol 10_3Bd in PT8.

The Danish Competent Authority (DK CA) proposes authorisation of the biocidal product Boracol 10_3Bd for use by professionals and non-professionals, as a wood preservative (PT8) for *in situ* preventative treatment of indoor/covered wood constructions such as roof trusses, braces, and floor separations (Use Class 2). Specifically in the case of the dry rot fungus, *Serpula lacrymans*, the product may be applied to masonry to prevent growth of the fungus into adjacent wood. The product should be applied by brushing (superficial method) at an application rate of 200 mL/m^2.

Boracol 10_3Bd contains the active substances boric acid (2.5% w/w), disodium tetraborate, anhydrous (2.38% w/w), and didecyldimethylammonium chloride (DDAC) (2.45%). Boric acid and disodium tetraborate, anhydrous, meet the Criteria for Exclusion under Article 5(1) of the Biocidal Products Regulation (BPR) (528/2012) due to their classification for reproductive toxicity (Repr. 1B, H360DF). A Comparative Assessment of the proposed label claims of use against wood-destroying fungi and mould conducted by the DK CA found, in the screening phase, only one biocidal product on the Danish market approved for mould and wood destroying fungi, including dry rot; the product contains propiconazole as active substance. Thus, chemical diversity for the intended use is not adequate to minimise risks of resistance. Furthermore, the alternative biocidal product is also classified for reproductive toxicity (Repr. 1B, H360DF). The DK CA is interested in having products against wood-destroying fungi and mould on the Danish market and, therefore, finds it justifiable to approve a product containing active substances that meet the exclusion criteria considering that the chemical diversity of approved active substances is low (or there is no better alternative on the market). Article 5(2) of the BPR states that a product containing an active substance which meets the criteria for exclusion can be approved if it fulfills at least one of three conditions: if the risk from the active substance to humans or the environment is negligible, if the active substance is essential to control a serious danger, or a non-approval would have a serious impact on society. It is the opinion of the DK CA that Boracol 10_3Bd, when used as recommended, meets the first criterion.

Based on the assessment of Boracol 10_3Bd the following was noted for phys/chem, efficacy, human health and environment:

Phys/chem

The submitted physic-chemical data for the product Boracol 10_3Bd has been evaluated and it is concluded that most endpoints have been adequately addressed by the applicant. The variation of the boron content identified in the long-term stability test exceeds the range given in guidance (GIFAP No. 17), expressed as an increasing boron content in the product over time. Based on the results presented, however, the DK CA finds it justified to accept the variation exceeding the range given in guidance. In addition, no risk concerning human toxicity/human health has been identified as a consequence of increased levels of boron.

The product will be approved with the following post-authorisation conditions;
A study on corrosiveness to metals must be submitted in January 2020.
A study on auto-ignition must be submitted in January 2020.

Based on the above, the DK CA preliminary accepts the long-term study and a shelf-life claim of two years; however, a new long-term stability study including more data points is requested.

Efficacy

Boracol 10_3Bd has documented efficacy at an application rate of 200 mL/m^2 to support claims for:

- Preventive treatment of: wood against brown rot fungi; masonry against dry rot fungus *Serpula lacrymans* to prevent adjacent wood from being affected; masonry against mould fungi to prevent adjacent wood from being affected; wood against mould fungi and,
- Curative treatment of: wood against mould fungi; masonry against the dry rot fungus *Serpula lacrymans*.

Human health

Professional use: Based on exposure- and risk assessment of the use applied for, acceptable use of Boracol 10_3Bd by professionals using appropriate personal protective equipment (PPE) was identified for application of the product by brushing. Additional tasks or activities that could result in exposure to Boracol 10_3Bd, and which reasonably could be expected to be performed by a professional, did not result in unacceptable exposure, including when their exposure contribution was added to that for the acceptable use (i.e. in a worst-case combined scenario). It is concluded that professional use of Boracol 10_3Bd, when used as proposed, does not pose acute- or chronic health risks when appropriate risk mitigation measures (RMMs) – including PPE – are employed.

Non-professional use: Based on exposure- and risk assessment of the use applied for, acceptable use of Boracol 10_3Bd by non-professionals was identified for application of the product by brushing. Additional tasks or activities that could result in exposure to Boracol 10_3Bd, and which reasonably could be expected to be performed by a non-professional, did not result in unacceptable exposure, including when their exposure contribution was added to that for the acceptable use (i.e. in a worst-case combined scenario). It is concluded that non-professional use of Boracol 10_3Bd, when used as proposed, does not pose acute- or chronic health risks when appropriate risk mitigation measures (RMMs) are employed.

General public: Considering the proposed situations of use, exposure of the general public is considered unlikely. A risk for toddlers touching freshly treated wood and subsequently mouthing their fingers was identified, triggering the labeling RMM '*Keep product and wet wood away from children during application and drying.*'

Environment

No emissions are expected to any environmental compartment as the product is applied in-door and the service life is in-door as well. No environmental exposure or risk will therefore occur based on the applied use.

Endocrine-disrupting properties

Boracol 10_3Bd has not been tested for potential endocrine-disrupting properties. The product does not have endocrine disruption indications based on current scientific knowledge, including available toxicological- and ecotoxicological information. Thus Boracol 10_3Bd is not considered to having endocrine-disrupting properties.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
Boracol 10_3Bd	Denmark Finland (cMS) Estonia (cMS) Netherlands (cMS) Norway (cMS) Germany (cMS) Spain (cMS)
Boracol Special (Tradename for Boracol 10_3Bd)	Sweden (cMS)

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	KRS ApS
	Address	Mandal Allé 9A, DK-5500 Middelfart, Denmark
Authorisation number	DK-0021935-0000	
Date of the authorisation	20 December 2019	
Expiry date of the authorisation	20 December 2024	

2.1.1.3 Manufacturer of the product

Name of manufacturer	KRS ApS
Address of manufacturer	Mandal Allé 9A, DK-5500 Middelfart, Denmark
Location of manufacturing sites	Mandal Allé 9A, DK-5500 Middelfart, Denmark

2.1.1.4 Manufacturers of the active substances

Active substance	Boric acid
Name of manufacturer	Borax Europe Limited
Address of manufacturer	2 Eastbourne Terrace, W2 6LG London, UK
Location of manufacturing sites	14486 Borax Road, Boron, CA 93516-2000 USA

Active substance	Boric acid
Name of manufacturer	Etimine S.A.
Address of manufacturer	Immeuble 67 204, Z.I. Scheleck 2 L-3225, Bettembourg, LUXEMBOURG
Location of manufacturing sites	Emet, Kütahya, Turkey

Active substance	Disodium tetraborate
Name of manufacturer	Borax Europe Limited
Address of manufacturer	2 Eastbourne Terrace, W2 6LG London, UK
Location of manufacturing sites	14486 Borax Road, Boron, CA 93516-2000 USA

Active substance	Disodium tetraborate
Name of manufacturer	Etimine S.A.
Address of manufacturer	Immeuble 67 204, Z.I. Scheleck 2 L-3225, Bettembourg, LUXEMBOURG
Location of manufacturing sites	Kırka, Eskişehir, Turkey.

Active substance	Didecyldimethylammonium chloride, DDAC
Name of manufacturer	Lonza Cologne GmbH
Address of manufacturer	Nettermannellee 1, DE-50829 Cologne, DE
Location of manufacturing sites	USA, 8316 West Route 24, Mapleton, IL 61547-0105

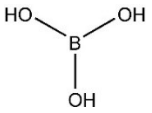
2.1.2 Product composition and formulation

NB: The full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

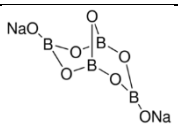
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

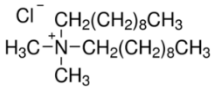
Yes ☐
No ☒

2.1.2.1 Identity of the active substances

Main constituent(s)	
ISO name	Boric acid
IUPAC or EC name	Boric acid
EC number	233-139-2
CAS number	10043-35-3
Index number in Annex VI of CLP	005-007-00-2
Minimum purity / content	990 g/kg
Structural formula	 Formula: $B(OH)_3$

Main constituent(s)	
ISO name	Disodium tetraborate, anhydrous
IUPAC or EC name	Disodium tetraborate, anhydrous
EC number	215-540-4
CAS number	1330-43-4
Index number in Annex VI of CLP	005-011-00-4
Minimum purity / content	990 g/kg

Structural formula	 Semi-empirical formula: Na2B4O7. The industrial product is amorphous.

Main constituent(s)	
ISO name	Didecyldimethylammonium chloride, DDAC
IUPAC or EC name	Didecyldimethylammonium chloride
EC number	230-525-2
CAS number	7173-51-5
Index number in Annex VI of CLP	612-131-00-6
Minimum purity / content	870 g/kg
Structural formula	 Formula: $C_{22}H_{48}N.Cl$

2.1.2.2 Candidate(s) for substitution

Boracol 10_3Bd contains boric acid and disodium tetraborate; active substances that meet the criteria for exclusion. Please see section 2.2.11 *Comparative assessment* for further information.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Information on the qualitative and quantitative information on the composition of active substances in Boracol 10_3Bd is provided in the table below. Full details of the formulation of the biocidal product is provided in section 3.7.1 of the Confidential annex.

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content TC (%)**
Boric acid	Boric acid	Active substance	10043-35-3	233-139-2	2.5
Didecyldimethylammonium chloride, DDAC*	Didecyldimethyl-ammonium chloride	Active substance	7173-51-5	230-525-2	2.45
Disodium tetraborate, anhydrous	Disodium tetraborate	Active substance	1330-43-4	215-540-4	2.38
Propan-2-ol	Propan-2-ol	Solvent	67-63-0	200-661-7	0.98

* Didecyldimethylammonium chloride (DDAC) is provided by BARDAC 22/IBC 907 KG BA, a mixture comprising 50% w/w DDAC.

The CARs for boric acid and disodium tetraborate, anhydrous (NL CA, 2009; pp. 6-7) address their dissociation in aqueous solutions depending on boron concentration and pH. The molarity of boron in Boracol 10_3Bd is 0.91 M[1] and the pH of the biocidal product is in the range pH 7.6 - 7.9 during the course of its shelf-life (see 2.2.2 *Physical, chemical and technical properties*). Thus the information in the CARs (reproduced below) regarding the dissociation of boric acid and disodium tetraborate, anhydrous at "higher boron concentrations" and at pH values "between values (pH 5-12)" is considered applicable to the biocidal product:

> "At higher boron concentrations (B > 0.025 M) an equilibrium is formed between $B(OH)_3$, polynuclear complexes of $B_3O_3(OH)_4^-$, $B_4O_5(OH)_4^{2-}$, $B_3O_3(OH)_5^{2-}$, $B_5O_6(OH)_4^-$ and $B(OH)_4^-$. In short: $B(OH)_3 \leftrightarrow$ polynuclear anions $\leftrightarrow B(OH)_4^-$.
>
> In acid solution at pH < 5, boron is mainly present as $B(OH)_3$ and in alkaline solution at pH > 12.5, boron is mainly present as $B(OH)4^-$. At in between values (pH 5-12), polynuclear anions are found as well as $B(OH)_3$ and $B(OH)_4^-$. In the presence of metal ions (e.g. Na, Mg, Ca) ion-pair complexes are formed, which further reduce the undissociated boric acid concentration: $M^+ + B(OH)_4^- \leftrightarrow MB(OH)_4^{(n-1)+}$. These ion-pair complexes are expected to be present in solutions of disodium tetraborate, disodium octaborate and buffered solutions of boric acid and boric oxide."

Considering the above, the active substances (a.s.) boric acid and disodium tetraborate are not considered present in the product as discrete substances but rather as boric acid/borate/diverse ion-pair complexes, with their total concentration equivalent to the sum of the nominal concentration of boric acid a.s. plus the nominal concentration of disodium tetraborate a.s. after conversion of the latter to the boric-acid equivalent (BAE) concentration.

Conversion factors for boron compounds to the equivalent dose of boric acid (BAE) are calculated using the formula:

$N \times (MW_{boric\ acid}/MW_{boron\ compound})$

where N is the number of boron atoms in the boron compound and MW is the molecular weight of boric acid or the boron compound. As boric acid is the reference borate, the conversion factor for boric acid into boric acid equivalents (BAE) is 1.00. A conversion factor for disodium tetraborate, anhydrous into BAE of 1.23 is derived from the formula (see the table below).

Conversion factors for boron compounds to equivalent dose of boric acid (BAE)

Compound	Molecular	MW	Conversion

[1] The quantities of boric acid (2.5% w/w) and disodium tetraborate (2.38% w/w) in the product can be converted to quantities of boron using conversion factors of 0.175 and 0.215, respectively (see under the heading *Considerations for boric acid and disodium tetraborate, anhydrous, in relation to exposure assessment* in 2.2.6.2 *Exposure assessment* for details). Thus the boron content of the product is calculated by: (2.5 x 0.175) + (2.38 x 0.215) = 0.95%, equivalent to 9.50 g boron/kg solution. Adjusting this value to account for the density of the biocidal product (1.036 mg/mL) gives a boron concentration of: 9.50 g x (1.036/1) = 9.84 g/L boron. The atomic mass of boron is 10.811, thus the boron molarity of the solution is: 9.84/10.811 = 0.91 M).

(expressed as weight unit e.g. gram)	formula		(multiplication) factor for boric acid equivalent (BAE) dose
Boric acid	H_3BO_3 (1 boron atom)	61.833	1.00
Disodium tetraborate, anhydrous	$Na_2B_4O_7$ (4 boron atoms)	201.22	1.23

Using the conversion factor of 1.23, the nominal concentration of disodium tetraborate a.s. (2.38% w/w) in Boracol_10 3Bd can be converted to its boric-acid equivalent (BAE) concentration (2.93% w/w). Summing this value with the nominal concentration of boric acid a.s. (2.5% w/w) in the product gives a total boric acid/borate equivalent concentration in Boracol 10_3Bd of 5.43% w/w (see the table below).

Boric acid equivalents (BAE) for the boron active substances in Boracol 10_3Bd, and total BAE in the product.

Boron compound	In Boracol 10_3Bd	As boric acid equivalents (BAE)
Boric acid (H_3BO_3)	2.5% w/w	2.5% w/w
Disodium tetraborate, anhydrous ($Na_2B_4O_7$)	2.38% w/w	2.93% w/w
Sum BAE	–	5.43% w/w

2.1.2.4 Information on technical equivalence

The active substances contained in the product are listed in the *Union list of approved active substances* under Regulation (EU) No. 528/2012. No technical equivalence assessment is therefore performed.

2.1.2.5 Information on the substance(s) of concern

Human Health

Boracol 10_3Bd contains 1 substance of concern (SoC) for human health (propan-2-ol (CAS-Nr. 67-63-0) according to Article 3(f) of Regulation (EU) No. 528/2012 (the Biocidal Products Regulation, BPR) and to Commission document *CA-Nov14-Doc.5.11*[2]. See section 3.7.2 of the Confidential Annex for discussion of SoCs. A

[2] Document entitled *Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products*. See also the associated document Annex A: *Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products* (Guidance on the BPR: Volume III Human Health – Assessment & Evaluation (Parts B+C), Dec. 2017).

co-formulant is also considered a SoC if it has known or possible endocrine-distrupting properties; these criteria are not met by any of the co-forumulants in Boracol 10_3Bd (see under the heading *Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)* in Section 2.2.6, and in Section 3.7.3 of the Confidential Annex, for futher information).

Environment

Boracol 10_3bd contains 1 substance of concern for the environment propan-2-ol (CAS-Nr. 67-63-0) according to article 3(f) of Regulation (EU) No. 528/2012, Annex A of the Guidance on the BPR: Volume IV Environment – Assessment & Evaluation, Parts B+C (Version 2.0, October 2017). A co-formulant is considered a SoC if it has known or possible endocrine-distrupting properties. The product does not have endocrine disruption indications based on current scientific knowledge, including available toxicological- and ecotoxicological information. Thus Boracol 10_3Bd is not considered to having endocrine-disrupting properties (see confidential annex section 3.7.3 for full evaluation).

2.1.2.6 Type of formulation

AL – Any other liquid

2.1.3 Hazard and precautionary statements

Classification and labelling of the product according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Skin Irritant 2 Eye Irritant 2
Hazard statement	H315: Causes skin irritation H319: Causes serious eye irritation H412: Harmful to aquatic life with long lasting effects
Labelling	
Signal words	Warning 
Hazard statements	H315: Causes skin irritation H319: Causes serious eye irritation H412: Harmful to aquatic life with long lasting effects
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P264: Wash hands thoroughly after handling. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/face protection.* P302+P352: IF ON SKIN: Wash with plenty of water. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P332 + P313: If skin irritation occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash it before reuse. P501: Dispose of contents/container to … in accordance with local/regional/ national/international regulations (to be specified).
Note	* Only applicable in relation to professional use.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Use #1 – Preventive and curative treatment for wood (Use Class 2) and adjacent masonry – professionals

Product Type	**Wood Preservative (PT8)**	**Product code**
Where relevant, an exact description of the authorised use	Preventive treatment of wood against brown rot fungi. Preventive treatment of wood against mould fungi. Treatment of masonry against mould fungi to prevent adjacent wood from being affected. Treatment of masonry against dry rot fungus *Serpula lacrymans* to prevent adjacent wood from being affected. Curative treatment of wood against mould fungi. Curative treatment of masonry against the dry rot fungus *Serpula lacrymans*. For wood: Use Class 2.	D.30 D.60 D.50 D.50
	<u>Danish restrictions to authorized use</u> <u>Churches, similar buildings, and other buildings worthy of preservation</u>:	

	The product is intended for use in churches, similar buildings, and other buildings worthy of preservation in which people do not work or reside for longer periods of time. Background information In general, the use of wood preservatives indoors in residential areas is not approved in Denmark (in accordance with Statutory Order No. 830 of 30/10/1999 and Article 37 of the EU Biocides Regulation (Regulation EU No. 528/2012)).	
Target organism (including development stage)	Brown rot fungi (*Coniophora puteana*, *Poria placenta*, *Gloeophyllum trabeum*) Dry rot fungus (*Serpula lacrymans*) Mould fungi (*Aspergillus versicolor spp.*, *Cladosporium cladosporioides spp.*, *Penicillium purpurogenum spp.*, *Phoma violacae spp.*, *Rhodotorula rubra spp.*, *Sporolobolomyces roseus spp.*, *Stachybotrys chartarum spp.*, *Ulocladium atrum spp.*)	G.10 G.11 G.21.1 G.21.2 G.22
Field of use	Softwood Masonry adjacent to treated wood Preventive treatment Curative treatment Use Class 2 (for wood) Indoor	B.10 D.40; E.20 D.50 E.20
Application method(s)	Brushing	F.10
Application rate(s) and frequency	200 mL/m^2 (~ 207 g/m^2) Once	
Category(ies) of users	Professionals	A.30
Pack sizes and packaging material	Bottle, HDPE: 1 liter Can, HDPE: 2.5, 5.0, 10, 20 liters Drum, HDPE: 200 liters IBC (intermediate bulk container), HDPE: 1000 liters	

Use #2 – Preventive and curative treatment for wood (Use Class 2) and adjacent masonry – non-professionals

Product Type	**Wood Preservative (PT8)**	**Product code**
Where relevant, an exact description of the authorised use	Preventive treatment of wood against brown rot fungi. Preventive treatment of wood against mould fungi. Treatment of masonry against mould fungi to prevent adjacent wood from being affected. Curative treatment of wood against mould fungi. For wood: Use Class 2.	D.30 D.50

	Danish restrictions to authorized use Churches, similar buildings, and other buildings worthy of preservation: The product is intended for use in churches, similar buildings, and other buildings worthy of preservation in which people do not work or reside for longer periods of time. Background information In general, the use of wood preservatives indoors in residential areas is not approved in Denmark (in accordance with Statutory Order No. 830 of 30/10/1999 and Article 37 of the EU Biocides Regulation (Regulation EU No. 528/2012)).	
Target organism (including development stage)	Brown rot fungi (*Coniophora puteana*, *Poria placenta*, *Gloeophyllum trabeum*) Mould fungi (*Aspergillus versicolor spp.*, *Cladosporium cladosporioides spp.*, *Penicillium purpurogenum spp.*, *Phoma violacae spp.*, *Rhodotorula rubra spp.*, *Sporolobolomyces roseus spp.*, *Stachybotrys chartarum spp.*, *Ulocladium atrum spp.*)	G.10 G.21.1 G.21.2 G.22
Field of use	Softwood Masonry adjacent to treated wood Preventive treatment Curative treatment Use Class 2 (for wood) Indoor	B.10 D.40; E.20 D.50 E.20
Application method(s)	Brushing	F.10
Application rate(s) and frequency	200 mL/m^2 (~ 207 g/m^2) Once	
Category(ies) of users	non-professionals	A.10
Pack sizes and packaging material	Bottle, HDPE: 1 liter Can, HDPE: 2.5, 5.0 liters	

2.1.4.2 Use-specific instructions for use

See general directions for use

2.1.4.3 Use-specific risk mitigation measures

See general directions for use

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use

2.1.5 General directions for use

2.1.5.1 Instructions for use

For *in situ* treatment of indoor/covered wood constructions such as roof trusses, braces, and floor separations. In the case of the dry rot fungus, *Serpula lacrymans*, the product may be applied to masonry to prevent growth of the fungus into adjacent wood.
If infestation by *Serpula lacrymans* is suspected, a professional must be contacted, as thorough measures are required with regard to confirming the identity of the fungus, identifying the extent of fungal infestation in both wood and masonry, as well as any removal and treatment measures taken subsequently.
Stir well before use.
Do not dilute (ready-to-use).
Ensure good ventilation when handling and applying.
Not for use on wood which may come in direct contact with food, animal feed or drinking water.
Do not treat wood that comes in direct contact with soil or water.
Processing conditions: Temperature 5 – 40°C, Relative humidity below 90%.
Brush application: Application rate of 200 mL/m^2 as a single application.
Product losses must be collected and re-use or disposed of as hazardous waste.
The product must not be released to soil, groundwater, surface water or any kind of drain, sewer or rainwater canal.

2.1.5.2 Risk mitigation measures

Read label before use.
Keep out of reach of children
Keep children and pets away from the product and treated wood during application and drying.
Keep away from food, drink, drinking water and animal feed.
Do not apply the product to wood or place treated wood in areas where food or animal feed, food utensils or food processing surfaces may come into contact with, or be contaminated by the product or treated wood.
Do not use on or near surfaces with which livestock can come into contact.
Avoid breathing vapour or mist.
Avoid contact with skin and eyes.
Wash hands after application and use of the product, and before eating, drinking or smoking.
During application and drying exposed ground must be covered and any spillage should be collected.
Product losses must be collected and re-use or disposed of as hazardous waste.
The product must not be released to soil, groundwater, or surface water.
Must not be disposed of in drains, sewers, or rainwater canals.

Can be harmful to protected organisms such as bats, hornets or birds. The presence of protected organisms in the area to be treated must be assessed prior to use of the product. Appropriate protective measures must be taken if necessary.

For the professional user:

Wear protective chemical-resistant gloves during product handling and application, and during eventual handling of treated wood (glove material to be specified by the authorisation holder within the product information).

A coated coverall is required.

Wear a face shield.

The product may only be loaded with an automatic dosing system when transferring from pack sizes larger than 20 litres.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

If medical advice is needed, have product container or label at hand.

Eye contact: Immediately flush with running water.

Skin contact: Immediately remove all contaminated clothing and wash with soap and water.

Ingestion: If swallowed, seek medical advice immediately. Do not induce vomiting.

Inhalation: Remove to fresh air. Keep person warm and at rest. Seek medical attention if symptoms persist.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Packaging, unused product and any product collected during application that is not re-used must be disposed of safely as hazardous waste in accordance with local / regional / national / international regulations.
Must not be disposed of in drains or sewers, including rainwater canals.
Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues.
Do not clean used materials (like brushes, contaminated covers and coveralls) with water, but reuse or discard them in a safe way to dry waste.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Store in a dry, cool well-ventilated area. Protect from frost.

Store only in opaque container.

Store below 40 °C.

The product is stable for two years at room temperature.

Opened containers must be carefully resealed and kept upright to prevent leakage.

Keep out of reach of children.

Store in accordance with local regulations.

Do not store where leakage to the ground or surface water can occur.

Keep away from: oxidizing agents, strong alkalis, and strong acids.

Do not store near food, drink, animal feed or drinking water.

2.1.6 Other information

Use biocides safely. Always read the label and product information before use. Resistance should be monitored on a continuous basis. Should the authorisation holder become aware of reports of resistance this should be reported to the competent authorities.

2.1.7 Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Bottle	1 liter	Plastic: HDPE	Plastic: PP (Child resistant)	Professional Non-professional	Yes
Can/tin	2½, 5 litres	Plastic: HDPE	Plastic: PP (Child resistant)	Professional Non-professional	Yes
Can/tin	10, 20 litres	Plastic: HDPE	Plastic: PP	Professional	Yes
Drum	200 litres	Plastic: HDPE	Plastic: PP	Professional	Yes
IBC (intermediate bulk container)	1000 litres	Plastic: HDPE	Plastic: PP	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

See Annex 1 for complete references.

2.1.8.2 Access to documentation

Letters of Access for all active substances are included in the product dossier.

2.2 Assessment of the biocidal product

2.2.1 Intended use as applied for by the applicant

Intended use #1 – Water-based wood preservative

Product Type(s)	8
Where relevant, an exact description of the authorised use	Wood preservative against mould and wood-destroying fungi in wood For wood and masonry Preventive and curative
Target organism (including development stage)	Wood-destroying fungi and mould fungi
Field of use	Indoor – UC 1 and 2 Ready to use product
Application method(s)	Brush treatment Injection
Application rate(s) and frequency	200 mL/m^2
Category(ies) of user(s)	Professional and non-professional
Pack sizes and packaging material	Please see Section 2.1.7: Packaging of the biocidal product.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 40 °C and 101.3 kPa	Visual inspection	Test substance: Boracol 10_3Bd Min. 990 g/kg (boric acid), min. 990 g/kg (disodium tetraborate, anhydrous) and min. 870 g/kg (didecyldimethylammonium chloride, DDAC) according to supplier.	The product is a liquid.	648104-1 Boracol 10_3Bd acceleratet stabilitetstest
Colour at 40 °C and 101.3 kPa	Visual inspection	Test substance: Boracol 10_3Bd Min. 990 g/kg (boric acid), min. 990 g/kg (disodium tetraborate, anhydrous) and min. 870 g/kg (didecyldimethylammonium chloride, DDAC) according to supplier.	The product is colourless.	648104-1 Boracol 10_3Bd accelerated stabilitetstest
Odour at 40 °C and 101.3 kPa	Olfactory inspection	Test substance: Boracol 10_3Bd Min. 990 g/kg (boric acid), min. 990 g/kg (disodium tetraborate, anhydrous) and min. 870 g/kg (didecyldimethylammonium chloride, DDAC) according to supplier.	The product has a light soapy odour.	648104-1 Boracol 10_3Bd accelerated stabilitetstest

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Acidity / alkalinity	CIPAC Method MT 75	Test substance: Boracol 10_3Bd Min. 990 g/kg (boric acid), min. 990 g/kg (disodium tetraborate, anhydrous) and min. 870 g/kg (didecyldimethylammonium chloride, DDAC) according to supplier.	Two measurements were made of the sample. pH 7.59 at 23°C.	648104-1 Boracol 10_3Bd accelerated stabilitetstest
	CIPAC MT 75.1		pH 7.59 at 20 °	
Relative density / bulk density	SOP-PR-004 analogous to EC 440/2008 A.3. Temperature 20° C.	Test substance: Boracol 10_3Bd Min. 990 g/kg (boric acid), min. 990 g/kg (disodium tetraborate, anhydrous) and min. 870 g/kg (didecyldimethylammonium chloride, DDAC) according to supplier.	1.036 g/mL	Report No.: AQ015-17 BioGenius, 2017
Storage stability test – **accelerated storage**	CIPAC 46.3 The test was conducted in a glass container.	Test substance: Boracol 10_3Bd Min. 990 g/kg (boric acid), min. 990 g/kg (disodium tetraborate, anhydrous) and min. 870 g/kg (didecyldimethylammonium chloride, DDAC) according to supplier.	The stability of the product was tested after storage for 8 weeks at 40 °C. After storage, no sedimentation or separation was seen. Prior to storage a content of boron of 0.97% and a content of DDAC of 2.58% were determined. After storage, a content of boron of 0.97% and a content of DDAC 2.44% were determined. *Variation of boron (after 8 weeks): 0%* *Variation of DDAC (after 8 weeks): -3.2%* After 8 weeks of storage at 40°C, Boracol 10_3Bd is considered stable for all tested parameters. After storage, no change in colour or odour was observed. Viscosity: Before storage at 40 °C: 3.6 cSt and	648104-1 Boracol 10_3Bd accelerated stabilitetstest

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			after storage 5.3 cSt The product should not be stored at temperatures above 40°C. Change in viscosity has no impact on the tox classification considering the formulation of the product and the low viscosity. Please, see tables 2.5 and 2.6 below for additional results and conclusion.	
Storage stability test – **long term storage at ambient temperature**	Storage in a 10 L HDPE bottle for 2 years at 20 °C (September 1st, 2016 to September 3rd, 2018).	Test substance: Boracol 10_3Bd Min. 990 g/kg (boric acid), min. 990 g/kg (disodium tetraborate, anhydrous) and min. 870 g/kg (didecyldimethylammonium chloride, DDAC) according to supplier.	The stability of the product was tested after storage in a 10 L HDPE bottle for two years at 20 °C, 65% relative humidity protected from light. After storage, no change in colour, pH or viscosity was observed. pH: Initial 7.59 at 23°C After storage: 7.65/7.73 at 24°C. Viscosity: Before storage at 20 °C 7.1 cSt after storage 7.8 cSt. Prior to storage a content of boron og 0.90% and a content of DDAC of 2.59% was determined. After storage, a content of boron of 1.00% and a content of DDAC of 2.68% was determine. *Variation of boron: +11.1%* *Variation of DDAC: +3.5%* Please, see tables 2.5 and 2.6 below	Test report. Storage stability of Boracol 10_3Bd. Report no.: 712726-3 (rev. 1)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			for additional results and conclusion.	
Storage stability test – **low temperature stability test for liquids**			Not tested. Therefore, the sentence 'protect from frost' is included on the label.	
Effects on content of the active substance and technical characteristics of the biocidal product – **light**			Not tested. Therefore, the sentence 'Store only in opaque container' is included on the label.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			The product is stable during 8 weeks at 40°C. Humidity is not relevant as the product contains water itself. A sentence is included on the label that the product is not to be stored at temperatures above 40°C.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The product was stable in its commercial packaging HDPE during 2 years at room temperature. No reactivity observed during storage.	
Wettability			Not applicable – Boracol 10_3Bd is a liquid formulation.	
Suspensibility, spontaneity and dispersion stability			Not applicable – Boracol 10_3Bd is a liquid formulation.	
Wet sieve analysis and dry sieve test			Not applicable – Boracol 10_3Bd is a liquid formulation.	
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable – Boracol 10_3Bd is a liquid formulation.	
Disintegration time			Not applicable – Boracol 10_3Bd is a liquid formulation.	
Particle size distribution, content of dust/fines, attrition, friability			Not applicable – Boracol 10_3Bd is a liquid formulation.	
Persistent foaming			Not applicable – Boracol 10_3Bd is a RTU (Ready To Use) liquid formulation.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Flowability/Pourability/Du stability	Not applicable – Boracol 10_3Bd is a liquid formulation		With a viscosity close to water and a product that does not form a film the pourability should not be an issue.	
Burning rate — smoke generators			Not applicable	
Burning completeness — smoke generators			Not applicable	
Composition of smoke — smoke generators			Not applicable	
Spraying pattern — aerosols			Not applicable – Boracol 10_3Bd is a liquid formulation not an aerosol.	
Physical compatibility			Not applicable – Boracol 10_3Bd is not to be used in combination with other products.	
Chemical compatibility			Not applicable – Boracol 10_3Bd is not to be used in combination with other products.	
Degree of dissolution and dilution stability			Not applicable – Boracol 10_3Bd is a RTU (Ready To Use) liquid formulation.	
Surface tension	SOP-PR-043 according to EC 440/ 2008 A.5.		28.3 mN/m	Report No.: AQ015-17 BioGenius, 2017
Viscosity	DS/EN ISO 2431: 2012 "Paints and varnishes - Determination of flow time by use of flow cups"		Accelerated stability study. Before storage at 20°C 7.1 cSt after storage 5.2cSt. Before storage at 40°C: 3.6 cSt and after storage 4.8 cSt.	648104-1 Boracol 10_3Bd accelerated stabilitetstest

Conclusion on the physical, chemical and technical properties of the product
The submitted physic-chemical data for the product Boracol 10_3Bd has been evaluated and are considered acceptable. The roduct is a colorless liquid with a light soapy odour. Neither the accelerated stability study or the 2 years shelf life revealed problematic changes in pH or viscosity. Change in viscosity has no impact on the tox classification considering the formulation of the product and the low viscosity. The product is considered acceptable for 2 years at ambient temperatures, however an additional study has been required to support the shelf life. The following information must be stated on the product label: The product should not be stored at temperatures exceeding 40 °C. To be stated in the label: "Store only in opaque container". **Long-term stability (shelf life)**

According to the GIFAP monograph no. 17, only a 10% deviation of active substance content over the time course of a long-term stability test is accepted. The results from the submitted long-term stability study are listed in Table 2.5 below.

Table 2.5: Long-term (24 months) stability study results (Jensen, T.O. and Klamer, M., 2018). Study conducted on Boracol 10_3Bd.

COMPOSITION ACCORDING TO THE SUBMITTED SPC	T_0	T_{24}	VARIATION $T_0 - T_{24}$ (ACCEPTED VARIATION ACCORDING TO GIFAP NO. 17 ±10%)	VARIATION NOMINAL A.S CONCENTRATION AND T_0 (ACCEPTED VARIATION ACCORDING TO FAO ±15%)
Disodium tetraborate (anhydrous) 2.38% + Boric acid 2,50% converted to Boric Acid Equivalents (BAE) 5.49% ~ 0.96% boron	0.90 % boron	1.00 % boron	+11.1%	-6.25%
Didecyldimethylammonium chloride, DDAC 2.45%	2.59 %	2.68 %	+3.47%	+5.71%

For both compounds, the difference between nominal and measured concentration at T_0 is within the accepted range. The concentration of both boron and DDAC increases over time; the variation in the measured boron concentration slightly exceeding the accepted variation according to GIFAP No. 17 of ±10%. Based on the results presented above, the observed variation in boron concentration over time may partly be explained by analytical variance; the measured concentration at T_0 being 6.25% lower than the nominal concentration while the measured concentration at T_{24} is 4.2% higher than the nominal boron concentration at T_0. The two samples (boron concentration at T_0 and T_{24}, respectively) have been measured at different time points and may, hence, be subject to different analytical circumstances.

Accelerated stability test

The results from the submitted accelerated stability study is listed in table 2.6 below.

Table 2.6: Accelerated (8 weeks) stability study (Morsing E. and Lindegaard B., September 2015). Study conducted on Boracol 10_3Bd.

COMPOSITION ACCORDING TO THE SUBMITTED SPC	T_0	T_8	VARIATION $T_0 - T_8$ (ACCEPTED VARIATION ACCORDING TO GIFAP NO. 17 ±10 %)	VARIATION NOMINEL A.S KONC AND T_0 (ACCEPTED VARIATION ACCORDING TO FAO ±15 %)	VARIATION NOMINEL – T_8

Disodium tetraborate 2.38% + Boric acid 2.50%	0.97 %	0.97 %	0%	0%	0%
N-didecyldimethylammonium chloride (DDAC) 2.45%	2.58 %	2.44 %	-5.4%	3,7%	-0.4%

As can be observed, all variations observed during the accelerated stability test lie within the acceptable range.

The overall conclusion concerning stability of Boracol 10_3Bd is that in principle the variation of the boron content identified in the long-term stability test exceeds the range given in guidance (GIFAP No. 17). Results for DDAC from the long-term stability test are acceptable. Furthermore, the results from the accelerated stability study show acceptable variations in active substance contents concerning both borates and DDAC, and thus, the DK RMS accepts the accelerated stability study. As shown in Table 2.5, the variation of boron content during long-term storage is due to an apparently increasing amount of the active substance. The results may indicate poor study conditions (e.g. evaporation of other product components) and/or analytical variations. Since the deviation from the acceptable variation is only of minor magnitude, and all other measurements during both long-term and accelerated stability studies are within acceptable ranges, the DK CA finds it justified to accept the variation exceeding the range given in guidance. In addition, no risk concerning human toxicity/human health has been identified as a consequence of increased levels of boron.

On this background, the DK CA preliminary accepts the long-term study and a shelf-life claim of two years; however, with a post-authorisation requirement for a new long-term stability study including more data points (taking out additional samples after e.g. 12 and 18 months).

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives			Boracol 10_3BD contains 78 % (w/w) water, a.s. and propane-2-ol, and propane-1,2-diol. None of these substances are classified as explosive, and they do not react under normal circumstances. Based on the high content of water alone explosive properties can be excluded.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Flammable gases			Not applicable – Boracol 10_3Bd is a liquid formulation.	
Flammable aerosols			Not applicable – Boracol 10_3Bd is a liquid formulation not an aerosol.	
Oxidising gases			Not applicable – Boracol 10_3Bd is a liquid formulation.	
Gases under pressure			Not applicable – Boracol 10_3Bd is a liquid formulation.	
Flammable liquids	SOP-PR-034 analogous to EC 440/2008 A.9.		No flashpoint was observed before the test item began to boil (99 – 100°C).	BioGenius report AQ014-17 B10_3Bd, BS flashpoints.
Flammable solids			Not applicable – Boracol 10_3Bd is a liquid formulation.	
Self-reactive substances and mixtures			Not applicable – Boracol 10_3Bd does not contain any self-reactive substances or mixtures.	
Pyrophoric liquids			Not applicable/study scientifically unjustified – Boracol 10_3Bd contains 78% (w/w) water.	
Pyrophoric solids			Not applicable – Boracol 10_3Bd is a liquid formulation.	
Self-heating substances and mixtures			Not applicable – Boracol 10_3Bd does not contain any self-heating substances or mixtures.	
Substances and mixtures which in contact with water emit flammable gases			Not applicable/study scientifically unjustified – Boracol 10_3Bd contains 78% (w/w) water.	
Oxidising liquids			Not applicable/ study scientifically unjustified – Boracol 10_3Bd contains no oxidising substances.	
Oxidising solids			Not applicable – Boracol 10_3Bd is a liquid formulation.	
Organic peroxides			Not applicable – Boracol 10_3Bd does not contain	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			any organic peroxides.	
Corrosive to metals	-		The study to be submitted as a post-authorisation requirement. The study will be submitted in January 2020.	
Auto-ignition temperatures of products (liquids and gases)			The study to be submitted as a post-authorisation requirement. The study will be submitted in January 2020.	
Relative self-ignition temperature for solids			Not applicable – Boracol 10_3Bd is a liquid formulation.	
Dust explosion hazard			Not applicable – Boracol 10_3Bd is a liquid formulation.	

Conclusion on the physical hazards and respective characteristics of the product
The submitted information on physical hazards for the product Boracol 10_3Bd has been evaluated and it is concluded that it does not lead to classification of the product according to the CLP Regulation (EC) No 1272/2008. Studies on corrosiveness to metals and auto-ignition have been requested for submission post-authorisation. Results will be available in January 2020.

2.2.4 Methods for detection and identification

Concerning analytical methods for "monitoring", "soil","air", "water", "animal and human body fluids and tissues" as well as "Analytical methods for monitoring of active substances and residues in food and feeding stuff" reference is made to the analytical methods provided in the CAR's for DDAC and Boric Acid.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Determination of the	Boric acid and Disodium	Fortified at	Linear in the mea	The contribution from	95 – 105%	101 %	3.6% n=5 deter	LOQ = 0.5 µg/mL	DTI report 7406

active substance Boric Acid Equivalents (BAE) in Boracol 10-3Bd, Batch no. 2790: Disodium tetraborate (CAS # 1330-43-4) Boric acid (CAS # 10043-35-3)	tetraborate is determined by analysing for boron by ICP-OES. Calculation of Boric Acid Equivalents (BAE): $H_3BO_3\ w/w\% = (\frac{2{\cdot}38\ \frac{w}{w}}{201{\cdot}22}$ * 4 * $61{\cdot}83\ \frac{g}{mol}$ Method developed by the Danish Technological Institute, The Laboratory for Chemistry and Microbiology	0.96 µg/mL n = 5 determinations Using matrix without component of interest	sured range 5 - 20 µg/mL r^2 = 0.9996 n = 6 calibration standards	the technical materials (matrix without component of interest) to the detection of boron is 0.028 µg/mL (n = 5 determinations) less than 6% of LOQ. The contribution from the method blank is 0.06 µg/mL (n = 5 determinations), less than 12% of LOQ.	n=5 determinations		minations		75 B10_3Bd, BA equivalent content, validation
Determination of the active substance (DDAC) in Boracol 10-3Bd	Guidance on Biocidal Products Regulation. Volume I: Identity/ physico-chemical properties/analytical methodology – Part A. Chapter II. Information Require	Fortified at 1.0% and 2.5%, n=3 for both levels	Linear in the measured range 1800-6750 ng/L r^2 = 0.998 y = 3.0964e^{-4} + 0.0216	The contribution from the technical materials (matrix without component of interest) to the detection of DDAC is less than 4.4% of the	Fortification at 1.0%: 100% to 103.5 % Fortification at 2.5%: 98.8% to 101.8 %	Fortification at 1%: 102 % Fortification at 2.5 %: 101 %	Fortification at 1%: RSD= 2.0% Fortification at 2,5%: RSD= 1.5%	LOD = 96 ng/L LOQ = 320 ng/L, corresponding to a sample content of 0.16 mg/kg.	DTI report 1379321 B10_3Bd, BS DDAC content, validation

	ments. Version 1.1. November 2014. LC-MS/MS method developed by the Danish Technological Institute, DMRI.		n = 5	lowest calibration standard (corre-sponding to 24% of the LOQ). Analysis of a method blank shows a similar contribution to the detection of DDAC (2.2%, or 12% of the LOQ).					

Conclusion on the methods for detection and identification of the product
The analytical information is considered acceptable. Analytical methods for the determination of boron and N-didecyldimethylammonium chloride (DDAC) residues in relevant environmental media (soil, air and water) as well as in animal and human body fluids and tissues were not submitted for the biocidal product since this point is covered by the data set of the active substance. Analytical methods for the determination of active substance residues in/on food or feedstuffs are required if the active substances or the material treated with it is to be used in a manner which may cause contact with food or feedstuffs, or is intended to be placed on, in or near soils in agricultural or horticultural use. The active substances are not intended to be used in an above described manner. The product is intended to be used as wood preservatives. According to label recommendations, the biocidal product is not to be used on wood that will be come in contact with food or feedstuffs. An exposure of the active substances to food and feedstuffs can be excluded when applied according to the recommended use. Therefore analytical methods for determination of active substances in/on food or feeding stuffs are not necessary.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Softwood.
Masonry adjacent to treated wood.
Preventive treatment.
Curative treatment.
Use Class 2.

2.2.5.2 Organisms to be controlled and products, organisms and objects to be protected

Wood rotting fungi

Mould fungi.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Interference with the metabolism of the target organisms.

2.2.5.4 Mode of action, including time delay

Boric acid/borate

The primary mode of action of the borate anion $B(OH)_4^-$ is the interaction with polyols and other macromolecules of biological significance, e.g. co-enzymes (NAD+, NMN+ and NADP+).

In fungi, borate acts by complexation with polyols and probably attacks decay fungi through extracellular substrate sequestration, intracellular substrate sequestration, enzyme inhibition, and change in membrane function (*The Probable Mechanisms Of Action of Boric Acid and Borates As Wood Preservatives* by JD Lloyd, DJ Dickinson & RJ Murphy, Imperial College of Science, Technology & Medicine Department of Biology, London, England. Paper presented to The International Research Group On Wood Preservation in the Working Group on Biological Problems at the twenty-first annual meeting, May 1990).

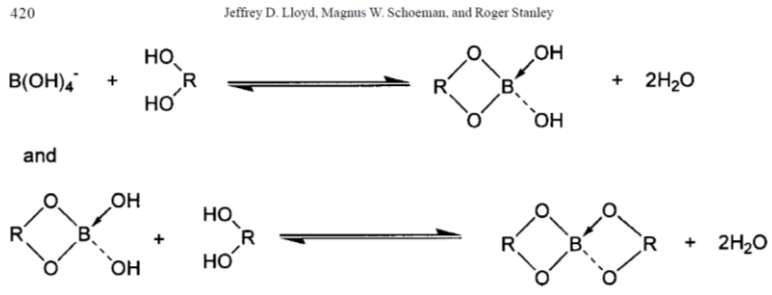


Figure 1. Chelate complex reactions of borate anion (shown) with oxidized co-enzymes probably lead to the biostatic effects of borate through metabolic inhibition.

N.B. complexes are negatively charged and are further stabilized with cationic polyols

(*REMEDIAL TIMBER TREATMENT WITH BORATES* by JD Lloyd, MS Schoeman & RS Stanley (1999), Borax Europe Ltd., 170 Priestley Road, Guildford GU1 4QT United Kingdom)

In insects, borate acts as a slow-acting poison, disrupts metabolic pathways.

There is no time delay for the toxic effect, though toxicity has gradual onset (sub-acute). No resistance is expected.

<u>DDAC</u>

The CAR (IT CA, 2015) provides the following information. DDAC is a cationic surfactant-type active substance. Its interaction with phospholipid-bilayer structures severely alters cell-wall permeability, disturbs membrane-bound ion translocation mechanisms and may facilitate the uptake of other biocides. DDAC acts as a wood preservative by preventing the growth of organisms as opposed to killing organisms that are present. This mechanism reduces the potential for resistant organisms to develop. There are no reports of selective acquisition of DDAC-resistance in the field of wood protection.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism (s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Determination of the prot	Preventive treatment	Boracol 10_3Bd	*Coniophora puteana*, *Poria placenta*,	EN 839 + EN 73	Scots pine, sapwood 200 mL/ m^2	No decay	648112-1 Boracol 10_3Bd

ective effectiveness against wood destroying basidiomycetes – Application by surface treatment	against brown rot fungi on wood in use class 2		*Gloeophyllum trabeum*				EN839 This report has been evaluated by the FCBA; see *FCBA Efficacy AR no. 401/18/042Z (22.05.2018) for Boracol 10_3Bd*)
Determination of the protective effectiveness of a preservative treatment against blue stain in wood in service - laboratory	Preventive efficacy against blue-stain in wood in use class 2	Boracol 10_3Bd	*Aureobasidium pullulans*. P 268 and *Sydowia pithyophila*. S 231	EN152+EN73	Scots pine, sapwood 200 mL/m2	Blue stain on surface (Average): 0 Smallest depth of blue stain-free zone – (mm): 0,5 Mean depth of blue stain-free zone – (mm): 1,0	628367-1 Boracol 10_3Bd EN 152+EN73 This report has been evaluated by the FCBA; see *FCBA Efficacy AR*

<table>
<tr>
<td>method</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>no. 401/18/042Z (22.05.2018) for Boracol 10_3Bd)</td>
</tr>
<tr>
<td>Boracol 10_3Bd’s efficacy as curative treatment of mould growth on painted wood surfaces</td>
<td>Curative efficacy against moulds on painted wood surfaces in use class 2</td>
<td>Boracol 10_3Bd</td>
<td>Aspergillus versicolor, IMI 45554
Aureobasidium pullulans, IMI 45533
Cladosporium cladosporioides, IMI 178517
Penicillium purpurogenum, IMI 178519
Phoma violaceae, IMI 49948ii
Rhodotorula rubra, NCYC 1659
Sporobolomyces roseus,</td>
<td>Modification of BS 3900 Part G6: 1989 Assessment of resistance to fungal growth.</td>
<td>Painted specimens of scots pine

200g/m2</td>
<td>
<table>
<tr><td colspan="3">MycoMeter® analysis</td><td colspan="3">CFU on V8-agar</td></tr>
<tr><td>Before treatment</td><td>24 hours after treatment</td><td>1 month after treatment</td><td>Before treatment</td><td>1 hour after treatment</td><td>24 hours after treatment</td></tr>
<tr><td>3629 Cat. C</td><td>462 Cat. C</td><td>101 Cat. B</td><td>>>300</td><td>~40</td><td>~20</td></tr>
</table>
One hour after treatment there is a clear reduction in CFU on V8-agar. After 24 hours there is no increase in CFU, which remains at the same level.
After 24 hours the results of the MycoMeter®analysis is clearly reduced to a value between category B and C. One month after treatment with Boracol 10 3Bd the MycoMeter®analysis is further reduced to moderate category B.
<u>The results indicate that Boracol 10_3Bd has a good curative effect on painted wood surfaces infected with mould fungi.</u>

The MycoMeter®-test is based on the detection and quantification of an enzyme that is present in both mycelium and spores of most fungi. The results of MycoMeter-analysis are divided into the following three categories:
The MycoMeter®values are divided into the following three categories:
A
MycoMeter®value ≤ 25
The level of mould is not above normal background level
B
25< MycoMeter®value ≤ 450
The level of mould is above the normal background level. This is typically due to high concentration of spores in dust deposits but may
</td>
<td>648118-1 Boracol 10_3Bd BS3900 painted surface

This report has been evaluated by the FCBA; see FCBA Efficacy AR no. 401/18/042Z (22.05.2018) for Boracol 10_3Bd)</td>
</tr>
</table>

<table>
<tr>
<td></td><td></td><td></td><td>NCYC 717 Stachybotrys chartarum, IMI 82021 Ulocladium atrum, IMI 7990</td><td></td><td></td><td>in some cases indicate the presence of an old damage (mould growth)
C
MycoMeter®value > 450
The level of mould is high above normal background level due to mould growth.</td><td></td>
</tr>
<tr>
<td>Boracol 10_3Bd's efficacy as preventive treatment of mould growth on Scots pine and Gypsum</td>
<td>Preventive efficacy against moulds on wood and masonry in use class 2</td>
<td>Boracol 10_3Bd</td>
<td>Aspergillus versicolor, IMI 45554 Aureobasidium pullulans, IMI 45533 Cladosporium cladosporioides, IMI 178517 Penicillium purpurogenum, IMI 178519 Phoma violaceae, IMI 49948ii Rhodotorula rubra, NCYC 1659 Sporobolomyces</td>
<td>BS 3900 Part G6: 1989 Assessment of resistance to fungal growth</td>
<td>Scots pine and Gypsum 200g/m2</td>
<td>
<table>
<tr><th>Material</th><th>Application rate</th><th>Rating after 4 weeks incubation</th><th>Rating after 6 weeks incubation</th><th>Rating after 12 weeks incubation</th></tr>
<tr><td>Scots pine</td><td>200 g/m^2</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Gypsum</td><td>200 g/m^2</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Reference Scots Pine</td><td></td><td>5</td><td>5</td><td>5</td></tr>
<tr><td>Reference Gypsum</td><td></td><td>5</td><td>5</td><td>5</td></tr>
</table>
Rating after 12 weeks incubation for wood: 0 = No growth
Rating after 12 weeks incubation for Gypsum: 0 = No growth

<table>
<tr><th colspan="2">Rating scale for assessment of fungal growth</th></tr>
<tr><th>Rating</th><th>Appearance</th></tr>
<tr><td>0</td><td>No growth</td></tr>
<tr><td>1</td><td>Trace of growth of up to 1% coverage of the test inoculated area</td></tr>
<tr><td>2</td><td>Growth more than 1% up to 10% coverage of test inoculated area</td></tr>
<tr><td>3</td><td>Growth more than 10% up to 30% coverage of test inoculated area</td></tr>
<tr><td>4</td><td>Growth more than 30% up to 70 % coverage of test inoculated area</td></tr>
</table>
</td>
<td>648118-2 Boracol 10_3Bd BS3900 Preliminary report

648118-3 Boracol 10_3Bd BS3900 final pine and gypsum

These reports have been evaluated by the FCBA; see FCBA Efficacy</td>
</tr>
</table>

			roseus, NCYC 717 *Stachybotrys chartarum*, IMI 82021 *Ulocladium atrum*, IMI 7990			5 Growth more than 70% coverage of test inoculated area	*AR no. 401/18/042Z (22.05.2018) for Boracol 10_3Bd*)
Determination of the preventive efficacy against *Serpula Lacrymans* – Application by surface treatment	Preventive efficacy against dry rot fungi on wood in use class 2	Boracol 10_3Bd	*Serpula lacrymans*	EN 839 + EN 73 ENV 12404	Scots pine, sapwood 200 mL/m2	No decay	735381-4_EN839 - Boracol 10_3Bd This report has been evaluated by the FCBA; see *FCBA Efficacy AR no. 401/18/042Z (22.05.2018) for Boracol 10_3Bd*)
Assessment of the	Preventive and Cur	Boracol 10_	*Serpula lacrymans*	DS/CEN/TS 12404,	Mortar 200 mL/m2	All Application rates (g/m^2) (500, 300 and 200) mortar test specimen = 0 No. of replicates with rating >1. Untreated mortar specimen = 10 No. of replicates with rating >1.	735381-2 - Boracol

effectiveness of a masonry fungicide to prevent growth into wood of Dry Rot *Serpula lacrymans*	active treatment against the dry rot fungus on masonry in use class 2	3Bd		2015: Durability of wood and wood-based products		All untreated mortar species have a rating of 2.	10_3Bd Mortar DS1240 4 This report has been evaluated by the FCBA; see *FCBA Efficacy AR no. 401/18/042Z (22.05.2018) for Boracol 10_3Bd*)

Conclusion on the efficacy of the product
The test reports for Boracol 10_3Bd support the following efficacy claims when the product is applied indoors (for wood: Use Class 2) at a rate of 200 mL/m^2: <u>Preventive treatment</u> of: - wood against wood brown rot fungi - wood against mould fungi - masonry against dry rot fungus *Serpula lacrymans* to prevent adjacent wood from being affected. - masonry against mould fungi to prevent adjacent wood from being affected. <u>Curative treatment</u> of: - treatment of wood against mould fungi - masonry against the dry rot fungus *Serpula lacrymans*. The full Efficacy Assessment is found in Appendix 2. * The *Conclusions* section of the Efficacy Assessment states an application rate of 200 – 220 g/m², however, studies used an application rate of 200 g/m² or

200 mL/m²; at a relative product density of 1.036 g/cm³ the latter is equivalent to 207.2 g/m². Consequently, an application rate of 200 mL/m² (the higher rate used in some of the studies) will be effective for all claims.

2.2.5.6 Evaluation of the label claims

The applicant of Boracol 10_3Bd have sought the following label claims:

Preventive treatment of:
- wood against wood brown rot fungi
- wood against blue stain fungi
- wood against mould fungi
- masonry against the dry rot fungus *Serpula lacrymans*
- masonry against mould fungi

Curative treatment of:
- treatment of wood against mould fungi
- masonry against the dry rot fungus *Serpula lacrymans*.

Based on the available documentation, the DK CA assessed that the product Boracol 10_3Bd have shown sufficient efficacy for preservation of wood used by professional and non-professional users:

- For the preventive efficacy of the product when used by superficial application on wood in use class 2 against brown rot fungi.
- For the preventive efficacy of the product when used by superficial application on wood in use class 2 against mould fungi.
- For the preventive efficacy of the product used by superficial application on masonry in use class 2 against mould fungi and the dry rot fungus *Serpula lacrymans*
- For the curative efficacy of the product when used by superficial application on wood in use class 2 against mould fungi.
- For the curative efficacy of the product when used by superficial application on masonry in use class 2 against the dry rot fungus *Serpula lacrymans*

The application rate validated is 200 mL/m^2 against all target organism.
Note that the claim for preventive treatment of wood against blue stain fungi was not validated, as the efficacy was not demonstrated in the submitted documentation.

2.2.6 Risk assessment for human health

The toxicology of the active substances boric acid, disodium tetraborate, anhydrous and didecyldimethyl-ammonium chloride (DDAC) was examined according to the standard requirements under the *Biocidal Products Directive (BPD) 98/8/EC*. The toxicological properties of the active substances are summarized in their respective Competent Authority Report (CAR):

- Boric acid – RMS Netherlands (February 2009)
- Disodium tetraborate – RMS Netherlands (February 2009)
- Didecyldimethylammonium chloride – RMS Italy (June 2015)

Boracol 10_3Bd is not sufficiently similar to any of the model products for the active substances to permit their use as reference products in this application (see *Annex I of Directive 98/8/EC*). No toxicity studies of Boracol 10_3Bd have been conducted. The requirement for such studies can be waived, with reference to the *Guidance on the Biocidal Products Regulation: Volume III Human Health, Part A (Information Requirements)*[3], on the basis that there is sufficient toxicological data on the active substances and co-formulants to allow classification of Boracol 10_3Bd according to *Regulation (EC) No 1272/2008 (CLP)*, and no synergistic effects between any of the components are expected.

According to the requirements of *Regulation (EC) No 1272/2008*, Boracol 10_3Bd should be classified for skin irritation (Skin Irrit. 2, H315) and serious eye irritation (Eye Irrit. 2, H319).

Boric acid and disodium tetraborate, anhydrous are classified for reproductive toxicity (Repr. 1B, H360FD: May damage fertility. May damage the unborn child)[4]. Boric acid has a Specific Concentration Limit (SCL) of ≥ 5.5% and disodium tetraborate, anhydrous has a SCL of ≥ 4.5% (see Annex VI (ATP10) of *Regulation (EC) No 1272/2008*). As noted in 2.1.2.3 *Qualitative and quantitative information on the biocidal product*, Boracol 10_3Bd can be considered to contain boric acid/borate/diverse ion-pair complexes at a total concentration equivalent to the sum of the concentration of boric acid active substance (2.5% w/w) plus the concentration of disodium tetraborate active substance after conversion of the latter to the boric-acid equivalent (BAE) concentration (2.93% w/w). Thus the concentration of boric acid/borate in the product (2.5% + 2.93% = 5.43%) is

[3] Guidance on the BPR: Volume III. Part A. "*Testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in* Directive 1999/45/EC *and* Regulation (EC) No 1272/2008 (CLP)*, and synergistic effects between any of the components are not expected.*"

[4] The CAR for boric acid (NL CA, 2009) and disodium tetraborate (NL CA, 2009) present the flowing information under the heading *Fertility*: "*In a multigeneration reproduction toxicity study in the rat with boric acid severely impaired reproductive potency was observed at 336 mg/kg bw/day. At this dose also marked reductions (70 %) in relative testes weights were observed. At lower doses no reproductive effects or effects on testes weight were observed. These findings suggest that a reduction in testes weight will result in an impaired fertility. Since this study was seriously flawed, no definitive conclusions on the effects of boron on fertility in the rat can be drawn. Other repeated dose studies in several animal species have consistently demonstrated that the testis is a primary target organ for boron. Based on the data from the 2 years feeding study with boric acid in rats, the overall NOAEL for fertility is therefore 100 mg/kg bw/day, equal to 17.5 mg B/kg bw/day. This conclusion is supported by the study with disodium tetraborate decahydrate.*"

below the SCL of 5.5% for boric acid, and the product does not require classification for reproductive toxicity.

Background information

CA SE submitted (Nov. 2018) a CLH report (Proposal for Harmonised Classification and Labelling) proposing reclassification of a number of boron compounds, including boric acid and disodium tetraborate, anhydrous. It is proposed that the Generic Concentration Limit (GCL) of 0.3% for substances classified Repr. 1A og 1B should be applied to the borates in question. If implemented, this proposal would, according to Article 5 of the BPR (Directive 528/2012), preclude use of the product by non-professionals. The proposal is scheduled to be considered by RAC (Risk Assessment Committee, ECHA) in September 2019. At its meeting of 16.09.2019, RAC was in favour of the proposal ('Opinion adopted').

The active substances in Boracol 10_3Bd (boric acid, disodium tetraborate, and didecyldimethylammonium chloride (DDAC) are currently not considered[5] to have endocrine-disrupting (ED) properties according to *Regulation (EU) 528/2012*. They have not been assessed according to the new ED criteria (*Commission Delegated Regulation* (EU) 2017/2100). Current guidance for application of these criteria (*CA March18 Doc.7.3b-final*, paragraph 19)[6] specifies that the evaluating body should not evaluate endocrine-disrupting properties nor request additional data on ED properties of active substances in the context of product authorisation procedures.

2.2.6.1 Assessment of effects on human health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Boracol 10_3Bd is to be classified for skin irritation.
Justification for the value/conclusion	No skin corrosion or skin irritation studies of Boracol 10_3Bd have been conducted. Testing of the active substances boric acid and disodium tetraborate revealed no skin corrosion or skin irritation potential, whereas DDAC is classified Skin Corr. 1, H314 (no SCL). The concentration (2.45%) of DDAC in the product is above the GCL (C ≥ 1%) for this end-point. None of the co-formulants are classified for skin corrosion or skin irritation. The skin corrosion potential of the product is determined as follows: H314 = ∑[(H314)] = 2.45%.

5 The CARs for boric acid and disodium tetraborate do not address potential endocrine-disrupting (ED) properties in relation to human health. In relation to the environment, the only reference (p. 16) to ED is: *"The chronic NOEC of boron for marine or freshwater organisms is > 0.01 mg B/L and boron is not considered to have endocrine disrupting effects*". The CAR (PT8) for DDAC states (pp. 46-47): "*Based on available experimental results, there is no indication that DDAC affects the endocrine system. Structural characteristics and SAR do not hint to possible effects of DDAC as endocrine disruptor."* This is true for both human health and the environment.

6 Document *The implementation of scientific criteria for the determination of endocrine-disrupting properties in the content of biocidal product authorisation* (CA-March18-Doc.7.3.b-final).

	This value below the concentration limit (C ≥ 5%) trigger classification for skin corrosion. (The concentration (2.45%) of DDAC in the product is below the cut-off limit (C ≥ 3%) for naming on the label in relation to H314.) The skin irritation potential of the product is determined as follows: H315 = ∑[(H314 x 10) + (H315)] = ∑[(2.45 x 10) + (0)] = 24.5%. This value is above the concentration limit (C ≥ 10%) triggering classification for skin irritation. Note: The skin corrosion classification of DDAC is considered when classifying the product for eye damage/irritation.
Classification of the product according to CLP and DSD	Classification for Skin Irrit. 2, H315 is required according to Regulation (EC) No 1272/2008.

Data waiving	
Information requirement	Studies not justified. Skin corrosion and skin irritation studies are not an information requirement for biocidal products according to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements) Chapter III. 8.1 Skin irritation or skin corrosion* (version 1.1, Nov. 2014) if there are valid data available on each of the components that is sufficient to allow classification of the product/mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and no synergistic effects between the any of the components are expected.
Justification	Testing of Boracol 10_3Bd for skin corrosion and skin irritation is not required as there is sufficient toxicological data on its active substances and co-formulants to allow classification of the product according to Regulation (EC) No 1272/2008, and no synergistic effects between the any of the components are expected.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Boracol 10_3Bd is to be classified for eye irritation.
Justification for the value/conclusion	No eye irritation studies of Boracol 10_3Bd have been conducted. Testing of the active substances boric acid and disodium tetraborate revealed no eye irritation potential. DDAC is classified Skin Corr. 1, H314 (no SCL), which should be considered when classifying the product for eye irritation. The concentration (2.45%) of DDAC in the product is above the GCL (C ≥ 1%) for this end-point. One co-formulant is classified Eye Dam. 1, H318 and Eye Irrit. 2, H319, and a second co-formulant is classified Eye Irrit. 2, H319, though as their concentrations in the product are below the respective GCL or SCL for the classified hazards they do not need to be considered here. The eye damage potential of the product is determined as follows: H318 = ∑[(H314) + (H318)] = ∑[(2.45) + (0)] = 2.45%. This value is below the concentration limit (C ≥ 3%) trigger classification for eye damage. The eye irritation potential of the product is determined as follows: H319 = ∑[(H314 x 10) + (H318 x 10) + (H319)] = ∑[(2.45 x 10) + (0) + (0)] = 24.5%.

	This value is above the concentration limit (C ≥ 10%) triggering classification for eye irritation.
Classification of the product according to CLP and DSD	Classification for Eye Irrit. 2, H319 is required according to Regulation (EC) No 1272/2008.

Data waiving	
Information requirement	Studies not justified. Eye irritation studies are not an information requirement for biocidal products according to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements), Chapter III. 8.2 Eye irritation* (version 1.1, Nov. 2014) if there are valid data available on each of the components that is sufficient to allow classification of the product/mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and no synergistic effects between the any of the components are expected.
Justification	Testing of Boracol 10_3Bd for eye irritation is not required as there is sufficient toxicological data on its active substances and co-formulants to allow classification of the product according to Regulation (EC) No 1272/2008, and no synergistic effects between the any of the components are expected.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not a respiratory tract irritant.
Justification for the value/conclusion	No respiratory tract irritation studies with Boracol 10_3Bd have been conducted. Testing of the active substances boric acid, disodium tetraborate, and DDAC did not reveal any respiratory tract irritation potential and none of co-formulant are classified for respiratory tract irritation.
Classification of the product according to CLP and DSD	Classification for respiratory tract irritation is not required according to Regulation (EC) No 1272/2008.

Data waiving	
Information requirement	Not part of the core data set. Studies not justified. Respiratory tract irritation studies are not an information requirement for biocidal products according to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements), Chapter III* (version 1.1, Nov. 2014).
Justification	Testing of Boracol 10_3Bd for respiratory tract irritation is not required as there is sufficient toxicological data on its active substances and co-formulants to allow classification of the product according to Regulation (EC) No 1272/2008, and no synergistic effects between the any of the components are expected.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitization	
Value/conclusion	Not a skin sensitizer.
Justification for the value/conclusion	No skin sensitization studies with Boracol 10_3Bd have been conducted. Testing of the active substances boric acid, disodium tetraborate, and DDAC did not reveal any skin sensitization and none of co-formulant are classified for skin sensitization.
Classification of the product according to CLP and DSD	Classification for skin sensitization is not required according to Regulation (EC) No 1272/2008.

Data waiving	
Information requirement	Studies not justified. Skin sensitization studies are not an information requirement for biocidal products according to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements), Chapter III. 8.3 Skin sensitization* (version 1.1, Nov. 2014) if there are valid data available on each of the components that is sufficient to allow classification of the product/mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and no synergistic effects between the any of the components are expected.
Justification	Testing of Boracol 10_3Bd for skin sensitization is not required as there is sufficient toxicological data on its active substances and co-formulants to allow classification of the product according to Regulation (EC) No 1272/2008, and no synergistic effects between the any of the components are expected.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitization	
Value/conclusion	Not a respiratory sensitizer.
Justification for the value/ conclusion	No respiratory sensitization studies with Boracol 10_3Bd have been conducted. Testing of the active substances boric acid, disodium tetraborate, and DDAC did not reveal any respiratory sensitization and none of co-formulant are classified for respiratory sensitization.
Classification of the product according to CLP and DSD	Classification for respiratory sensitization is not required according to Regulation (EC) No 1272/2008.

Data waiving	
Information requirement	Not part of the core data set. Studies not justified. Respiratory sensitization studies are not an information requirement for biocidal products according to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements), Chapter III. 8.4 Respiratory sensitization* (version 1.1, Nov. 2014) if there are valid data available on each of the components that is sufficient to allow classification of the product/mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and no synergistic effects between the any of the components are expected.
Justification	Testing of Boracol 10_3Bd for respiratory sensitization is not required as there is sufficient toxicological data on its active substances and co-formulants to allow classification of the product according to Regulation (EC) No 1272/2008, and no synergistic effects between the any of the components are expected.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route – value > 2000 mg/kg bw.
Justification for the selected value	No acute oral toxicity studies of Boracol 10_3Bd have been conducted. Testing of the active substances boric acid and disodium tetraborate revealed no acute oral toxicity, while DDAC is classified Acute Tox. 4, H302 (no SCL). The LD_{50} for DDAC is 329 mg/kg bw. One co-formulant is classified Acute Tox. 4, H303, though as its concentration in the product is below the GCL (C ≥ 1%) for this end-point it does not need to be

	considered here. As the product contains a single component classified for acute toxicity, the estimated acute oral toxicity of the product is calculated as follows: $ATE_{mix} = 100/(C_i/ATE_i)^n = 100/(2.45\%/329 \text{ mg/kg bw}) = 13{,}333 \text{ mg/kg bw}$ 13,333 mg/kg bw is above the 2000 mg/kg bw cut-off for acute oral toxicity, thus no classification for acute oral toxicity is required.
Classification of the product according to CLP and DSD	Classification for acute oral toxicity is not required according to Regulation (EC) No 1272/2008.

Data waiving	
Information requirement	Studies not justified. Acute oral toxicity studies are not an information requirement for biocidal products according to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements)* and *Chapter III. 8.5.1 Acute oral toxicity* (version 1.1, Nov. 2014) if there are valid data available on each of the components that is sufficient to allow classification of the product/mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and no synergistic effects between the any of the components are expected.
Justification	Testing of Boracol 10_3Bd for acute oral toxicity is not required as there is sufficient toxicological data on its active substances and co-formulants to allow classification of the product according to Regulation (EC) No 1272/2008, and no synergistic effects between the any of the components are expected.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route – value >20 mg/L/4t for vapour.
Justification for the selected value	No acute inhalation toxicity studies of Boracol 10_3Bd have been conducted. Testing of the active substances boric acid, disodium tetraborate, and DDAC revealed no acute inhalation toxicity. None of the co-formulants are classified for acute inhalation toxicity. Thus the acute inhalation toxicity of the product is estimated to be >20 mg/L/4t (cut-off value for acute inhalation toxicity for vapours).
Classification of the product according to CLP and DSD	Classification for acute inhalation toxicity is not required according to Regulation (EC) No 1272/2008.

Data waiving	
Information requirement	Studies not justified. Acute inhalation toxicity studies are not an information requirement for biocidal products according to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements), Chapter III. 8.5.2 Acute inhalation toxicity* (version 1.1, Nov. 2014) if there are valid data available on each of the components that is sufficient to allow classification of the product/mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and no synergistic effects between the any of the components are expected.
Justification	Testing of Boracol 10_3Bd for acute inhalation toxicity is not required as there is sufficient toxicological data on its active substances and co-formulants to allow classification of the product according to Regulation (EC) No 1272/2008, and no synergistic effects between the any of the components are expected.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route – value >2000 mg/kg bw.

Justification for the selected value	No acute dermal toxicity studies of Boracol 10_3Bd have been conducted. Testing of the active substances boric acid, disodium tetraborate, and DDAC revealed no acute dermal toxicity. None of the co-formulants are classified for acute dermal toxicity. Thus the acute dermal toxicity of the product is estimated to be >2000 mg/kg bw (cut-off value for acute dermal toxicity).
Classification of the product according to CLP and DSD	Classification for acute dermal toxicity is not required according to Regulation (EC) No 1272/2008.

Data waiving	
Information requirement	Studies not justified. Acute dermal toxicity studies are not an information requirement for biocidal products according to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements), Chapter III. 8.5.3 Acute dermal toxicity* (version 1.1, Nov. 2014) if there are valid data available on each of the components that is sufficient to allow classification of the product/mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and no synergistic effects between the any of the components are expected.
Justification	Testing of Boracol 10_3Bd for acute dermal toxicity is not required as there is sufficient toxicological data on its active substances and co-formulants to allow classification of the product according to Regulation (EC) No 1272/2008, and no synergistic effects between the any of the components are expected.

Information on dermal absorption

Document *CA-July13-Doc.6.2.b* describes the preferred, step-wise approach for identifying the most appropriate dermal absorption value(s) for use during assessment of exposure to the active substance(s) in a biocidal product. The document refers to EFSA's 2012 *Guidance on Dermal Absorption*[7]. The first choice source of data is a dermal absorption study for the biocidal product. This is not an option for Boracol 10_3Bd as no relevant studies have been made. In the absence of product-specific dermal absorption data, read-across to a reference product(s) in the CAR for the active substance(s) should be considered. This also is not an option for Boracol 10_ 3Bd as its qualitative and quantitative composition differs from the reference product(s) in the CARs (NL CA, 2009) for boric acid and disodium tetraborate anhydrous to an extent that read-across is not permissible according to EFSA (2012, 2017).

As an alternative to read across, document *CA-July13-Doc.6.2.b* proposes using the EFSA (2012) guidance to select a default value for dermal absorption. If Boracol 10_3Bd is considered a solution of boric acid/borate with boric-acid equivalent (BAE) concentration of 5.49% w/w[8], the product is categorised as a concentrate/concentrated solution according to EFSA (2012, 2017), and as it is water-based formulation the appropriate dermal absorption value is 25% (EFSA 2012) or 10% (EFSA 2017)[9]. However, Boracol 10_3Bd contains 2.45% w/w of the active substance DDAC (classified for skin corrosion (H314), and while this level of DDAC does not trigger classification of the product for skin irritation it could potentially influence (enhance) the absorption of boric acid/borate from the

7 EFSA Journal 2012; 10(4): 2665. Updated: EFSA Journal 2017; 15(6): 4873.

8 See 2.1.2.3 *Qualitative and quantitative information on the composition of the biocidal product.*

9 Either guidance can be used, as the application was received December 2017.

product. In addition; Boracol 10_3Bd contains co-formulants (~ 13.5%)[10] that are not classified for skin- corrosion or irritation but which could potentially enhance the absorption of boric acid/borate from the product by other mechanisms, although this is considered unlikely[11].

An alternative to using a default value for dermal absorption of boric acid/borate from Boracol 10_3Bd is to apply expert judgement to identify a reasonable worst-case value for dermal absorption. This approach has previously been taken for a product containing boric acid and disodium tetraborate, pentahydrate authorised for use in PT8. In the absence of specific data on dermal absorption for the product, inapplicability of read-across to a model product, and no validated methods available for quantitative prediction of the effect of penetration enhancers, the RMS (DE CA) used expert judgement[12] to identify a worst-case estimate for dermal absorption of 20%. The approach was subsequently taken for a product (Boracol 20), authorised for use in PT8 (RMS DK CA), containing the active substance disodium octaborate, tetrahydrate (DOT)[13] and a co-formulant that may enhance skin penetration. In relation to the former product, DE CA subsequently noted that derivation of the value of 20% was not in accordance with guidance current at the time of authorisation[14], but that the issue had been discussed at several Co-ordination Group meetings and was accepted by Member States and the Commission. The information of 'particular relevance' for the expert judgement for the above products is considered applicable to Boracol 10_3Bd. Selection of a default dermal absorption value of 20% for boric acid/borate from Boracol 10_3Bd gives a safety factor of 40 compared to the value of 0.5% considered a "*reasonable worst case*" in the CARs for boric acid and disodium tetraborate (NL CA, 2009).

---

10 See 3.7.1 *Product composition and formulation* of the Confidential Annex for further details.

11 See 3.7.2 *Information on the Substances of Concern* of the Confidential Annex for further details.

12 The expert judgement took into account all available information and in particular: i) a total dermal delivery of 25 ± 16% for the finite dose group with 5% boric acid in an in vitro dermal absorption study, representing a conservative estimate for 5% boric acid in water due to long exposure time (24 hours) and inclusion of outermost layers of stratum corneum; ii) an *in vivo* dermal absorption study in humans evaluated as "not reliable" during the Annex I inclusion procedure: When correcting for variability and loss of material (approx. 10% of the applied dose was available for absorption), a worst-case estimate of 5% can be proposed for 5% boric acid, 5% borax and 10% DOT; iii) an up to 34-fold increase of urinary boron excreted with damaged skin compared to intact skin (24 - 33% of the applied dose) reported for a 2.5% boric acid hydrogel containing 10% methyl cellulose and water in rats: It can be expected that skin absorption from a product in the presence of penetration enhancers will not be higher than absorption under damaged skin conditions; iv) a 7-fold enhancement of *in vitro* skin permeation measured over 12 hours of the glycoside Scutellarin by ethanolamin, and other observations of skin penetration enhancement by ethanolamine; and v) defaults values of 25% and 75% for dermal absorption recommended by EFSA (2012) for plant protection products containing > 5% or ≤5% a.s., respectively. The worst-case estimate for dermal absorption of 20% was obtained by multiplying (and rounding-up) the value of 0.5% for dermal absorption in the CAR (NA CA, 2009) for boric acid (also applicable to disodium tetraborate and DOT) by the 34-fold degree of enhancement seen with damaged skin (and considered to cover the maximum degree of enhancement due to the presence of skin penetration enhancers).

13 According to the CAR (NL CA, 2009), disodium octaborate tetrahydrate (DOT) can be expected to dissociate to boric acid/borate on dissolution in water.

14 EFSA Guidance on Dermal Absorption (2012); OECD Guidance Notes on Dermal Absorption (2011).

In conclusion, for consistency in relation to authorised biocidal products formulated with boric acid and disodium tetraborate (pentahydrate) or with DOT, and with co-formulants other than water, a dermal absorption value of 20% is proposed for use in the exposure assessments for Boracol 10_3Bd. However, the appropriateness of this value should be reviewed at the time of renewal of the authorization for Boracol 10_3Bd.

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	**Boric acid Disodium tetraborate, anhydrous**	**Didecyldimethylammonium chloride (DDAC)**
Value(s)*	20%	100%
Justification for the selected value(s)	No dermal absorption studies with Boracol 10_3Bd have been conducted. Please see the text above for discussion of an appropriate value for the dermal absorption of boric acid and disodium tetraborate.	No dermal absorption studies with Boracol 10_3Bd have been conducted. The dermal absorption of DDAC was discussed at at WG-II-2015[1]. It was concluded that as an estimated worst-case dermal absorption of DDAC is limited to ~ 10% at non-irritant concentrations, and that a value of 100% is assumed at and above irritant concentrations. Boracol 10_3Bd is classified as Skin Irrit. 2: H315. As no systemic risk characterization will be performed for DDAC, no dermal absorption value for DDAC in the product will be set.

[1] WGII2015_TOX_6.2_DDAC_QUATs_agreements.

Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)

Boracol 10_3Bd contains 1 substance of concern (SoC) for human health (propan-2-ol (CAS-Nr. 67-63-0); see section 3.7.2 of the Confidential Annex for discussion of SoCs.

A co-formulant is considered a SoC if it has known or possible endocrine-distrupting (ED) properties. The guidance for application of ED criteria (*CA March18 Doc.7.3b-final*[15]) notes that: "Evaluating bodies have to decide whether there is a need to evaluate a specific non-active substance in detail and, if necessary, to ask additional information to the applicant for the appropriate assessment. This should only occur where there are indications that a non-active substance may have ED properties based on the existing knowledge and the available scientific information." To address this requirement, Member States Competent Authorities have agreed on step-wise approach[16] for a targeted determination of whether a non-active substance (co-formulant) in a biocidal product is an ED or has 'indications' of ED properties. The approach proposed has been applied to the co-formulants in Boracol 10_3Bd; none were found to have known ED properties or were judged to have possible ED properties.

[15] Applicable as of 7 June 2018 to co-for

mulants in products under assessment.

[16] Described in the document *Assessment of endocrine disruption (ED) properties of co-formulants in biocidal products – instructions for applicants*.

Available toxicological data relating to a mixture

No information additional to that in SDSs was provided.

2.2.6.2 Exposure assessment

Boracol 10_3Bd is a ready-to-use biocidal product intended for the preservation of wood (PT8) – prevention and treatment of fungal attack – via *in situ* brush application. The product is intended for indoor/covered wood constructions such as roof trusses, braces, and floor separations and, in specific cases, adjacent masonry.

Boracol 10 3Bd contains 2.5% w/w boric acid, 2.38% w/w disodium tetraborate, anhydrous, and 2.45% w/w didecyldimethylammonium chloride (DDAC), with water as the primary solvent. The human exposure assessment relates to the use phases of the product, and addresses primary- and secondary exposure, with exposure of professionals, non-professionals and the general public considered.

The workplace risk for professional users of the product will be controlled via observance of statutory requirement such as formal control measures (i.e. engineering controls and occupational safety measures). Professionals have access to Material Safety Data Sheets (MSDS) and may have basic knowledge of classification and labeling of biocidal products. They are expected to be trained and skilled in the main activities of their occupation, and have some experience and skill in the use of personal protective equipment (PPE) if such equipment is required for their normal work.

Non-professional users are expected to have limited experience with biocidal products and may or may not read/adequately follow a product label. They are not expected to have access to formal PPE, though it is expected that they will follow basic recommendations such as: do not eat, drink or smoke when working with wood preservative biocidal; avoid contact with eyes and skin and do not inhale vapour (ensure adequate ventilation); wash hands after use. The main paths of human exposure to the product are presented in the following table.

Identification of main paths of human exposure to active substance(s) and substances of concern with the proposed uses of the biocidal product

Summary table: relevant paths of human exposure							
	Primary (direct) exposure			Secondary (indirect) exposure			
Exposure path	**Industrial use**	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	Yes	Yes	n.a.	Yes	No[1]	n.a.
Dermal	n.a.	Yes	Yes	n.a.	Yes	Yes	n.a.
Oral	n.a.	No	No	n.a.	No	No[2]	n.a.

n.a. = not applicable.

[1] Not considered warranted as the intended situations (locations) of use, coupled with the low vapour pressure of the respective active substances is expected to result in negligible exposure of the general public via inhalation.

[2] The scenario *Toddler touching freshly treated wood with subsequent mouthing* has been included in order to assess the risk of incidental exposure.

Considerations for boric acid and disodium tetraborate, anhydrous, in relation to exposure assessment

Section 2.2.1 *Human Health Risk Assessment* of the CARs for boric acid and disodium tetraborate (NL CA, 2009) states that as the toxicokinetics and toxicological effects of boric acid and disodium tetraborate are likely to be similar on a boron-equivalent basis, data obtained from studies with different borates can be read across in the human health assessment for each individual substance. Expressing exposure/dose rates for the two boron active substances in Boracol 10_3Bd as boron equivalents (BE) permits comparison with AELs for the two compounds, which are expressed as weight units of boron (B) per kg body weight per day (mg B/kg bw/day) in their respective CARs (NL CA, 2009)[17].

Conversion factors for boron compounds to the equivalent dose of boron (BE) are calculated using the formula:

$N \times (MW_{boron}/MW_{active\ substance})$

where N is the number of boron atoms in the boron compound and MW is the molecular weight of boron (MW = 10.811 g/mol) or the boron compound. Conversion factors for the boron active substances in Boracol 10_3Bd to their boron equivalent are presented in the table below.

Conversion factors for boron compounds to equivalent doses of boron

Compound (expressed as weight unit e.g. gram)	**Molecular formula**	**MW**	**Conversion (multiplication) factor for boron-equivalent (BE) dose**
Boric acid	H_3BO_3	61.833	0.175

[17] The short-term AEL, medium-term AEL and long-term AEL for both boron compounds is 0.096 mg B/kg/bw/day (rounded to 0.1 mg B/kg bw/day).

	(1 boron atom)		
Disodium tetraborate, anhydrous	$Na_2B_4O_7$ (4 boron atoms)	201.22	0.215

Considerations concerning didecyldimethylammonium chloride (DDAC) in relation to exposure assessment

According to the CAR for DDAC (IT CA, 2015), systemic effects observed in studies of this active substance are regarded as secondary to the local irritation/corrosion caused by the test substance and, consequently, no adverse systemic effects were identified. Due to the lack of systemic effects in the absence of local effects, derivation of an AEL was not considered appropriate and, consequently, a systemic exposure assessment was not considered necessary. This approach was agreed on at WGII2015 (*WGII2015_TOX_6.2_DDAC_QUATs_agreements*). Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed (see Local effects in 2.2.6.3 *Risk Characterisation for human health*).

List of scenarios

Scenarios considered relevant for assessing primary- and secondary exposure of professionals and non-professionals applying Boracol 10_3Bd are addressed. The product is intended for *in situ* treatment of indoor/covered wood construction such as roof trusses, braces, and floor separations and, in specific cases, adjacent masonry. These structural elements are generally not expected to be handled (e.g. moved or mounted) or worked (e.g. sawed or sanded), though handling and working of treated wood cannot be excluded. Exposure of the general public is, for adults, assessed via laundering of professional work clothes at home.

Justification for non-inclusion of specific scenarios

The product is intended to be applied *in situ* in situations (locations / structures) where exposure of the general public – and especially infants, toddlers and children – is considered unlikely during both the application and post-application phases. Consequently, exposure scenarios such as 'infant/toddler chewing treated wood off-cut' and 'infant/toddler having contact with dried surfaces of treated wood' (e.g. a playground structure) are not considered warranted. The incidental exposure scenario of a toddler touching freshly treated wood with subsequent mouthing of fingers has been included in order to evaluate risk associated with this severe exposure scenario. A scenario addressing inhalation of volatile residues indoors is

not considered warranted due to the intended situations (locations) of use of the product and the low vapour pressure[18] of the respective active substances.

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1a.	Mixing and loading	Primary exposure. Transfer (semi-automatic) of the product from pack sizes > 20 litres to a painting pot.	Professionals
1b.	Application by brushing	Primary exposure. Professional applying the product using a brush.	Professionals
2.	Cleaning the brush	Primary exposure. Professional cleaning the brush after application.	Professionals
3.	Sanding treated wood	Secondary exposure, chronic. Professional cutting and sanding treated wood.	Professionals
4.	Application by brushing	Primary exposure. Non-professional applying the product using a brush.	Non-professionals
5.	Cleaning the brush	Primary exposure. Non-professional cleaning the brush after application.	Non-professionals
6.	Sanding treated wood	Secondary exposure, acute. Non-professional cutting and sanding treated wood.	Non-professionals
7.	Handling treated wood once dry	Secondary exposure, acute Non-professional (adult) handling treated wood after application of the product.	Non-professionals
8.	Toddler touching freshly treated wood	Acute secondary exposure, incidental. Toddler touching freshly treated wood with subsequent mouthing of fingers.	General public
9.	Launderin g professional work clothes at home	Acute intermediary secondary exposure. Contaminated work clothing is handled during laundering.	General public

[18] The vapour pressure of boric acid and of disodium tetraborate, anhydrous is not listed as an endpoint in their respective CARs (NL CA, 2009) as the value at ambient temperature is expected to be less than 10^{-5} Pa, and the vapour

Industrial exposure

Not relevant. The product is to be applied by brushing in non-industrial settings.

Professional exposure

Description of Scenario [1a] – Mixing and loading (professionals)		
Boracol_10_3Bd is a ready-to-use (RTU) product and does not require mixing, however as pack sizes of 20 litres and greater are intended to be available to professionals, exposure during transfer of the product from a large container to a painting pot should be considered. HEEG Opinion no. 1 *On the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale* provide models for assessing such exposure. Loading of Boracol 10_3Bd in relation to professional use may be performed via automated- or semi-automated transfer/pumping, and is expected to be a relatively brief activity. Exposure during automated transfer/pumping is expected to be associated with very low or only accidental exposure (see HEEG Opinion no. 1, under *Comments*, p. 8), and semi-automated transfer/pumping is considered more relevant for professional users of the product, thus a model for the latter is considered most relevant / worst case. The RISKOFDERM *Potential Dermal Exposure Model* calculator was used to estimate exposure to the product (process for assessment: Filling, mixing or loading; level of automation: Automated or semi-automated task), and assuming negligible inhalation exposure. The model does not estimate body exposure, though this is considered acceptable for the task. Assuming a daily exposure (task) duration of 10 minutes and a product transfer rate of 10 L/min as a worst-case (giving a daily transfer of 100 L product), a hand exposure of 13 mg/min was calculated (refer to Appendix 3.2 for details). For details on the exposure calculation refer to Appendix 3.2.		
Tier 1	**Parameter**	**Value**
	Dermal exposure, hands (90% percentiles)[1]	13 mg/min
	Indicative dermal exposure, body[1]	No exposure foreseen
	Indicative inhalation exposure[1]	Negligible; normal or good ventilation
	Exposure duration[1]	10 min
	Transfer rate of product	10 L/min (as a worst case)[1]
	Body weight, adult[2]	60 kg
Tier 2	Glove penetration[3]	10%

[1] RISKOFDERM Dermal Model *Loading liquid, automated or semi-automated*.

pressure of DDAC is listed as < 5.8^{-3} Pa and 1.1^{-5} Pa at 25°C (DDAC source used in Boracol 10_3Bd) its CAR (IT CA 2015), thus inhalation of volatile residues indoors is expected to be negligible. As systemic effects observed in studies of DDAC are regarded as secondary to its local irritation/corrosion effects systemic exposure assessment of DDAC is not performed, instead exposure to DDAC is addressed via Local Risk Assessment.

[2] HEEG Opinion 17 *Default human factor values for use in exposure assessment for biocidal products*.
[3] HEAdhoc Recommendation no. 14 *Default human factor values for use in exposure assessment for biocidal products*.

Description of Scenario [1b] – Application by brushing (professionals)		
Recommendation no. 6 of the *BPC Ad hoc Working Group on Human Exposure point no. 23*, and the *Biocides Human Health Exposure Methodology* (October 2015) document's scenario *Professional brush treatment* (p.120) (based on the *Summary Report - Human Exposure to Wood* Preservatives by Lingk et al. 2006), provide values for use in calculation of dermal and inhalation exposure to a wood preservative. The indicative values are normalized to 1% active substance. Professionals are expected to wear coveralls, reducing exposure of the body, and to wear gloves, reducing exposure of the hands (Tier 2 assessment). For details on the exposure calculation refer to Appendix 3.2.		
	Parameter	**Value**
Tier 1	Indicative dermal exposure, hands[1]	0.5417 mg/m^2 (normalized to 1% a.s.)
	Indicative dermal exposure, body[1]	0.2382 mg/m^2 (normalized to 1% a.s.)
	Indicative inhalation exposure[1]	0.0016 mg/m^2 (normalized to 1% a.s.)
	Inhalation rate[2]	1.25 m^3/h
	Exposure duration[1]	240 min
	Application area[2]	31.6 m^2
	Body weight, adult[2]	60 kg
Tier 2	Glove penetration[3]	10%
	Coveralls penetration[3]	10%

[1] *Consumer painting Model 3/Professional brush treatment* scenario, in *Biocides Human Health Exposure Methodology* (version 1, October 2015, p. 120).
[2] HEAdhoc Recommendation no. 14 *Default human factor values for use in exposure assessment for biocidal products*.
[3] HEEG Opinion 9 *Default protection factors for protective clothing and gloves*.

Description of Scenario [2] - Cleaning the brush (professionals)

A post-application task which may lead to some degree of exposure is cleaning the brush used to apply the product. Brush cleaning by professionals can be expected to last for no more than 15 minutes, and might result in some exposure to hands. Exposure during brush cleaning is not covered by any of the proposed TNsG models. A water-based formulation might be removed by washing the brush under a water stream, a process that would result in negligible dermal exposure. Thus, as discussed at WGIII2017, inclusion of a brush washing scenario may not be warranted for water-based products (such as Boracol 10_3Bd). However, in order to assess the contribution of an eventual brush-washing phase to exposure, exposure of professionals and non-professionals to the product is assessed using the *General Exposure Calculator for Washing out Of Brushes* of the annex to HEEG Opinion 11. It is considered a worst-case scenario as it is normally intended for non-water based paints, and does not involve cleaning under a stream of water.

Cleaning a brush used for water-based formulations may be done by repeated dipping and swaying it in a vessel containing clean water. A large brush might have a size of 10 x 10 x 2 cm, corresponding to a volume of 200 mL. The brush is assumed to be cleaned (dipped and swayed) three times, using fresh water on each occasion (step). The volume of water should be large enough to allow a sufficient dilution of the residues in the brush. For a brush having a volume of 200 mL, the required water volume would be at least 400 mL per step. Each washing step is assumed to result in an approximately 10-fold dilution of the residues in the brush. After each step the brush is assumed to be squeezed by hand to remove as much liquid as possible. It is assumed that with each step 50% of the solution in the brush is released and may potentially contaminate the hand. It is further assumed that the squeezing is not done by the bare hand but rather by wrapping it first with a cleaning rag, which may absorb ~ 90% of the released liquid. Washing and squeezing may each be done a maximum of three times. During brush cleaning, professionals may retain gloves worn during brush application of the product (Tier 2 assessment). No exposure of areas of the body other than the hands is assumed to occur; and exposure via inhalation is considered negligible.

The Tier 1 exposure assessment for professionals is considered a worst-case scenario and thus is also used to calculate exposure associated with cleaning the brush by non-professionals (Scenario [7]).

For details on the exposure calculation refer to Appendix 3.2.

	Parameter	**Value**
Tier 1	Brush size	200 mL
	Volume of residual solution in brush	1/8 of brush volume = 25 mL
	Volume of each washing solution[1]	at least 400 mL
	Remaining residues in brush after each washing step[1]	10%
	Remaining residues in brush after each squeezing[1]	50%
	Penetration through cleaning cloth during squeezing[1]	10%
	Body weight, adult[2]	60 kg

Tier 2	Glove penetration[3]	10%

[1] HEEG Opinion 11 *General Exposure Calculator for Washing out Of Brushes*.
[2] HEAdhoc Recommendation no. 14 *Default human factor values for use in exposure assessment for biocidal products*.
[3] HEEG Opinion 9 *Default protection factors for protective clothing and gloves*.

Description of Scenario [3] - Sanding treated wood (professionals)

The cutting and sanding scenario (acute exposure) for non-professionals (Scenario [6]) is extrapolated to a scenario for professionals (chronic exposure) by increasing the exposure time from 1 to six hours per day. Professionals may be instructed to wear a respiratory protection mask (RPE) when sanding treated wood, though as a worst-case scenario, inhalation exposure without RPE – resulting in an inhalation exposure six times higher than the 1-hour exposure set in Scenario [6] – is assumed. Professionals are expected to wear gloves, reducing exposure of the hands (Tier 2 assessment).

Inhalation route:
A person (professional) is sanding (power sander) the surface of treated wood (4 cm x 4 cm x 2.5 m, surface area 4032 cm²) (TNsG 2002, Part 3, p. 50). The active substances are in the outer 1 cm. The product is applied at a rate of ~ 200 mL/m² (at a relative product density of 1.036 g/cm³ this is equivalent to 207.2 g/m²). If 100% retention of the product by the wood is assumed as the ultimate worst case, the wood contains:

Boric acid: 207.2 g/m² × 2.5% = 5.18 g/m² (0.518 mg/cm²)
Disodium tetraborate, anhydrous: 207.2 g/m² x 2.38% = 4.93 g/m² (0.493 mg/cm²)

It is not possible to predict how much wood dust will be inhaled while sanding wood treated with a wood preservative. As a surrogate parameter, it is assumed that the wood dust concentration does not exceed the applicable Occupational Exposure Limit (OEL) of the EU for respirable hardwood dust, i.e. 5 mg/m³ (Directive 2004/37/EC); the same value is used in TNsG 2002.

Dermal route:
The surface area of both palms of hands is 410 cm² and this is the assumed transfer coefficient per day. Transfer efficiency is 2% for rough sawn wood (*Biocides Human Health Exposure Methodology* 2015, p. 171). With this assumption, dermal exposure is independent of the daily exposure duration and is thus equal to the acute sanding scenario (Scenario [6]).

The duration of a sanding task for professionals is estimated to be 6 hours.

For details on the exposure calculation refer to Appendix 3.2.

	Parameter	**Value**
Tier 1	Concentration of a.s. on the surface	Boric acid: 0.518 mg/cm²
		Disodium tetraborate, anh. 0.493 mg/cm²
	Density of wood	0.4 g/cm³
	Wood dust concentration[1]	5 mg/m³
	Task duration	6 h
	Inhalation rate[2]	1.25 m³/h
	Surface area of palms of hands[3]	410 cm²
	Transfer efficiency[4]	2%

Tier 2	Glove penetration[5]	10%

[1] Directive 2004/37/EC and TNsG (2002), Part 3, p. 50.
[2] HEAdhoc Recommendation no. 14 *Default human factor values for use in exposure assessment for biocidal products*.
[3] *Biocides Human Health Exposure Methodology* 2015, p. 15.
[4] *Biocides Human Health Exposure Methodology* 2015, p. 171.
[5] HEEG Opinion 9 *Default protection factors for protective clothing and gloves*.

Calculations for Scenarios [1a, 1b, 2, 3] (professionals)

In the following calculations, systemic exposure to the active substances boric acid and disodium tetraborate, anhydrous is expressed as the equivalent dose of boron (B), permitting comparison with AELs for the two compounds, which are expressed as weight units of boron (mg B/kg bw/day) in their respective CARs (NL CA, 2009).

Summary table: systemic exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
Boric acid (values are equivalent dose of boron, B)					
Scenario [1a]	1	Negligible	0.0020	-	0.0020
	2	Negligible	0.0002	-	0.0002
Scenario [1b]	1	0.0004	0.0359	-	0.0363
	2	0.0004	0.0036	-	0.0040
Scenario [2]	1	Negligible	0.0020	-	0.0020
	2	Negligible	0.0002	-	0.0002
Scenario [3]	1	0.0002	0.0025	-	0.0027
	2	0.0002	0.0002		0.0004
Disodium tetraborate, anhydrous (values are equivalent dose of boron, B)					
Scenario [1a]	1	Negligible	0.0023	-	0.0023
	2	Negligible	0.0002	-	0.0002
Scenario [1b]	1	0.0004	0.0420	-	0.0425
	2	0.0004	0.0042	-	0.0046
Scenario [2]	1	Negligible	0.0023	-	0.0023
	2	Negligible	0.0002	-	0.0002
Scenario [3]	1	0.0002	0.0029	-	0.0031
	2	0.0002	0.0003		0.0005

Combined scenarios for systemic exposure (professionals)

Two combined scenarios are assessed. In the most limited combined scenario the professional loads Boracol 10_3Bd into a painting pot, applies the product by brushing and washes the brush [1a+1b+2]. The scenario is calculated without and with PPE. In the worst-case combined scenario [1a+1b+2+3+7+9], the professional is exposed via loading the product into a painying pot, application by brushing, cleaning the brush, sanding treated wood, handling treated wood once dry, and laundering professional work clothes at home; Tier 2 is applied for exposure scenerios [1a, 1b, 2, 3]. The scenario for handling treated wood once dry (Scenario [7]) is described under *Non-professional exposure*, while the scenario for laundering professional work clothes at home (Scenario [9]) is described under *Exposure of the general public*.

Summary table: combined systemic exposure from professional uses					
Scenarios combined	**Tier/ PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
Boric acid (values are equivalent dose of boron, B)					
Scenarios [1a+1b+2]	1	0.0004	0.0399	-	0.0403
	2	0.0004	0.0040	-	0.0044
Scenarios [1a+1b+2+3+7+9]	1 or 2[1]	0.0006	0.0172	-	0.0177
Disodium tetraborate, anhydrous (values are equivalent dose of boron, B)					
Scenarios [1a+1b+2]	1	0.0004	0.0467	-	0.0471
	2	0.0004	0.0047	-	0.0051
Scenarios [1a+1b+2+3+7+9]	1 or 2[1]	0.0007	0.0201	-	0.0207

[1] Tier 2 for Scenarios [1a, 1b, 2, 3].

Non-professional exposure

Description of Scenario [4] – Application by brushing (non-professionals)		
Non-professional application of wood preservative with a brush will differ from a professional application, mainly due to the lesser experience of the user. To assess exposure, *Consumer painting Model 3** is used with default values from Recommendation no. 10 of BPC HEAdhoc (expected indicative values). The default values are for water-based products. As a worst case, the duration of exposure is 155 minutes (the longest duration of the recommendation). There is no refinement, since non-professionals cannot be expected to wear protective equipment. Boracol 10_3Bd is ready-to-use and intended to be available to non-professionals at pack sizes not exceeding 5 litres, thus no scenario for mixing and loading is considered in relation to brush application. (* *Consumer painting model 1* was also considered for this scenario as it addresses painting of wooden surfaces with textures representative of those to which Boracol 10_3Bd will be applied, though it assumes that the paint is applied overhead and incorporates exposure due to decanting. *Consumer painting model 3* also addresses application to wooden surfaces with textures considered representative of those to which Boracol 10_3Bd will be applied. These surfaces can be expected to be primarily vertical and sloping, permitting painting with the brush at or below shoulder height – a situation in which hand and body exposure is significantly lower than in model 1. The latter surface orientations are considered more representative of surfaces to be treated with Boracol 10_3Bd than the strictly overhead painting assessed in model 1. Furthermore, model 3 assumes that paint is applied direct from the can.)For details on the exposure calculation refer to Appendix 3.2.		
	Parameter	**Value**
Tier 1	Indicative value (hands)[1]	4.07 µL/min
	Indicative value (body)[1]	1.7 µL/min
	Indicative value (inhalation)[1]	1.63 mg/m^3
	Density of Boracol 10_3Bd	1.036 g/mL
	Clothing penetration[2]	100%
	Inhalation rate[3]	1.25 m^3/h
	Duration of application[1]	155 minutes

[1] *Consumer painting Model 3* and HEAdhoc Recommendation no. 10 *The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling*.

[2] HEAdhoc recommendation no. 8 *Consumer use of biocidal products and protection from typical clothing*.

[3] HEAdhoc Recommendation no. 14 *Default human factors values for use in exposure assessment for biocidal products*.

Description of Scenario [5] – Cleaning the brush (non-professionals)
Please refer to Scenario [2]. For details on the exposure calculation refer to Appendix 3.2.

Description of Scenario [6] – Sanding treated wood (non-professionals)

(Note: Revision of this scenario to increase the duration of exposure from 1 h (as an acute exposure) to 6 hours (as a chronic exposure), and refinement for use of PPE, is used to assess sanding of treated wood by professionals (Scenario [3]).)

Inhalation route:
A person (non-professional) is sanding (power sander) the surface of treated wood (4 cm x 4 cm x 2.5 m, surface area 4032 cm²) (TNsG 2002, Part 3, p. 50). The active substances are in the outer 1 cm. The product is applied at a rate of ~ 200 mL/m² (at a relative product density of 1.036 g/cm³ this is equivalent to 207.2 g/m²). If 100% retention of the product by the wood is assumed as the ultimate worst case, the wood contains:

Boric acid: 207.2 g/m^2 × 2.5% = 5.18 g/m^2 (0.518 mg/cm^2)
Disodium tetraborate, anhydrous: 207.2 g/m^2 x 2.38% = 4.93 g/m^2 (0.493 mg/cm^2)

It is not possible to predict how much wood dust will be inhaled while sanding wood treated with a wood preservative. As a surrogate parameter, it is assumed that the wood dust concentration does not exceed the applicable Occupational Exposure Limit (OEL) of the EU for respirable hardwood dust, i.e. 5 mg/m³ (Directive 2004/37/EC); the same value is used in TNsG 2002.

Dermal route:
The surface area of the palms of both hands is 410 cm² and this is the assumed transfer coefficient per day. Transfer efficiency is 2% for rough sawn wood (*Biocides Human Health Exposure Methodology* 2015, p. 171).

The duration of a sanding task for non-professionals is estimated to be 1 hour.

For details on the exposure calculation refer to Appendix 3.2.

	Parameter	**Value**
Tier 1	Concentration of a.s. on the wood surface	Boric acid: 0.518 mg/cm^2
		Disodium tetraborate, anh. 0.493 mg/cm^2
	Density of wood	0.4 g/cm^3
	Wood dust concentration[1]	5 mg/m^3
	Task duration	1 h
	Inhalation rate[2]	1.25 m^3/h
	Surface area of palms of hands[3]	410 cm^2
	Transfer efficiency[4]	2%

[1] Directive 2004/37/EC and TNsG (2002), Part 3, p. 50.
[2] HEAdhoc Recommendation no. 14 *Default human factor values for use in exposure assessment for biocidal products*.
[3] *Biocides Human Health Exposure Methodology* 2015, p. 15.
[4] *Biocides Human Health Exposure Methodology* 2015, p. 171.

Description of Scenario [7] – Handling treated wood (non-professionals)		
Although the product is intended to be applied *in situ*, it is possible that a non-professional may handle treated wood after application either directly when moving treated wood, or when moving around in already treated areas of a construction under treatment (the intended use of the product is in situations in which workers are required to move around and manoeuver their body in structures / confined areas such as roof constructions, behind wooden walls, in spaces below wooden floors). The wood-preservative is assumed to be completely dry at the time of handling/contact. The number of exposure (handling) cycles has been set to 3, which is considered conservative for a product intended for *in situ* use. Exposure via inhalation is considered negligible. This scenario is included in the worst-case combined scenario for professionals. Although professionals could be expected to wear gloves when handling treated wood or moving around in treated structures, Tier 2 exposure has not been calculated for professionals. For details on the exposure calculation refer to Appendix 3.2.		
	Parameter	**Value**
Tier 1	Concentration of a.s. on the surface[1]	Boric acid: 0.518 mg/cm^2
		Disodium tetraborate, anh.: 0.493 mg/cm^2
	Adult hand surface (palms)[2]	410 cm^2
	Percentage dislodgeble[3]	3%
	Handling cycles (number)	3

[1] Calculated for Scenario [6].
[2] *Biocides Human Health Exposure Methodology* 2015, p. 15.
[3] *Biocides Human Health Exposure Methodology* 2015, p. 171.

A laundering work clothes scenario for non-professionals has not been assessed as in the single application scenario (Scenario [4] – Application by brushing (non-professionals)) penetration of the product through clothing has been set to 100%.

Calculations for Scenario [4, 5, 6, 7] (non-professionals)

In the following calculations, systemic exposure to the active substances boric acid and disodium tetraborate, anhydrous is expressed as the equivalent dose of boron (B), permitting comparison with AELs for the two compounds, which are expressed as weight units of boron (mg B/kg bw/day) in their respective CARs (NL CA, 2009).

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
Boric acid (values are equivalent dose of boron, B)					
Scenario [4]	1	0.0004	0.0139	-	0.0139
Scenario [5]	1	Negligible	0.0020	-	0.0020
Scenario [6]	1	0.00003	0.0025	-	0.0025
Scenario [7]	1	Negligible	0.0111	-	0.0111
Disodium tetraborate, anhydrous (values are equivalent dose of boron, B)					
Scenario [4]	1	0.0004	0.0154	-	0.0159
Scenario [5]	1	Negligible	0.0023	-	0.0023
Scenario [6]	1	0.00004	0.0029	-	0.0029
Scenario [7]	1	Negligible	0.0130	-	0.0130

Combined scenarios for systemic exposure (non-professionals)

Two combined scenarios are assessed. In the most limited combined scenario, the non-professional applies Boracol 10_3Bd by brushing and washes the brush [4+5]. In the worst-case combined scenario, the non-professional is exposed via application by brushing, cleaning the brush, sanding treated wood, and handling treated wood once dry [4+5+6+7].

Scenarios combined	**Tier/ PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
Boric acid (values are equivalent dose of boron, B)					
Scenarios [4+5]	1	0.0004	0.0155	-	0.0159
Scenarios [4+5+6+7]	1	0.0004	0.0291	-	0.0295
Disodium tetraborate, anhydrous (values are equivalent dose of boron, B)					
Scenarios [4+5]	1	0.0004	0.0177	-	0.0182
Scenarios [4+5+6+7]	1	0.0005	0.0337	-	0.0342

Exposure of the general public

Description of Scenario [8] – Toddler touching freshly treated wood (general public)		
It is possible that a toddler or child may come into contact with wood preservative being applied by non-professionals. Contact with freshly-treated surfaces is assumed to be of short duration, as parents/guardians will remove the product from the toddler's or child's hands as soon as the incident is observed. It is assumed that 100% of the palms of both hands is exposed. The transfer coefficient (from freshly-treated wood to hands) is set to 50% as Boracol 10_3Bd is intended to penetrate the wood. All of the material on the palms of both hands is considered available for mouthing; the amount ingested is set to 10%, constituting the area of two fingers. The toddle is used as the worst-case. For details on the exposure calculations please refer to Appendix 3.2.		
	Parameter	**Value**
Tier 1	Concentration of a.s. on the surface[1]	Boric acid: 0.518 mg/cm^2
		Disodium borate, anh.: 0.493 mg/cm^2
	Toddler hand surface (palm)[2]	115.2 cm^2
	Hand area contaminated[3]	100%
	Transfer coefficient[3]	50%
	Transferable fraction to mouth[3]	10%
	Toddler body weight[2]	10 kg
	Oral absorption[4]	Boric acid: 100%
		Disodium borate, anhydrous: 100%

[1] Calculated for Scenario [6].
[2] HEAdhoc Recommendation no. 14 *Default human factors values for use in exposure assessment for biocidal products*.
[3] HEAdhoc Recommendation no. 5, *Non-professional use of antifouling paints: exposure assessment for a toddler*.
[4] CARs for boric acid (NL CA, 2009) and disodium borate, anhydrous, (NL CA, 2009).

Description of Scenario [9] – Laundering professional work clothes at home (general public)		
An activity that may result in exposure to Boracol 10_3Bd is the laundering of contaminated professional work clothing. Persons at risk are adults (professionals and the general public; non-professionals are not considered at risk as penetration of the product though their work clothes is set to 100% (i.e. no retention) and it is unlikely that they both apply the product and launder the clothes of a professional who was applied the product). Exposure duration is acute to short-term. Laundering is assumed to occur mechanically without any exposure risk to humans. Contact with effluent is unlikely to occur. The only likely exposure is during handling of the contaminated clothing while preparing it for laundry. Exposure is restricted to the hands and is dependent on the area and concentration of dislodgeable residues on the surface of the clothing and the transfer coefficient to skin. It is assumed that the clothing to be washed is a coated coverall worn by a professional, that the coverall is washed after one working week (corresponding to five working days), and that the total residue accumulated during this time is equivalent to 5-times the daily contamination associated with application by brushing. The sum transfer area is determined by estimating how many times the coated coverall is touched by the hands while preparing it for laundering. Assuming that this happens three times, twice with the palms of both hands and once with the total hands surface, the sum transfer area is 1640 cm^2. As a worst-case assumption, 50% of the residues in the touched area are considered to be transferred to the skin (transfer coefficient). The scenario is modelled after the CAR for Propiconazole (FI CA, 2007). For details on the exposure calculation, please refer to Appendix 3.2.		
	Parameter	**Value**
Tier 1	Clothing contamination[1]	Boric acid: 16.936 mg/day
		Disodium borate, anh.: 16.124 mg/day
	Days before washing	5 days
	Percentage dislodgeable (transfer coefficient)	50%
	Surface of medium coated coverall[2]	22700 cm^2
	Sum transfer area[3]	1640 cm^2

[1] Clothing contamination equals the highest potential body exposure (Scenario [1]) minus the amount that penetrates through the clothing (10%, Scenario [1]), and is expressed as mg a.s./day.

[2] See the CAR for Propiconazole (FI CA, 2007).

[3] Based on a surface area of both palms of 410 cm^2 and total surface of both hands of 820 cm^2; see HEAdhoc Recommendation no. 14 *Default human factors values for use in exposure assessment for biocidal products*.

Calculations for Scenarios [8, 9]

In the following calculations, systemic exposure to the active substances boric acid and disodium tetraborate, anhydrous is expressed as the equivalent dose of boron

(B), permitting comparison with AELs for the two compounds, which are expressed as weight units of boron (mg B/kg bw/day) in their respective CARs (NL CA, 2009).

Summary table: systemic exposure of general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
Boric acid (values are equivalent dose of boron, B)					
Scenario [8]	1	Negligible	0.1044	0.0522	0.1566
Scenario [9]	1	Negligible	0.0018	-	0.0018
Disodium tetraborate, anhydrous (values are equivalent dose of boron, B)					
Scenario [8]	1	Negligible	0.1221	0.0611	0.1832
Scenario [9]	1	Negligible	0.0021	-	0.0021

Combined scenarios for systemic exposure (general public)

Not relevant; the two scenarios for the general public are not both relevant for any one population group.

Monitoring data

No further information on studies or surveys of human exposure to Boracol 10_3Bd or a surrogate were submitted.

Dietary exposure

Exposure of food or drinking water to the active substances in Boracol 10_3Bd (boric acid, disodium borate, anhydrous, and didecyldimethylammonium chloride (DDAC) can be excluded when it is applied according to the recommended uses and relevant RMMs specified.

Information on non-biocidal use of the active substances

None of the active substances in Boracol 10_3Bd is authorised as an active substance in Plant Protection Products (PPPs).

Boron is primarily used in chemical compounds. About half of all boron consumed globally is an additive in fiberglass for insulation and structural materials. The next leading use is in polymers and ceramics in high-strength, lightweight structural and refractory materials. Borosilicate glass is desired for its greater strength and thermal

shock resistance than ordinary soda lime glass. Boron as sodium perborate is used as a bleach. A small amount of boron is used as a dopant in semiconductors, and reagent intermediates in the synthesis of organic fine chemicals. A few boron-containing organic pharmaceuticals are used or are in under study. Natural boron is composed of two stable isotopes, one of which (boron-10) has a number of uses as a neutron-capturing agent.

DDAC is exclusively used as a biocide.

Estimating livestock exposure to active substances used in biocidal products

Livestock exposure to the active substances in Boracol 10_3Bd can be excluded when it is applied according to the recommended uses and relevant RMMs specified.

Estimated transfer of biocidal active substances into foods as a result of professional and/or industrial applications

Transfer of the active substances in Boracol 10_3Bd into food (or drinking water) can be excluded when the product is applied according to the recommended uses and the RMMs are followed.

Estimated transfer of biocidal active substances into foods as a result of non-professional use

Transfer of the active substances in Boracol 10_3Bd into food (or drinking water) can be excluded when the product is applied according to the recommended uses and the RMMs are followed.

Exposure associated with production, formulation and disposal of the biocidal product

Occupational exposure during production and formulation of a biocidal product is not assessed under the requirements of the BPD (Regulation No. 528/2012). The Biocides Technical Meeting (TMI06) agreed that risk assessment for production and formulation of an active substance is not required unless it is totally new to the EU market and manufactured in the EU. This is not the case for boric acid, disodium tetraborate, anhydrous, and didecyldimethylammonium chloride (DDAC) which are existing biocidal active substances within the EU.

Aggregated exposure

The active substances boric acid, disodium tetraborate, anhydrous, and DDAC are currently only authorised for use in PT8, though application for approval of DDAC for use in several other PTs is in progress.

An aggregate exposure assessment has not been performed as exposure to the active substances in Boracol 10_3Bd from sources other than the biocidal product is expected to be negligible.

2.2.6.3 Risk characterisation for human health

In the following risk assessments, the estimates for systemic exposure to the active substances boric acid and disodium tetraborate, anhydrous – expressed as their equivalent dose of boron (B) – and to the total systemic dose of boron provided by both active substances[19], are compared to the appropriate AEL (exposure/AEL = %AEL) to determine if use Boracol 10_3Bd is acceptable (i.e. %AEL ≤ 100) for the task(s) in question. The a.s. DDAC is not addressed here as only a Local Risk Assessment is performed for this a.s.

The reference values and other information presented in the following 2 tables are derived from the CARs for the respective active substances.

Reference values* to be used in Risk Characterisation of boric acid and disodium tetraborate, anhydrous (*values are equivalent dose of boron)

Reference	**Study**	**NOAEL (LOAEL)** (mg B/kg bw/day)	**AF**[1]	**Correction for oral absorption**	**Value** (mg B/kg bw/day)
$AEL_{short\text{-}term}$	developmental study rat	9.6	100	No[2]	0.096 Rounded to 0.1
$AEL_{medium\text{-}term}$	developmental study rat	9.6	100	No[2]	0.096 Rounded to 0.1
$AEL_{long\text{-}term}$	developmental study rat	9.6	100	No[2]	0.096 Rounded to 0.1

[1] Default value of 100 that accounts for inter-species variation (x10) and intra-species variation (x10).
[2] Not required, as the CARs for both active substances (NL CA, 2009) state 100% oral absorption.

Reference values[1] to be used in Risk Characterisation[2] of DDAC

Reference	**Study**	**NOAEC** (%)	**AF**[3]	**Correction for oral absorption**	**Value** (%)
Dermal NOAEC	5 days application to rat skin	0.6	-	n.a.	0.6%

[1] The CAR for DDAC (IT CA, 2015) derived a dermal NOAEC of 0.3% based on a 2-week repeated-exposure rat study, though a NOAEC for skin irritation in the rat of 0.6% was derived following 5 days application. The latter value can be considered to better reflect the acute irritant effects of DDAC, and at WGIV2017 (*Conclusions – WGV2017_TOX_6-1*) it was agreed that the dermal NOAEC of 0.6% should be used in risk assessment for the dermal route.
[2] The CAR for DDAC notes that systemic effects observed in studies of DDAC are regarded as secondary to it local irritation/corrosion effects, thus in this PAR only a Local Risk Assessment of DDAC is performed. Dermal exposure is considered the only significant route of exposure.

19 As noted in 2.2.6.2 *Exposure assessment*, exposure/dose rates for the two boron active substances can be expressed as boron equivalents (BE), permitting: a) their comparison with the identical AELs for the two compounds which are expressed as weight units of boron (B) per kg body weight per day in their respective CARs, and b) pooling of boron exposure to the two boron active substances for each exposure scenario, negating the need to perform a separate 'Risk characterisation from combined exposure to several active substances within a biocidal product' on the basis of its boron active substances.

[3] Not required for dermal exposure.

Risk for industrial users

Not applicable.

Risk for professional users

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/AEL** (%)	**Acceptable** (Yes/No)
Boric acid (values are equivalent dose of boron, B)						
[1a] Mixing and loading	1	9.6	0.1	0.0020	2.0	Yes
	2	9.6	0.1	0.0002	0.2	Yes
[1b] Application by brushing	1	9.6	0.1	0.0363	36.3	Yes
	2	9.6	0.1	0.0040	4.0	Yes
[2] Cleaning the brush	1	9.6	0.1	0.0020	2.0	Yes
	2	9.6	0.1	0.0002	0.2	Yes
[3] Sanding treated wood	1	9.6	0.1	0.0027	2.7	Yes
	2	9.6	0.1	0.0004	0.4	Yes
Disodium tetraborate, anhydrous (values are equivalent dose of boron, B)						
[1a] Mixing and loading	1	9.6	0.1	0.0023	2.3	Yes
	2	9.6	0.1	0.0002	0.2	Yes
[1b] Application by brushing	1	9.6	0.1	0.0425	42.5	Yes
	2	9.6	0.1	0.0046	4.6	Yes
[2] Cleaning the brush	1	9.6	0.1	0.0023	2.3	Yes
	2	9.6	0.1	0.0002	0.2	Yes
[3] Sanding treated wood	1	9.6	0.1	0.0031	3.1	Yes
	2	9.6	0.1	0.0005	0.5	Yes
Total boron (B) exposure (via boric acid and disodium tetraborate, anhydrous)						
[1a] Mixing and loading	1	9.6	0.1	0.0043	4.3	Yes
	2	9.6	0.1	0.0004	0.4	Yes
[1b] Application by brushing	1	9.6	0.1	0.0788	78.8	Yes
	2	9.6	0.1	0.0086	8.6	Yes
[2] Cleaning the brush	1	9.6	0.1	0.0043	4.3	Yes
	2	9.6	0.1	0.0004	0.4	Yes
[3] Sanding treated wood	1	9.6	0.1	0.0058	5.8	Yes
	2	9.6	0.1	0.0009	0.9	Yes

Combined scenarios

In the most limited combined scenario [1a+1b+2], the professional loads Boracol 10_3Bd into a painting pot, applies the product by brushing, and washes the brush.

This scenario is calculated without and with PPE. In the worst-case combined scenario [1a+1b+2+3+7+9], the professional is exposed via loading the product into a painting pot, application by brushing, cleaning the brush, sanding treated wood, handling treated wood once dry, and laundering professional work clothes; Tier 2 is applied for the primary exposures [1a, 1b, 2], and chronic secondary exposure [3].

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/AEL** (%)	**Acceptable** (Yes/No)
Boric acid (values are equivalent dose of boron, B)						
[1a+1b+2]	1	9.6	0.1	0.0403	40.3	Yes
	2	9.6	0.1	0.0044	4.4	Yes
[1a+1b+2+3+7+9]	1 or 2[1]	9.6	0.1	0.0177	17.7	Yes
Disodium tetraborate, anhydrous (values are equivalent dose of boron, B)						
[1a+1b+2]	1	9.6	0.1	0.0471	47.1	Yes
	2	9.6	0.1	0.0051	5.1	Yes
[1a+1b+2+3+7+9]	1 or 2[1]	9.6	0.1	0.0207	20.7	Yes
Total boron (B) exposure (via boric acid and disodium tetraborate, anhydrous)						
[1a+1b+2]	1	9.6	0.1	0.0874	87.4	Yes
	2	9.6	0.1	0.0095	9.5	Yes
[1a+1b+2+3+7+9]	1 or 2[1]	9.6	0.1	0.0385	38.5	Yes

[1] Tier 2 for Scenarios [1a, 1b, 2, 3].

Conclusion on the risk assessment for professional users

The risk assessment for professionals shows an acceptable risk for each boron active substance, and for total boron exposure via both active substances, when Boracol 10_3Bd is loaded into a painting pot (Scenario [1a]), applied by brushing (Scenario [1b]), and the brush is cleaned (Scenario [2]) without PPE, and that the exposure is significantly reduced when appropriate PPE (gloves, coveralls) is worn. No other tasks performed by the professional – sanding treated wood (Scenario [3]), handling treated wood once dry (Scenario [7]), or laundering professional work clothes (Scenario [9]) – result in unacceptable exposure to either boron active substance, or to total boron exposure via both active substances, without PPE. The worst-case combined scenario for professional use, which includes all of the above exposure scenarios (i.e. Scenarios [1a+1b+2+3+7+9]), shows acceptable risk for each boron active substance, and for total boron exposure via both active substances, when appropriate PPE (gloves, coveralls) is used during the primary exposures and the chronic secondary exposure sanding treated wood. The risk is also acceptable if Tier 1 for Scenario [3] is used in the worst-case combined scenario for professional use.

Local effects

Boric acid and disodium tetraborate, anhydrous are not classified for local effects. DDAC is classified for skin corrosion (Skin Corr. 1, H314) and its concentration in Boracol 10_3Bd results in classification of the product for skin and eye irritation (Skin Irrit. 2, H315; Eye Irrit. 2, H319). The following Local Risk Assessment addresses local effects of DDAC associated with professional use of Boracol 10_3Bd.

According to the CAR for DDAC (IT CA, 2015), systemic effects observed in studies of DDAC are regarded as secondary to its local irritation/corrosion effects. Due to the lack of systemic effects in the absence of local effects, derivation of an AEL was not considered appropriate and, consequently, a systemic exposure assessment was not considered necessary. This approach was agreed at WGII2015 (*WGII2015_TOX_6.2_DDAC_QUATs_agreements*). Thus in this PAR only a local effect risk assessment of the a.s. DDAC is performed. A qualitative- and semi-quantitative Local Risk Assessments has been performed based on the requirements set out in the *Guidance on the BPR: Volume III Human Health – Assessment & Evaluation (Parts B+C), Dec. 2017,* Section 4.3.2 *Local effects (irritation/corrosion, sensitisation) – Qualitative and semi-quantitative risk characterisation*.

DDAC a.s. is corrosive, classified as Skin Corr. 1, H314. The CAR for DDAC derived a dermal NOAEC of 0.3% based on a 2-week repeated-exposure rat study, though a NOAEC for skin irritation in the rat of 0.6% was derived following 5 days application. The latter value can be considered to better reflect the acute irritant effects of DDAC, and at WGIV2017 (*Conclusions – WGV2017_TOX_6-1*) it was agreed that the dermal NOAEC of 0.6% should be used in semi-quantitative local risk assessment (dermal route) for DDAC in a biocidal product.

The corrosive properties of DDAC a.s. result in classification of a biocidal product containing DDAC as Skin Corr. 1, H314 when DDAC is present at a concentration ≥ 5%, and as Skin Irrit. 2, H315 when it is present at ≥ 1% but < 5%. The 2.45% w/w DDAC in Boracol 10_3Bd results in classification of the product as Skin Irrit. 2, H315 and Eye Irrit. 2, H319. Consequently, a risk assessment for local effects associated with skin- and eye contact with Boracol 10_3Bd is necessary. The concentration of the product in the relevant phases of its use, the maximum frequency and duration of potential exposure, and the potential degree of exposure for the particular hazard category are taken into account. According to the aforementioned *Guidance on the BPR* the data tables/calculations presented in the following sub-sections should be prepared/performed in a qualitative risk assessment of a biocidal product for local effects associated with skin- and eye contact during relevant exposure scenarios. The scenarios relevant for professional use of Boracol 10_3Bd are: loading the product into a painting pot (Scenario [1a]), application by brushing (Scenario [1b]), cleaning the brush[20] (Scenario [2]), sanding treated wood (Scenario [3]), handling treated wood once dry (Scenario [7]), and laundering professional work clothes at home (Scenario [9]). As Scenario [9] is also relevant for the general public, it is presented in the assessment of local effects for the general public. As Boracol 10_3Bd is only expected to contact the eye on an incidental basis (i.e. due to splashes) and the product is a water-based formulation with low volatilization, the local risk assessment addresses eye exposure in an incidental basis only. Professionals are assumed to follow good personal hygiene when working with a biocidal product.

20 As mentioned in '*Description of Scenario [2] - Cleaning the brush (professionals)*', a brush washing scenario may not be warranted for a water-based product such as Boracol 10_3Bd, though it has been included in order to assess the contribution of an eventual brush-washing phase to exposure of professionals (and non-professionals).

Semi-quantitative Local Risk Assessment for the active substance DDAC

Comparison of the NOAEC for skin irritation for DDAC of 0.6% with the concentration of DDAC in the ready-to-use (RTU) product Boracol 10_3Bd (2.45%) indicates that dermal exposure to the biocidal product can be expected to cause skin irritation.

Qualitative Local Risk Assessment of Boracol 10_3Bd

Summary of qualitative local risk assessment for Boracol 10_3Bd for Scenarios [1a, 1b, 2, 3, 7] – application by brushing, cleaning the brush, sanding treated wood, and handling treated wood once dry (professionals)

Task, uses, process	Concentration of DDAC in Boracol 10_3Bd	Local effects C&L	Hazard category[1]	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE based on qualitative assessment of risk[2]	Acceptability of risk and PPE based on qualitative risk assessment
Loading the product into a painting pot	2.45%	Skin Irrit. 2, H315 Eye Irrit. 2, H319	Low	Few minutes per day (maximum 10)	Skin: Occasional contact Eyes: Incidental contact	**RMM:** Technical and organizational measures as for application by brushing **PPE:** - Substance/task appropriate gloves - Protective coverall - Face protection	**Acceptable:** As for application by brushing
Application of wood preservative using a brush	2.45%	Skin Irrit. 2, H315 Eye Irrit. 2, H319	Low	240 min per day	Skin: Frequent contact Eyes: Incidental contact	**RMM**: <u>Technical</u>: - Minimisation of splashes and spills - Avoidance of contact with contaminated tools and objects <u>Organisational</u>: - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - Substance/task appropriate gloves - Protective coverall - Face protection	**Acceptable:** + revesible effect + low frequency of event (incidental eye contact) + high degree of organisational RMMs already in use or recommended and compliance expected + professionals using appropriate PPE + experience expected
Washing out a brush	2.45%	Skin Irrit. 2, H315 Eye Irrit. 2, H319	Low	Few minutes per day (maximum 15 minutes)	Skin: Frequent contact Eyes: Incidental contact	**RMM:** Technical and organizational measures as for application by brushing **PPE:** - Substance/task appropriate gloves - Protective coverall - Face protection	**Acceptable:** As for application by brushing
Sanding treated wood	2.45%	Skin Irrit. 2, H315	Low	6 h per day	Skin: Frequent	**RMM:** <u>Technical</u>:	**Acceptable:** + revesible effect

		Eye Irrit. 2, H319			contact to hands Eyes: negligible contact	- Regular cleaning of equipment Organisational: - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - Task appropriate gloves	+ high degree of organisational RMMs already in use or recommend-ded and compliance expected + professionals using appropriate PPE + experience expected
Handling treated wood (dry)	2.45%	Skin Irrit. 2, H315 Eye Irrit. 2, H319	Low	Few minutes per day (maximum 15)	Skin: Occasion-al contact Eyes: Negligibl e contact	**RMM:** Organisational: - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - Task appropriate gloves	**Acceptable:** As for sanding treated wood

[1] According to Table 24: *Hazard categorisation of local effects* in the *Guidance on BPR: Volume III Human Health – Assessment & Evaluation (Parts B+C), Dec. 2017,* Section 4.3.2 *Local effects (irritation/corrosion, sensitisation) – Qualitative and semi-quantitative risk characterisation*.

[2] Consistent with recommendations in Table 27: *Guidance for concluding qualitatively on the acceptability for professional exposure* in the *Guidance for Human Health Risk Assessment*.

Conclusion on Local Risk Assessment for professionals

The semi-quantative local risk assessment for the a.s. DDAC in Boracol 10_3Bd indicates that dermal exposure to the biocidal product can be expected to cause skin irritation. DDAC is the only component of the biocidal product classified for skin corrosion or skin irritation; its concentration results classification of Boracol 10_3Bd for Skin Irrit. 2 (H315) (and Eye Irrit. (H319)) when classified via the calculation methods of Regulation (EC) No 1272/2008 (CLP). The qualitative local risk assessment for Boracol 10_3Bd indicates that the risk of skin irritation and eye irritation (the latter following incidental contact only) with professional use of the biocidal product can be acceptably managed by appropriate risk mitigation measures (RMMs) and appropriate personal protective equipment (PPE).

Risk for non-professional users

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/AEL** (%)	**Acceptable** (Yes/No)
Boric acid (values are equivalent dose of boron, B)						
[4] Application by brushing	1	9.6	0.1	0.0139	13.9	Yes

[5] Cleaning the brush	1	9.6	0.1	0.0020	2.0	Yes
[6] Sanding treated wood	1	9.6	0.1	0.0025	2.5	Yes
[7] Handling treated wood	1	9.6	0.1	0.0111	11.1	Yes
Disodium tetraborate, anhydrous (values are equivalent dose of boron, B)						
[4] Application by brushing	1	9.6	0.1	0.0159	15.9	Yes
[5] Cleaning the brush	1	9.6	0.1	0.0023	2.3	Yes
[6] Sanding treated wood	1	9.6	0.1	0.0029	2.9	Yes
[7] Handling treated wood	1	9.6	0.1	0.0130	13.0	Yes
Total boron (B) exposure (via boric acid and disodium tetraborate, anhydrous)						
[4] Application by brushing	1	9.6	0.1	0.0298	29.8	Yes
[5] Cleaning the brush	1	9.6	0.1	0.0043	4.3	Yes
[6] Sanding treated wood	1	9.6	0.1	0.0054	5.4	Yes
[7] Handling treated wood	1	9.6	0.1	0.0242	24.2	Yes

Combined scenarios

In the most limited combined scenario [4+5], the non-professional applies Boracol 10_3Bd by brushing and washes the brush. In the worst-case combined scenario [4+5+6+7], the non-professional is exposed via application by brushing and cleaning the brush, sanding treated wood, and handling treated wood once dry.

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/AEL** (%)	**Acceptable** (Yes/No)
Boric acid (values are equivalent dose of boron, B)						
[4+5]	1	9.6	0.1	0.0159	15.9	Yes
[4+5+6+7]	1	9.6	0.1	0.0295	29.5	Yes
Disodium tetraborate, anhydrous (values are equivalent dose of boron, B)						
[4+5]	1	9.6	0.1	0.0182	18.2	Yes
[4+5+6+7]	1	9.6	0.1	0.0342	34.2	Yes
Total boron (B) exposure (via boric acid and disodium tetraborate, anhydrous)						
[4+5]	1	9.6	0.1	0.0341	34.1	Yes
[4+5+6+7]	1	9.6	0.1	0.0637	63.7	Yes

Conclusion on the risk assessment for non-professional users

The risk assessment for non-professionals shows an acceptable risk for each boron active substance, and for total boron exposure via both active substances, when Boracol 10_3Bd is applied by brushing (Scenario [4]) and the brush is cleaned (Scenario [5]). No other tasks performed by the non-professional – sanding treated wood (Scenario [6]) or handling treated wood (dry) (Scenario [7]) – result

in unacceptable exposure to either boron active substance, or to total boron exposure via both active substances, without PPE. The worst-case combined scenario for non-professional use, which includes all of the above exposure scenarios (i.e. Scenarios [4+5+6+7]), shows acceptable risk for each boron active substance, and for total boron exposure via both active substances, without PPE.

Local effects

Information regarding the requirements for a semi-quantitative local risk assessment of the a.s. DDAC, and qualitative local risk assessment of Boracol 10_3Bd, is provided in the *Local effects* section under the heading *Risk for professional users*. The scenarios relevant for qualitative risk assessment of non-professional use of Boracol 10_3Bd are: application by brushing (Scenario [4]), cleaning the brush[21] (Scenario [5]), sanding treated wood (Scenario [6]), and handling treated wood (Scenario [7]). As Boracol 10_3Bd is only expected to contact the eye on an incidental basis (i.e. due to splashes) and the product is a water-based formulation with low volatilization, the local risk assessment addresses eye exposure on an incidental basis only. Non-professionals are assumed to follow good personal hygiene when working with a biocidal product.

Semi-quantitative Local Risk Assessment of the active substance DDAC

As Boracol 10_3Bd is a RTU product, non-professionals using the product will be exposed to the same concentration of DDAC as professional users. Consequently, the semi-quantitative local risk assessment for professional exposure to DDAC is applicable to non-professionals. That assesement found the concentration of DDAC can be expected to cause skin irritation.

Qualitative Local Risk Assessment for Boracol 10_3Bd

Summary of qualitative local risk assessment for Boracol 10_3Bd for Scenarios [4, 5, 6, 7] – application by brushing, cleaning the brush, sanding treated wood, and handling treated wood once dry (non-professionals)

Task, uses, process	Concentration of DDAC in Boracol 10_3Bd	Local effects C&L	Hazard category[1]	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE based on qualitative assessment of risk[2]	Acceptability of risk and PPE based on qualitative risk assessment
Application of wood preservative using a brush	2.45%	Skin Irrit. 2, H315 Eye Irrit. 2, H319	Low	155 min per day	Skin: Frequent contact Eyes: Incidental contact	**RMM**: Labelling and instructions for use (including 'avoid contact with skin and eyes') that minimise exposure or possible health	**Acceptable:** + reversible effect + low frequency of event (incidental eye contact) + low frequency of use

21 As mentioned in '*Description of Scenario [2] - Cleaning the brush (professionals)*', a brush washing scenario may not be warranted for a water-based product such as Boracol 10_3Bd, though it has been included in order to assess the contribution of an eventual brush-washing phase to exposure of professionals (and non-professionals).

						effects	
Washing out a brush	2.45%	Skin Irrit. 2, H315 Eye Irrit. 2, H319	Low	Few minutes per day (maximum 15)	Skin: Frequent contact Eyes: Incidental contact	**RMM**: As for application by brushing	**Acceptable:** As for application by brushing
Sanding treated wood	2.45%	Skin Irrit. 2, H315 Eye Irrit. 2, H319	Low	1 h per day	Skin: Frequent contact to hands Eyes: Negligible contact	**RMM**: As for application by brushing	**Acceptable:** + reversible effect + low frequency of use
Handling treated wood (dry)	2.45%	Skin Irrit. 2, H315 Eye Irrit. 2, H319	Low	Few minutes per day (maximum 15)	Skin: Occasional contact Eyes: Negligible contact	**RMM**: As for application by brushing	**Acceptable:** As for sanding treated wood

[1] According to Table 24: *Hazard categorisation of local effects* in the *Guidance on BPR: Volume III Human Health – Assessment & Evaluation (Parts B+C), Dec. 2017,* Section 4.3.2 *Local effects (irritation/corrosion, sensitisation) – Qualitative and semi-quantitative risk characterisation*.

[2] Consistent with recommendations in Table 26: *Guidance for concluding qualitatively on the acceptability for general public* in the *Guidance for Human Health Risk Assessment*.

Conclusion on Local Risk Assessment for non-professionals

The semi-quantative local risk assessment for the a.s. DDAC in Boracol 10_3Bd indicates that dermal exposure to the biocidal product can be expected to cause skin irritation. DDAC is the only component of the biocidal product classified for skin corrosion or skin irritation; its concentration results classification of Boracol 10_3Bd for Skin Irrit. 2 (H315) (and Eye Irrit. (H319)) when classified via the calculation methods of Regulation (EC) No 1272/2008 (CLP). The qualitative local risk assessment for Boracol 10_3Bd indicates that the risk of skin irritation and eye irritation (the latter following incidental contact only) with non-professional use of the biocidal product can be acceptably managed by appropriate risk mitigation measures (RMMs), including specific instructions to avoid contact with skin and eyes

Risk for general public

Systemic effects

Task/ Scenario	**Tier**	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake** (mg/kg bw/d)	**Estimated uptake/AEL** (%)	**Acceptable** (Yes/No)

Boric acid (values are equivalent dose of boron, B)						
[8] Toddler touching freshly treated wood	1	9.6	0.1	0.1566	157	**No**
[9] Laundering professional work clothes at home	1	9.6	0.1	0.0018	1.8	Yes
Disodium tetraborate, anhydrous (values are equivalent dose of boron, B)						
[8] Toddler touching freshly treated wood	1	9.6	0.1	0.1832	183	**No**
[9] Laundering professional work clothes at home	1	9.6	0.1	0.0021	2.1	Yes
Total boron (B) exposure (via boric acid and disodium tetraborate, anhydrous)						
[8] Toddler touching freshly treated wood	1	9.6	0.1	0.3399	340	**No**
[9] Laundering professional work clothes at home	1	9.6	0.1	0.0039	3.9	Yes

Combined scenarios

Not relevant; the 2 scenarios for the general public are not relevant for any one population group.

Conclusion on the risk assessment for the general public

The risk assessment for the general public shows an unacceptable risk for a toddler touching wood freshly treated with Boracol 10_3Bd and subsequently mouthing fingers for each boron active substance, and for total boron exposure via both active substances. This triggers the requirement for appropriate RMMs. The only other exposure of the general public envisaged – laundering professional work clothes[22] at home – did not result in unacceptable exposure to either boron active substance, or to total boron exposure via both active substances, without PPE. No combined exposures were considered in the risk assessment.

Local effects

Information regarding the requirements for a semi-quantitative local risk assessment of the a.s. DDAC, and qualitative local risk assessment of Boracol 10_3Bd, is provided in the *Local effects* section under the heading *Risk for professional users* for background information. The single scenario relevant for qualitative local risk assessment for the general public is laundering professional work clothes at home (Scenario [9]). Assessment of local effects for the other general public exposure (toddler touching freshly treated wood (Scenario [8]) has not been performed as the risk assessment for the scenario calculated a systemic exposure to boron that is 340% of the AEL, such that RMMs identified to address

[22] The coveralls of a professional applying the product on a daily basis for 5 days.

local effects will include those identified to mitigate risk of systemic effects. As Boracol 10_3Bd is only expected to contact the eye on an incidental basis (i.e. due to splashes) and the product is a water-based formulation with low volatilization, the local risk assessment addresses eye exposure on an incidental basis only.

Semi-quantitative Local Risk Assessment of the active substance DDAC

As Boracol 10_3Bd is a RTU product, general public exposed to the product will be exposed to the same concentration of DDAC as professional users. Consequently, the semi-quantitative local risk assessment for professional exposure to DDAC is applicable to the general public. That assesement found the concentration of DDAC can be expected to cause skin irritation. However, in the exposure scenarios identified for the general public there is direct exposure to the biocidal product with the exception of an incidental exposure.

Qualitative Local Risk Assessment for Boracol 10_3Bd

Summary of qualitative local risk assessment for Boracol 10_3Bd for Scenario [8] – laundering professional work clothes at home (general public).

Task, uses, process	Concentration of DDAC in Boracol 10_3Bd	Local effects C&L	Hazard category[1]	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE based on qualitative assessment of risk[2]	Acceptability of risk and PPE based on qualitative risk assessment
Laundering professional work clothes at home	2.45%	Skin Irrit. 2, H315 Eye Irrit. 2, H319	Low	A few minutes (maximum 2) once a week	Skin: Brief contact to hands Eyes: negligible contact	**RMM**: Labelling and instructions for use that minimise exposure or possible health effects (relevant for a professional who washes their work clothes)	**Acceptable:** + reversible effect + brief exposure + low frequency of event

[1] According to Table 24: *Hazard categorisation of local effects* in the *Guidance on BPR: Volume III Human Health – Assessment & Evaluation (Parts B+C), Dec. 2017,* Section 4.3.2 *Local effects (irritation/corrosion, sensitisation) – Qualitative and semi-quantitative risk characterisation*.

[2] Consistent with recommendations in Table 26: *Guidance for concluding qualitatively on the acceptability for general public* in the *Guidance for Human Health Risk Assessment*.

Conclusion on Local Risk Assessment for the general public

The semi-quantative local risk assessment for the a.s. DDAC in Boracol 10_3Bd indicates that dermal exposure to the biocidal product can be expected to cause skin irritation. DDAC is the only component of the biocidal product classified for skin corrosion or skin irritation; its concentration results classification of Boracol 10_3Bd for Skin Irrit. 2 (H315) (and Eye Irrit. (H319)) when classified via the calculation methods of Regulation (EC) No 1272/2008 (CLP). The qualitative local risk assessment for Boracol 10_3Bd indicates that the risk of skin irritation and eye irritation (the latter considered negligible) for the general public is acceptable based on the low duration and frequency of the exposure, and the reversibile nature of the effects if experienced.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

While Boracol 10_3Bd is formulated with 3 active substances and contains 1 SoC, an assessment of risk due to combined exposure to the active substances and the SoC has not been performed as:

a) exposure/dose rates for boric acid a.s. and disodium tetraborate, anhydrous a.s. can be expressed as their equivalent doses of boron (B) and the values pooled, permitting the total systemic dose of boron provided by both active substances to be compared to the appropriate AEL (expressed as mg B/kg bw/day) in the CARs (NL CA, 2009) for the two boron active substances,

b) according to the CAR for DDAC (IT CA, 2015), systemic effects observed in studies of this a.s. are regarded as secondary to its local irritation/corrosion effects and, consequently, no adverse systemic effects were identified (see under the heading *Local effects* in *Risk assessment for professional users*), and

c) the single substance of concern (SoC) identified (propan-2-ol, CAS no. 67-63-0) did not pose an unacceptable risk for its human health end-points and is not expected to have synergistic interactions with the active substances in the biocidal product (no significant alteration (enhancement or amelioration) of the dermal absorption of boric acid/borate or the skin irritant/corrosion effect of DDAC (see section 3.7.2 of the Confidential Annex for discussion of SoCs.

2.2.7 Risk for animal health

Exposure of pets and livestock directly, or via their food or drinking water, to the active substances in Boracol 10_3Bd (boric acid, disodium tetraborate, anhydrous, and DDAC) can be excluded when the product is applied according to the recommended uses.

2.2.8 Risk assessment for the environment

Boracol 10_3Bd contains 3 active substances: 2.5% (w/w) boric acid, 2.45% (w/w) DDAC and 2.38% (w/w) disodium tetraborate, and one substance of concern 0.98 % (w/w) Propan-2-ol. It is used as wood preservative (Product Type 8) - for use as a surface treatment in buildings to prevent fungal attack and to preserve against attack from mould and wood destroying fungi (applied for). This includes wooden structures in buildings such as roof trusses, wood braces and floor separation and, in specific cases, adjacent masonry. Places where there may be a risk of wetting of the wood and thus risk of fungal attack. Can also be used as an initial preventative treatment. It's only for use indoor (Use Class 2). The product is intended for professional and non-professional use, with applicant by brush/roller.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

DDAC has no harmonized classification as Aquatic acute or chronic, however the SDS supplied by the applicant of Boracol 10_3Bd shows that the DDAC used in the product is considered to be both H400 (m-factor = 10) and H410 (m-factor = 1).

Several joint entries of in the C & L inventory also proposes a classification as H400 (m-factor = 10) and H410 (m-factor = 1). The DK CA have therefore performed the environmental classification of Boracol 10_3Bd according to the SDS of DDAC supplied by the applicant. As Boracol 10_3Bd contains 2.45% (w/w) of DDAC this triggers a classification of the product as H412.
No other substance in the product have an environmental hazard classification.

2.2.8.1 Exposure assessment

General information

Assessed PT	PT 8
Assessed scenarios	Scenario 1: Use Class 2
ESD(s) used	OECD Revised Emission Scenario Document for Wood Preservatives (PT8), 2013
Approach	Not relevant as no emissions occur
Distribution in the environment	Not relevant as no emissions occur
Groundwater simulation	Not relevant as no emissions occur
Confidential Annexes	No
Life cycle steps assessed	Scenario 1: Production: No Formulation No Use: Yes (In-situ treatment) Service life: Yes (Treated wood in service)
Remarks	

Scenario 1:

In-situ treatment
The product is intended for in situ treatment of indoor/covered constructions and therefore there are no emissions to any environmental compartment. No risk assessment has therefore been performed for the *in-situ* treatment phase.

Service life
For the life cycle stage, treated wood in service no emissions to any environmental compartment will occur as the product is intended for UC2. No risk assessment has therefore been performed for the service life phase.

No data/information on environmental exposure or effects have been handed in for the active substance nor for the product.

2.2.8.2 Emissions

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Freshwater	No emission	
Freshwater sediment	No emission	
Seawater	No emission	
Seawater sediment	No emission	
STP	No emission	

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**	**Remarks**
Air	No emission	
Soil Groundwater	No emission No emission	

2.2.8.3 Risk characterisation

Overall conclusion on the risk assessment for the environment of the product
No emissions are expected to any environmental compartment as the product is intended for *in situ* treatment of indoor/covered constructions and the service life is indoors. No environmental exposure or risk will therefore occur based on the applied use.

2.2.9 Measures to protect man, animals and the environment

2.2.9.1 Recommended methods and precautions concerning handling, use, storage, disposal, transport or fire.

Handling

Safe handling advice:
- Observe label precautions.
- Avoid contact with skin and eyes.
- Ensure good ventilation. Avoid breathing vapour or mist.
- Wash hands and forearms after use of the product and before eating, drinking, smoking or using the lavatory, and at the end of a working period.

For the professional user:
- A coated coverall is required (coverall material to be specified by the authorisation holder within the product information).
- Wear protective chemical resistant gloves during use of the product and if dry treated wood is handled (glove material to be specified by the authorisation holder within the product information; e.g. *Use chemical resistant gloves classified under Standard EN 374: Protective gloves against chemicals and micro-organisms. Recommended gloves: Viton® or Nitrile*.).

Use

- Observe label precautions.
- Keep children and pets away from the product and treated wood during application and drying.
- Do not apply the product to wood or place treated wood in areas where food/feed, food utensils or food processing surfaces may come into contact with, or be contaminated by the product or treated wood.
- Do not use on or near surfaces with which livestock can come into contact.
- Do not treat wood that comes in direct contact with soil or water.

- Can be harmful to protected organisms such as bats, hornets or birds. The presence of protected organisms in the area to be treated must be assessed prior to use of the product. Appropriate protective measures must be taken if necessary
- Avoid run-off. Collect losses for re-use or disposal.
- Avoid breathing vapour or mist.
- Stir well before use.
- Do not dilute (ready-to-use).
- Processing conditions: Temperature 5 – 40°C, Relative humidity below 90%

Brush application: Application rate of 200 mL/m^2 as a single application.

Additional information regarding treatment of external, covered wood constructions:
- During application to timbers and whilst surfaces are drying prevent product losses to soil or water (avoid release to the environment). Losses should be contained by covering the ground below/adjacent to treated timbers with impenetrable material that is disposed of in an appropriate manner.

Storage

- Observe label precautions.
- Store in accordance with local regulations.
- Keep out of reach of children.
- Store in a dry, cool and well-ventilated area. Protect from frost.
- Containers that have been opened must be carefully resealed and kept upright to prevent leakage.
- Do not store where leakage to the ground or surface water can occur.
- Keep away from: oxidizing agents, strong alkalis, strong acids.
- Do not store near food, drink, animal feed or drinking water.
- The product is stable for two years at room temperature.

Disposal

Product:
- Unused product and any product collected during application that is not re-used must be disposed of safely as hazardous waste in accordance with local / regional / national / international regulations.
- Do not dispose unwanted product to drains, sewers, or rainwater canals.
- The product must not be released to soil, groundwater, or surface water.

Packaging:
- Dispose in compliance with local regulations.
- Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues.

Materials:
- Do not clean used materials (like brushes, contaminated covers and coveralls) with water, but reuse or discard them in a safe way to dry waste.

Transport

- The product is not covered by the rules for transport of dangerous goods by road and sea according to ADR
and IMDG.

Fire

- Extinguish with powder, foam or carbon dioxide. Do not use water stream, as it may spread the fire.

- Send contaminated extinguishing water for destruction. If there is a risk of exposure to vapour and flue
gases, a self-contained breathing apparatus must be worn.
- Collect contaminated fire-fighting run-off.
- Dispose of relevant fire debris and contaminated fire-fighting run-off in accordance with local regulations.

2.2.9.2 Identity of relevant combustion products in case of fire

- The product is not directly flammable. Avoid inhalation of vapour and fumes – seek fresh air. Hazardous
fumes are formed in fire conditions.

2.2.9.3 Specific treatment in case of accident

First aid measures

- If medical advice is needed, have product container or label at hand.
- If symptoms occur, when symptoms persist, or in case of doubt seek medical attention.
- In case of unconsciousness, do not give anything by mouth; place in recovery position and seek medical advice.>
- Inhalation: Remove to fresh air. Keep person warm and at rest.
- Eye contact: Rinse open eye(s) (remove contact lens(es) if worn) for several minutes with copious clean water. Seek immediate medical advice.

- Skin contact: Remove contaminated clothing and shoes. Wash skin with soap and water. With persistent skin irritation consult a doctor.
- Ingestion: If swallowed, seek medical advice immediately and show this container or label. Keep person warm and at rest. Do NOT induce vomiting.

<u>Most important symptoms, acute and delayed</u>

- Irritation effects: This product contains substances which cause irritation to skin and eyes, or when inhaled.
Contact with locally irritative substances can cause the area of contact to be more prone to absorb
damaging substances such as allergens.

Emergency measures to protect the environment

- Prevent from spreading (e.g. by …).
- Contain and collect spillage with a suitable absorbent and put into a labelled lockable container for disposal as hazardous waste.
- Avoid an accidental discharge into sewers, surface water or soil. Soil contaminated by the undiluted product should be treated as hazardous waste.
- In case of an accidental discharge of a large amount of the concentrated product to surface water, groundwater or sewer inform the appropriate authorities according to local regulations.

2.2.9.4 Possibility of destruction or decontamination following release

Soil

Methods and materials for containment and cleaning up:
- Contain and collect spillage with non-combustible, absorbent material (e.g. sand, earth, vermiculite or diatomaceous earth) that should be transferred to a suitable container.
- Dispose of contaminated material as waste according to local regulations.

2.2.10 Assessment of a combination of biocidal products

This product is not intended to be used together with other biocidal products.

2.2.11 Comparative assessment

DK CA COMPARATIVE ASSESSMENT REPORT FOR Boracol 10_3Bd

In Article 5(2) of the BPR it is stated that a product containing an active substance which fulfils the Criteria for Exclusion can be approved if it fulfils at least one of three conditions; if the risk from the active substance to humans or the environment is negligible, if the active substance is essential to control a serious danger, or a non-approval would have a serious impact on society. It is the DK CA's opinion that Boracol 10_3Bd fulfils the first of these conditions. Therefore, the DK CA has performed a Comparative Assessment. The Comparative Assessment is conducted for boric acid and disodium tetraborate combined, as they can be considered as boric acid equivalents (BAEs).

Background

The Danish competent authority has been processing an application for a biocidal product (Boracol 10_3Bd) which contains two active substances which meet the criteria for exclusion under Article 5(1) of the Biocidal Products Regulation (528/2012) (boric acid and disodium tetraborate). Therefore in line with Article 23(1) of the Regulation the DK CA has conducted a comparative assessment for the product and has produced the following comparative assessment report.

Active substance in the biocidal product and criteria for substitution and exclusion

The biocidal product Boracol 10_3Bd is a wood preservative product containing three active substances: boric acid, disodium tetraborate, and DDAC. The two boron compounds are considered to meet the criteria for exclusion under Article 5(1)c as they have been classified according to Regulation (EC) No 1272/2008 as toxic for reproduction category 1B (H360DF). Under Article 23(1) of Regulation 528/2012, Member States evaluating biocidal product containing an active substance that is a Candidate for Substitution in accordance with Article 10(1) are required to perform a Comparative Assessment. The DK CA has therefore used the approach in the most recent EU guidance[23] on the Comparative Assessment of the biocidal product. In line with this Note for Guidance, the DK CA began the Comparative Assessment with the screening phase (Annex 1.1 of guidance document) to identify whether the diversity of the active substances - mode of action combination in authorised biocidal products is adequate.

23 Notes for guidance: Comparative assessment of biocidal products – Consolidated version of CA Sept13-Doc.5.1.f & CA-Dec13-Doc5.1.k-Final: Ca-March14-Doc.5.

Screening phase of comparative assessment

Intended use of the biocidal product and properties of active substances

Article 23(3) and the Note for Guidance focus the comparative assessment on the uses specified in the application of the biocidal product, as the comparative assessment has to be product specific. The table only presents the uses which had no unacceptable risks to human health or the environment based on the respective assessments as well as only the target organisms for which appropriate efficacy tests were available.

Intended uses of the biocidal product

Product type	PT8, wood preservative
Where relevant, an exact description of the authorised use	Wood preservative for wood in Use Class 2.
Target organism (including, where relevant development stage)	• Mould and wood-destroying fungi including dry rot.
Field(s) of use	Indoor. For use as a surface application *in-situ* building material to preserve against attack from mould and wood-destroying fungi.
Application method(s)	Brushing
Category(ies) of users	Professionals, non-professionals

Chemical diversity of the active substances – mode of action combination in authorised biocidal products

According to the information available to the DK CA, there are approximately 104 biocidal products authorised under product type 8 (wood preservatives) of the Biocidal Products Directive and the Biocidal Products Regulations (including Mutual Recognitions and same product authorisations) in Denmark. These authorised products are based on seven active substances: tebuconazole, propiconazole, cypermethrin, IPBC, two boron compounds (disodiumoctaborat, tetrahydrate and boric acid) and basic copper carbonate, which are added either alone or in combination.

DK CA conclusions on the screening phase of the comparative assessment

During the screening phase only one other product on the Danish market with efficacy claim against mould and wood destroying fungi, including dry rot, was identified, and this product contains propiconazole, but is only authorised for indoor use in Use Class 2+3. This means that this product has a similar use to Boracol 10_3Bd, and can be considered an alternative BP. Therefore, the conclusion to the screening phase is that adequate chemical diversity to minimise resistance development was not found.

As boric acid and disodium tetraborate fulfill the Criteria for Exclusion, the assessment also needs to include Tier I-B and Tier II.

Tier I-B: Detailed comparison

The relevant use for this Comparative Assessment is: PT8, against mould and wood destroying fungi, including dry rot, professional and non-professional users, indoor, brushing and injection.

Boric acid and disodium tetraborate meet the Criteria for Exclusion due to their classification as toxic for reproduction category 1B, therefore this criteria is to be compared. The active substance in the alternative biocidal product (propiconazole) was recently agreed on by the REACH Committee to have the harmonised classification revised to toxic for reproduction category 1B. This classification will become legally applicable approximately 18 months after an amendment to Annex VI of the CLP regulation is performed, which was agreed on the 20th of February 2018. It can therefore be considered that the alternative biocidal product on the market does not have a lower risk to human health and the environment compared to Boracol 10_3Bd.

Further, an assessment of the economic and practical disadvantages have to be taken into consideration according to section 6.2.1.2 of the *'Technical Guidance Note on Comparative Assessment of Biocidal Products'.*
Boric acid has a unique characteristic as it can be used for remedial treatment and treatment where damage to the wood is likely or imminent, when the wood has a high moisture content; for example, to stop beginning degradation in a window frame outdoor or a beam in a cellar indoors. In both cases, it can be impossible to dry the wood enough before treatment and boron-containing products may be the only option.
Borates are unique preservatives, as they are the only system that so actively diffuses, making them useful materials in remedial applications and where traditional vacuum pressure applications are not effective enough (e.g. in the treatment of heartwood or refractory species).
As other authorised active substances do not show the same ability to diffuse and as this is a significant advantage for wood preservation, it can be argued that the alternative biocidal product show significant economical and practical disadvantages.

Tier II: Comparison to non-chemical alternatives

For the Tier II assessment, non-chemical alternatives need to be considered. This could e.g. be waiting for the wood to dry, and the applicant has also submitted an eligible non-chemical alternative, which is a method for enclosing a structure in a plastic tent and drying out the structure with heat or microwaves. While in some situations it is possible to enclose a structure and dry out the wood it is an expensive and time consuming method. Merely waiting for the wood to dry out can be very time consuming and is likely to establish decay fungi in the wood and cause mould growth on the surfaces that may lead to health problems. Using heat or microwaves to dry the wood also increases the carbon footprint. The use of a wood preservative product would not be eliminated.

DK CA conclusion on the comparative assessment

Boric acid and disodium tetraborate meet the exclusion criteria, due to the classification as toxic for reproduction category 1B and thus, a Comparative Assessment was conducted. The applicant had applied for Boracol 10_3Bd to have label claims against wood destroying fungi, mould and dry rot, for which efficacy has been shown. Therefore all intended uses were relevant for the comparative assessment.

During the screening phase the DK CA only found one biocidal product on the Danish market approved for mould and wood destroying fungi, including dry rot; this product had propiconazole as the active substance. Thus the chemical diversity for the intended use is not adequate to minimise risks of resistance.

The Comparative Assessment showed that the chemical diversity for the intended use is not sufficient to minimise resistance, i.e. less than three different active

substances approved for the use. In Tier I-B the specific characteristics such as penetrative properties and possibility to use on wet wood of boric acid as wood preservative were discussed. Further the only alternative biocidal product have the same classification as Boracol 10_3Bd as toxic for reproduction category 1B, and so the alternative biocidal product would have the same impact on human and environmental health.

The DK CA is interested in having products against mould and wood destroying fungi on the Danish market. Therefor the DK CA finds it justifiable to approve a product with boric acid and/or disodium tetraborate, which meet the Criteria for Exclusion, as there is no better alternative on the market.

In Article 5(2) of the BPR it is stated that a product containing an active substance which meet the Criteria for Exclusion can be approved if it fulfills at least one of three conditions; if the risk from the active substance to humans or the environment is negligible, if the active substance is essential to control a serious danger, or a non-approval would have a serious impact on society. It is the opinion of the DK CA that Boracol 10_3Bd with the intended use currently accepted fulfill the first condition. Consequently, the product can be approved.

3 ANNEXES

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

IUCLID Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
6.001	648112-1	Danish Technological Institute	2016	EN839+EN73 Trænedbrydning, overfladebeh. UC 2	KRS ApS			X	
6.006	735381-4	Danish Technological Institute	2017	EN839+EN73 Trænedbrydning, overfladebeh. UC 2 *Serpula lacrymans*	KRS ApS			X	
6.005	735381-2	Danish Technological Institute	2017	ENV12404 Serpula lacrymans - mortar	KRS ApS			X	
6.004	628367-1	Danish Technological Institute	2014	Boracol 10_3Bd EN 152 +EN 73	KRS ApS			X	
6.002	648118-1	Danish Technological Institute	2014	Boracol 10_3Bd BS3900 painted surface	KRS ApS			X	
6.003	648118-2	Danish Technological Institute	2015	Boracol 10_3Bd BS3900 Preliminary report	KRS ApS			X	
6.003	648118-3	Danish Technological Institute	2014	Boracol 10_3Bd BS3900 final pine and gypsum	KRS ApS			X	
6.001	16-093Z	FCBA	2016	FCBA_assessment_report_n_16-093Z_(D.M.E.)_-_V4-1	KRS ApS			X	
3.4.1.001	648104-1	Danish Technological Institute	2016	Boracol 10_3Bd accelerated stabilitetstest	KRS ApS			X	
3.4.1.004	712726-2	Danish Technological Institute	2017	one year intermediate results	KRS ApS			X	
3.8	AQ015-17	BioGenius	2017	B10_3Bd, BS surface tension and density	KRS ApS			X	
4.001	AQ014-17	BioGenius	2017	BioGenius report AQ014-17 B10_3Bd, BS flashpoints	KRS ApS			X	

IUCLID Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
5.001	740675	Danish Technological Institute	2017	DTI report 740675 B10_3Bd, BA equivalent content, validation	KRS ApS			X	
5.002	1379321	Danish Technological Institute	2017	DTI report 1379321 B10_3Bd, BS DDAC content, validation	KRS ApS			X	
3.4.1	J712726-3	Danish Technological Institute	2018	Test report. Storage stability of Boracol 10_3Bd. Report no.: 712726-3 (rev. 1)	KRS ApS			X	
13.12		KRS ApS		B10_3Bd compliance with Article 5.2	KRS ApS			X	
13.13		KRS ApS		B10_3Bd info for Article 10(1) comparative assessment	KRS ApS			X	
13.14		Peter J. Beutel and Philip D. Evans	2000	A Comparison of the Diffusion…..	KRS ApS				X
13.15				AWPA-Freeman-Boron-Paper-08	KRS ApS				X
13.16				Boracol 20 Axial and lateral penetration in pine and spruce 1993-03-04	KRS ApS				X
13.17				Boron non-resistance Dr Jeff Lloyd emails 151117	KRS ApS			X	
13.18.				Historical Structures and Object preserved with Boracol	KRS ApS				X
13.19				Pt 8 approved products					X
13.20				LoA Boron DK		X			
13.21				LoA Boron DE		X			
13.22				LoA Boron EE		X			
13.23				LoA Boron FI		X			
13.24				LoA Boron NL		X			
13.25				LoA Boron NO		X			
1326				LoA Boron SE		X			
13.1				LoA DDAC DK		X			
13.2				LoA DDAC DE		X			
13.3				LoA DDAC EE		X			
13.4				LoA DDAC FI		X			
13.5				LoA DDAC NO		X			
13.33				LoA DDAC SE		X			
13.34				LoA DDAC NL		X			
13.7				MSDS Bardac 22_DA					X
13.8				MSDS Dehybor Borax Anh SMDS DK					X
13.9				MSDS Boric Acid DK					X
13.10				MSDS PROPYLENGLYCOL_IBC 1000					X

IUCLID Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
13.11				MSDS Marlipal					X
13.6				MSDS B10_3BD DK					X
13.27				MSDS B10_3BD EE					X
13.28				MSDS B10_3BD FI					X
13.29				MSDS B10_3BD NL					X
13.30				MSDS B10_3BD NO					X
13.31				MSDS B10_3BD SE					X
13.32				MSDS B10_3BD DE					X
5.003				Assessment report Disodiumborate					X
5.003				Assessment report Boric acid					X
5.003				Assessment report DDAC					X
13.35				Cover letter					

3.2 Output tables from exposure assessment tools

Scenario [1a] – Mixing & loading for application by brushing (professionals)

Activity / Parameter	Units	Boric acid	Disodium tetraborate, anhydrous
Concentration of a.s. in Boracol 10 3Bd	% w/w	2,50%	2,38%
Duration of activity	min	10	10
Hand Exposure			
Hands, rate (90% percentile)[1]	mg/min	13	13
Hands, loading (90% percentile)[1]	mg	135	135
Hand dermal deposit as a.s.	mg	3,375	3,213
Hand dermal deposit as boron[2]	mg	0,591	0,691
Total dermal exposure			
A Total (= hand) dermal deposit as boron	mg	0,591	0,691
B Dermal absorption	%	20%	20%
Total systemic exposure via dermal route as boron[3]	mg/kg bw/day	0,0020	0,0023
Total systemic exposure, Tier 1			
Total systemic exposure as boron from the a.s.[4]	mg/kg bw/day	0,0020	0,0023

D Total systemic exposure as boron from both a.s.	mg/kg bw/day	0,0043	
AEL (boron)	mg/kg bw/day	0,1	
% AEL	**%**	**4,27%**	
Total systemic exposure, Tier 2 (refinements: glove penetration 10%)			
Total systemic exposure as boron from the a.s.[5]	mg/kg bw/day	0,0002	0,0002
Total systemic exposure as boron from both a.s.	mg/kg bw/day	0,0004	
AEL (boron)	mg/kg bw/day	0,1	
% AEL	**%**	**0,43%**	

[1] Determined using RISKOFDERM Dermal Model *Loading liquid, automated or semi-automated.*

[2] Conversion factor from mg a.s. to mg boron is 0.175 for boric acid and 0.215 for disodium tetraborate, anhydrous.

[3] Calculation: (A x B) / body weight (60 kg).

[4] Total system exposure = total dermal (hands) exposure, as rest-of-body exposure and inhalation exposure are considered negligible.

[5] Calculation: D / 10.

Output from RISKOFDERM *Potential Dermal Exposure Model* calculator estimating potential dermal exposure to Boracol_10 3BD during *Loading liquid, automated or semi-automated*. The 90% percentile value (marked with yellow) was used for further calculation of dermal exposure.

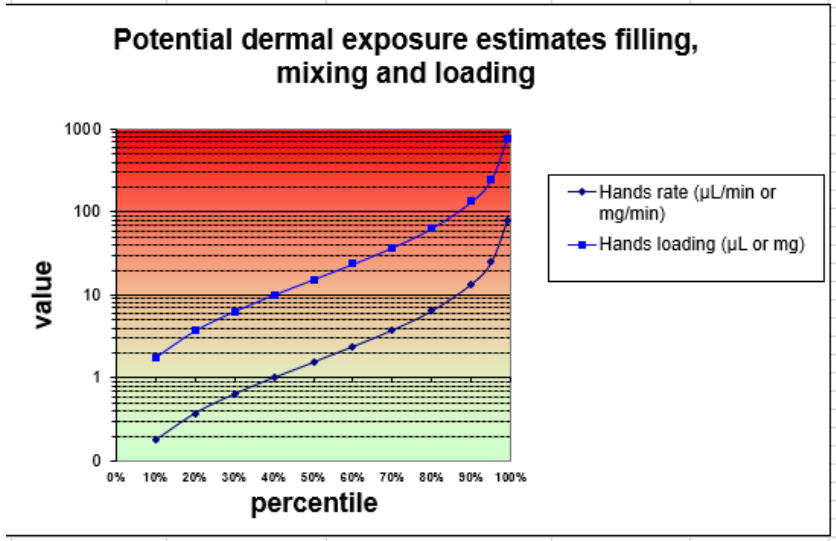
Inputs	Boracol 10	Warnings
What is the quality of the ventilation?	Normal or good ventilation	
What is the frequency of skin contact with the contamination?	Rare contact	
What kind of skin contact occurs?	Light contact	
What type of product is handled?	Liquid	
Do significant amounts of aerosols occur?	No	
What is the level of automation of the task?	Automated or semi-automated task	
Application rate of product (L/min or kg/min)	10	
Cumulative duration of scenario per shift (min)	10	

Back

Print

See the guidance for some remarks on different criteria for the performance of the model.

Results - percentile	Hands (820 cm²)		
	Hands rate (µL/min or mg/min)	Hands loading (µL or mg)	Remarks
10,0%	0	2	
20,0%	0	4	
30,0%	1	6	
40,0%	1	10	
50,0%	2	**16**	
60,0%	2	24	
70,0%	4	38	
80,0%	6	64	
90,0%	13	135	
95,0%	25	248	
99,0%	78	784	



Scenario [1b] – Application by brushing (professionals)

Activity / Parameter	Units	Boric acid	Disodium tetraborate, anhydrous
Concentration of a.s. in Boracol 10_3Bd	% (w/w)	2,50%	2,38%
Duration	min	240	240
Body exposure			
Indicative value (normalised to 1% a.s.)	mg/m^2	0,2382	0,2382
Indicative value (corrected to a.s.)	mg/m^2	0,596	0,567
Application area	m^2	31,6	31,6
D Body dermal deposit as a.s.	mg	18,818	17,915
Body dermal deposit as boron[1]	mg	3,293	3,852
Hand exposure			
Indicative value (normalised to 1% a.s.)	mg/m^2	0,5417	0,5417
Indicative value (corrected to a.s.)	mg/m^2	1,354	1,289

Application area	m^2	31,6	31,6
C Hand dermal deposit as a.s	mg	42,794	40,740
Hand dermal deposit as boron[1]	mg	7,489	8,759
Total dermal exposure			
A Total dermal deposit as boron	mg	10,782	12,611
B Dermal absorption	%	20%	20%
Total systemic exposure via dermal route as boron[2]	mg/kg bw/day	0,0359	0,0420
Exposure by inhalation			
Indicative value (normalised to 1% a.s.)	mg/m^2	0,0016	0,0016
Indicative value (corrected to a.s.)	mg/m^2	0,004	0,004
Application area	m^2	31,6	31,6
E Inhaled a.s.	mg	0,126	0,120
Systemic exposure via inhalation route as a.s.[3]	mg/kg bw/day	0,0021	0,0020
Systemic exposure via inhalation route as boron[1]	mg/kg bw/day	0,0004	0,0004
Total systemic exposure, Tier 1			
Total systemic exposure as boron from the a.s.	mg/kg bw/day	0,0363	0,0425
Total systemic exposure as boron from both a.s.	mg/kg bw/day	0,0788	
AEL of boron	mg/kg bw/day	0,1	
% AEL	**%**	**78,8%**	
Total systemic exposure, Tier 2 (refinements: coveralls penetration 10%, glove penetration 10%)			

Total systemic exposure via dermal route as boron from the a.s.	mg/kg bw/day	0,0036	0,0042
Total systemic exposure as boron from the a.s.	mg/kg bw/day	0,0040	0,0046
Total systemic exposure as boron from both a.s.	mg/kg bw/day	0,0086	
AEL boron	mg/kg bw/day	0,1	
%AEL	**%**	**8,6%**	

[1] Conversion factor from mg a.s. to mg boron is 0.175 for boric acid and 0.215 for disodium tetraborate, anhydrous.

[2] Calculation: (**A** x **B**) / body weight (60 kg).

[3] Calculation: **E** / body weight (60 kg).

Scenario [2] – Cleaning the brush (professionals) & Scenario [5] – Cleaning the brush (non-professionals)

	Tier 1	Tier 1	Tier 2	Tier 2	Units
	No gloves	No gloves	Gloves	Gloves	
Activity / Parameter	**Boric acid**	**Disodium tetraborate, anhydrous**	**Boric acid**	**Disodium tetraborate, anhydrous**	

Volume of brush	200	200	200	200	mL
Volume of paint remaining on brush after painting ($^1/_8$ of 200 ml = 25 ml)	25	25	25	25	mL
Density of paint	1,036	1,036	1,036	1,036	g/mL
Weight of paint on brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	25,90	25,90	25,90	25,90	g
Concentration of a.s. in paint	2,50	2,38	2,50	2,38	% (w/w)
A. Weight of a.s. on brush after painting	647,5000	616,4200	647,5000	616,4200	mg
B. Residues of a.s. on brush after 1st washing (10% of A)	64,7500	61,6420	64,7500	61,6420	mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	582,7500	554,7780	582,7500	554,7780	mg
C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	32,3750	30,8210	32,3750	30,8210	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of C)	3,2375	3,0821	3,2375	3,0821	mg
Penetration of a.s. through gloves	100	100	10	10	%
J Weight of a.s. on hand	3,23750	3,08210	0,32375	0,30821	mg

Dermal absorption of a.s.	20	20	20	20	%
Weight of a.s. entering the body	0,64750	0,61642	0,06475	0,06164	mg
D. Weight of a.s. left on the brush after 1st wash and squeezing (B – C)	32,3750	30,8210	32,3750	30,8210	mg
E. Residues of a.s. on brush after 2nd washing (10% of D)	3,2375	3,0821	3,2375	3,0821	mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	29,1375	27,7389	29,1375	27,7389	mg
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	1,6188	1,5411	1,6188	1,5411	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of F)	0,1619	0,1541	0,1619	0,1541	mg
Penetration of a.s. through gloves	100	100	10	10	%
K Weight of a.s. on hand	0,16188	0,15411	0,01619	0,01541	mg
Dermal absorption of a.s.	20	20	20	20	%
Weight of a.s. entering the body	0,03238	0,03082	0,00324	0,00308	mg
G. Weight of a.s. left on the brush after 2nd wash and squeezing (**E** – **F**)	1,6188	1,5411	1,6188	1,5411	mg

H. Residues of a.s. on brush after 3rd washing (10% of G)	0,1619	0,1541	0,1619	0,1541	mg
Amount of a.s. removed from the brush into the cleaning fluid (G – H)	1,4569	1,3869	1,4569	1,3869	mg
I. Weight of a.s. squeezed out from a brush onto a cloth (50% of H)	0,0809	0,0771	0,0809	0,0771	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of I)	0,0081	0,0077	0,0081	0,0077	mg
Penetration of **a.s.** through gloves	100	100	10	10	%
L Weight of a.s. on hand	0,00809	0,00771	0,00081	0,00077	mg
Dermal absorption of a.s.	20	20	20	20	%
Weight of a.s. entering the body	0,00162	0,00154	0,00016	0,00015	mg
A Total weight of a.s. entering the body	0,6815	0,6488	0,0681	0,0649	mg
B Body weight	60	60	60	60	kg
Total systemic exposure[2] as boron[1] from the a.s.	0,0020	0,0023	0,0002	0,0002	mg/kg bw/day
Total systemic exposure as boron from <u>both</u> a.s.	0,0043		0,0004		mg/kg bw/day
AEL boron	0,1		0,1		mg/kg bw/day
%AEL	**4,3%**		**0,4%**		**-**

[1] Conversion factor from mg a.s. to mg boron is 0.175 for boric acid and 0.215 for disodium tetraborate, anhydrous.

[2] Calculation: (**A** / **B**) x conversion factor for the respective borate.

Scenario [3] – Sanding treated wood (professionals)

Activity / Parameter	Boric acid, Tier 1	Disodium tetraborate, anhydrous,Tier 1	Boric acid, Tier 2	Disodium tetraborate, anhydrous,Tier 2
Concentration of a.s. in Boracol 10_3Bd (% w/w)	2,50%	2,38%	2,50%	2,38%
Density (g/cm³)	1,036	1,036	1,036	1,036
Concentration in wood				
Application rate (mL/m²)	200	200	200	200
Application rate of b.p. (g/m²)	207,2	207,2	207,2	207,2
A Application rate of a.s. (mg/cm²)	0,518	0,493	0,518	0,493
Area of wood to be sanded surface area cm² (4 x 4cm x 250cm + 2 x 4cm x 4cm)	4032	4032	4032	4032
Volume of outer layer cm³ (4 x 3cm x 249cm x 1cm + 2 x 3cm x 3cm x 1cm)	3008	3008	3008	3008
Amount of a.s. in wood (mg)	2088,6	1988,3	2088,6	1988,3
Exposure by inhalation				

Concentration of a.s. in wood dust (mg/cm³)	0,694	0,66	0,69	0,66
Wood dust concentration in air (mg/m³)	5	5	5	5
Exposure duration (h)	6	6	6	6
Inhalation rate (m^3/h)	1,25	1,25	1,25	1,25
Mitigation by RPE (PF)	1	1	1	1
Retention of a.s. in wood	100%	100%	100%	100%
Density of wood (g/cm³)	0,40	0,40	0,40	0,40
Amount dust inhaled in 6 hour (cm³)	0,09	0,09	0,09	0,09
Inhaled a.s (mg)	0,07	0,06	0,07	0,06
Body weight (kg)	60	60	60	60
Systemic exposure by inhalation route as a.s. (mg/kg bw/day)	0,0011	0,0010	0,0011	0,0010
Systemic exposure by inhalation route as boron[1] (mg/kg bw/day)	0,0002	0,0002	0,0002	0,0002
Dermal exposure				
A Concentration on the wood surface (mg/cm^2)	0,518	0,493	0,518	0,493
B Transfer coefficient (%): Tier 2 = with gloves	2%	2%	0,2%	0,2%
C Surface of palm of hand (cm^2)	410	410	410	410
D Dermal absorption (%)	20%	20%	20%	20%
E Body weight (kg)	60	60	60	60

Systemic exposure by dermal route as a.s. (mg/kg bw/day)[2]	0,0142	0,0135	0,0014	0,0013
Systemic exposure by dermal route as boron[1] (mg/kg bw/day)	0,0025	0,0029	0,0002	0,0003
Total systemic exposure				
Total systemic exposure as boron from the a.s. (mg/kg bw/day)	0,0027	0,0031	0,0004	0,0005
Total systemic exposure as boron from both a.s. (mg/kg bw/day)	0,0058		0,0009	
AEL boron (mg/kg bw/day)	0,1		0,1	
%AEL	**5,8%**		**0,9%**	

[1] Conversion factor from mg a.s. to mg boron is 0.175 for boric acid and 0.215 for disodium tetraborate, anhydrous.

[2] Calculation: (**A** x **B** x **C** x **D**) / **E**.

Scenario [4] – Application by brushing (non-professionals)

Activity / Parameter	Units	Boric acid	Disodium tetraborate, anhydrous
Concentration of a.s. in Boracol 10 3Bd	% (w/w)	2,50%	2,38%
Potential body exposure			
Indicative value	µL/min	1,70	1,70
Density Boracol 10 3Bd	mg/mL	1,036	1,036
Duration	min	155,00	155,00

Potential dermal deposit as b.p.	mg	272,99	272,99
A Actual dermal deposit as a.s	mg	6,82	6,50
Potential hand exposure			
Indicative value (potential)	µL/min	4,07	4,07
Density Boracol 10_3Bd	mg/mL	1,04	1,04
Duration	min	155,00	155,00
Hand deposit	mg	653,56	630,85
Mitigation by gloves		1	1
Actual hand deposit as b.p.	mg	653,56	630,85
B Actual hand deposit as a.s.	mg	16,34	15,01
Total dermal exposure			
Total dermal deposit as a.s.	mg	23,16	21,51
Total dermal deposit as boron[1]	mg	4,05	4,62
Dermal absorption	%	20%	20%
Systemic exposure via dermal route as boron	mg	0,81	0,92
Systemic exposure via dermal route as boron	mg/kg bw/day	0,0135	0,0154
Exposure by inhalation			
Indicative value	mg/m³	1,63	1,63
Duration	min	155,00	155,00

Inhalation rate	m^3/h	1,25	1,25
Mitigation by RPE (PF)		1	1
Inhaled b.p.	mg	5,26	5,26
Inhaled a.s. as boron[1]	mg	0,0230	0,0269
Body weight	kg	60	60
Systemic exposure via inhalation as boron	mg/kg bw/day	0,0004	0,0004
Total systemic exposure, Tier 1			
Total systemic exposure as boron from a.s.	mg/kg bw/day	0,0139	0,0159
Total systemic exposure as boron from both a.s.	mg/kg bw/day	0,0298	
AEL boron	mg/kg bw/day	0,1	
%AEL	**%**	**29,8%**	

[1] Conversion factor from mg a.s. to mg boron is 0.175 for boric acid and 0.215 for disodium tetraborate, anhydrous.

Scenario [5] – Cleaning the brush (non-professionals)

See under Scenario [2].

Scenario [6] – Sanding treated wood (non-professionals)

Activity / Parameter	Boric Acid	Disodium tetraborate, anhydrous
Concentration of a.s. in Boracol 10 3Bd (% w/w)	2,50%	2,38%
Density (g/cm³)	1,036	1,036
Concentration in wood		
Application rate (mL/m²)	200	200
Application rate of b.p. (g/m²)	207,2	207,2
A Application rate of a.s. (mg/cm²)	0,518	0,493
Area of wood to be sanded surface area (cm²) (4 x 4cm x 250cm + 2 x 4cm x 4cm)	4032	4032
Volume of outer layer (cm³) (4 x 3cm x 249cm x 1cm + 2 x 3cm x 3cm x 1cm)	3008	3008
Amount of a.s. in wood (mg)	2088,6	1988,3
Exposure by inhalation		
Concentration of a.s. in wood dust (mg/cm³)	0,69	0,66
Wood dust concentration in air (mg/m³)	5	5
Exposure duration (h)	1	1

Inhalation rate (m^3/h)	1,25	1,25
Retention of a.s. in wood	100%	100%
Density of wood (g/cm^3)	0,40	0,40
Amount dust inhaled in 1 hour (cm^3)	0,02	0,02
Inhaled a.s (mg)	0,011	0,010
Body weight (kg)	60	60
Systemic exposure by inhalation route as a.s. (mg/kg bw/day)	0,0002	0,0002
Systemic exposure via inhalation as boron[1] (mg/kg bw/day)	3,2E-05	3,7E-05
Dermal exposure		
A Concentration of a.s. on wood surface (mg/cm^2)	0,52	0,49
B Transfer coefficient (%)	2%	2%
C Surface of palm of hand (cm^2)	410	410
D Dermal absorption (%)	20%	20%
E Body weight (kg)	60	60
Systemic exposure by dermal route as a.s. (mg/kg bw/day)	0,0142	0,0135
Systemic exposure via dermal route[2] as boron[1] (mg/kg bw/day)	0,0025	0,0029
Total systemic exposure, Tier 1		

Total systemic exposure as boron from a.s. (mg/kg bw/day)	0,0025	0,0029
Total systemic exposure as boron from both a.s. (mg/kg bw/day)	0,0054	
AEL boron (mg/kg bw/day)	0,1	
%AEL	**5,4%**	

[1] Conversion factor from mg a.s. to mg boron is 0.175 for boric acid and 0.215 for disodium tetraborate, anhydrous.

[2] Calculation: ((**A** x **B** x **C** x **D**) / **E**) x conversion factor for the respective borate.

Scenario [7] – Handling treated wood once dry (non-professionals)

Activity / Parameter	Unit	Boric acid	Disodium tetraborate, anhydrous
Concentration of a.s. in Boracol 10 3Bd	% (w/w)	2,50%	2,38%
Wood contamination			
Application rate as b.p.	g/m²	207,2	207,2
Application rate as a.s.	mg/cm²	0,518	0,493
Percentage dislodgeable	%	3%	3%
A Dislodgeable a.s. residues	mg/cm²	0,0155	0,0148

Hand exposure			
B Transfer coefficient	cm²/day	410	410
C Number of cycles	episodes/day	3	3
Hand deposit as a.s.[1]	mg/day	19,11	18,20
Dermal absorption	%	20%	20%
D Systemic exposure via dermal route as a.s.	mg	3,82	3,64
E Body weight	kg	60	60
Total systemic exposure, Tier 1			
Systemic exposure via dermal route[3] as boron[2] from a.s.	mg/kg bw/day	0,0111	0,0130
Systemic exposure via dermal route[3] as boron[2] from both a.s.	mg/kg bw/day	0,0242	
AEL boron	mg/kg bw/day	0,1	
%AEL	**%**	**24,2%**	

[1] Calculation: (**A** x **B** x **C**).

[2] Conversion factor from mg a.s. to mg boron is 0.175 for boric acid and 0.215 for disodium tetraborate, anhydrous.

[3] Calculation: (**D** / **E**) x conversion factor for the respective borate.

Scenario [8] – Toddler touching freshly treated wood (general public)

Activity / Parameter	Boric acid	Disodium borate, anhydrous
Concentration of a.s. in Boracol 10_3Bd (% w/w)	2,50%	2,38%
Wood contamination		
Application rate of b.p. (g/m²)	207,2	207,2
Application rate of a.s. (mg/cm²)	0,518	0,493
Percentage dislodgeable (%)	50%	50%
Dislodgeable a.s. residues (mg/cm²)	0,259	0,247
Hand exposure		
Area: both palms (HEEG Opinion 17) (cm²)	115,2	115,2
Fraction of palms in contact with b.p. (%)	100%	100%
Hand deposit of a.s. (mg/day)	29,84	28,40
Dermal absorption (%)	20%	20%
Body weight (kg)	10	10
Systemic exposure via dermal route to a.s. (mg)	5,97	5,68
Systemic exposure via dermal route as boron[1] (mg/kg bw/d)	0,1044	0,1221
Oral exposure		
Hand deposit of a.s. (mg/day)	29,837	28,405

Transfer efficiency for hand to mouth (%)	10%	10%
Oral absorption (%)	100%	100%
Body weight (kg)	10	10
Systemic exposure via oral route to a.s. (mg)	2,98	2,84
Systemic exposure via oral route as boron[1] (mg/kg bw/d)	0,0522	0,0611
Total systemic exposure, Tier 1		
Total systemic exposure as boron[1] from a.s. (mg/kg bw/day)	0,1566	0,1832
Total systemic exposure as boron[1] from both a.s. (mg/kg bw/day)	0,3399	
AEL boron (mg/kg bw/day)	0,1	
%AEL	**340%**	

[1] Conversion factor from mg a.s. to mg boron is 0.175 for boric acid and 0.215 for disodium tetraborate, anhydrous.

Scenario [9] – Laundering professional work clothes at home (general public)

Activity / Parameter	Boric acid	Disodium tetraborate, anhydrous
Concentration of a.s. in Boracol 10 3_Bd (% w/w)	2,50%	2,38%

Clothing contamination		
Clothes deposit of a.s.[3] (mg/day)	18,818	17,915
Clothing contamination (%)	90%	90%
Actual clothes deposit of a.s. (mg/day)	16,936	16,123
Overall surface (cm²)	22700	22700
Surface concentration of a.s. (mg/cm²/day)	0,0007	0,0007
No of working days before washing	5	5
Percentage dislodgeable (%)	50%	50%
A Dislodgeable residues of a.s. (mg/cm²)	0,0019	0,0018
Hand exposure		
Area: both palms 3-times + backs of hands once (cm²)	1640	1640
Hand deposit of a.s. (mg/day)	3,06	2,91
Dermal absorption (%)	20%	20%
A Systemic exposure via dermal route as a.s. (mg)	0,6118	0,5824
B Body weight (kg)	60	60
Total systemic exposure, Tier 1		
Systemic exposure[2] as boron[1] from a.s. (mg/kg bw/day)	0,0018	0,0021

Systemic exposure[2] as boron[1] from both a.s. (mg/kg bw/day)	0,0039
AEL boron (mg/kg bw/d)	0,10
%AEL	**3,9%**

[1] Conversion factor from mg a.s. to mg boron is 0.175 for boric acid and 0.215 for disodium tetraborate, anhydrous.

[2] Calculation: (**A** / **B**) x conversion factor for the respective borate.

[3] **D** from Scenario [1b].

Summary of exposure calculations and combined exposure calculations

Scenario	Exposed group	Tier	Total systemic uptake of boron from boric acid (mg/kg bw/d)	% AEL	Total systemic uptake of boron from disodium tetraborate (mg/kg bw/d)	% AEL	Total systemic exposure to boron from boric acid and disodium tetraborate (mg/kg bw/d)	%AEL
1a. Mixing & loading	Professionals	1	0,0020	**2,0%**	0,0023	**2,3%**	0,0043	**4,3%**
1a. Mixing & loading	Professionals	2	0,0002	**0,2%**	0,0002	**0,2%**	0,0004	**0,4%**
1b. Application by brushing	Professionals	1	0,0363	**36,3%**	0,0425	**42,5%**	0,0788	**78,8%**
1b. Application by brushing	Professionals	2	0,0040	**4,0%**	0,0046	**4,6%**	0,0086	**8,6%**
2. Cleaning the brush	Professionals	1	0,0020	**2,0%**	0,0023	**2,3%**	0,0043	**4,3%**
2. Cleaning the brush	Professionals	2	0,0002	**0,2%**	0,0002	**0,2%**	0,0004	**0,4%**

3. Sanding treated wood	Professionals	1	0,0027	**2,7%**	0,0031	**3,1%**	0,0058	**5,8%**
3. Sanding treated wood	Professionals	2	0,0004	**0,4%**	0,0005	**0,5%**	0,0009	**0,9%**
4. Application by brushing	Non-professionals	1	0,0139	**13,9%**	0,0159	**15,9%**	0,0298	**29,8%**
5. Cleaning the brush	Non-professionals	1	0,0020	**2,0%**	0,0023	**2,3%**	0,0043	**4,3%**
6. Sanding treated wood	Non-professionals	1	0,0025	**2,5%**	0,0029	**2,9%**	0,0054	**5,4%**
7. Handling treated wood once dry	Non-professionals	1	0,0111	**11,1%**	0,0130	**13,0%**	0,0242	**24,2%**
8. Toddler touching wet treated wood	General public	1	0,1566	**156,6%**	0,1832	**183,2%**	0,3399	**339,9%**
9. Laundering prof. work clothes at home	General public	1	0,0018	**1,8%**	0,0021	**2,1%**	0,0039	**3,9%**

Combined exposure calculations

		Boric acid (mg/kg bw/d as boron)			**Disodium tetraborate, anh.** (mg/kg bw/d as boron)			**Boron** (mg/kg bw/d)	
Professionals	**Tier**	**Inhalation**	**Dermal**	**Total systemic**	**Inhalation**	**Dermal**	**Total systemic**	**Total systemic**	**%AEL for boron**
1a+1b+2	Tier 1	0,0004	0,0399	0,0403	0,0004	0,0467	0,0471	0,0874	**87,4%**
1a+1b+2	Tier 2	0,0004	0,0040	0,0044	0,0004	0,0047	0,0051	0,0095	**9,5%**
1a+1b+2+3+7+9	Tier 1 or 2*	0,0006	0,0172	0,0177	0,0007	0,0201	0,0207	0,0385	**38,5%**
Non-professionals	**Tier**								
4+5	Tier 1	0,0004	0,0155	0,0159	0,0004	0,0177	0,0182	0,0341	**34,1%**

DK				Boracol 10_3Bd			PT8		
4+5+6+7	Tier 1	0,0004	0,0291	0,0295	0,0005	0,0337	0,0342	0,0637	**63,7%**

* Tier 2 for scenarios [1a, 1b, 2, 3]

3.3 New information on the active substance

No new information on the active substances is submitted.

3.4 Residue behaviour

Residues are not relevant in relation to the applied use.

3.5 Summaries of the efficacy studies (IUCLID 6.7.001, 6.7.002)

Find study summaries of the efficacy studies in IUCLID and the evaluation of these in Appendix 2.

3.6 Environmental Risk Assessment

Not required.

3.7 Confidential annex

The *Confidential annex* to this PAR can be found in a separate document.

4 APPENDIX 1 – ADDENDUM TO PAR

Major change of the product formulation

R4BP3 case no: BC-GG069449-31

Authorisation no: BPR-reg. nr: 17-17

Date: 27.06.2022

OVERVIEW OF APPLICATIONS FOR BORACOL 10_3BD

Application type	RMS	Case number in the RMS	Decision date	Assessment carried out (i.e. first authorisation/ amendment/renewal)
NA-APP	DK	BC-TF035619-29	20.12.2019	First authorisation
NA-MAC	DK	BC-GG0069449-31	27.06.2022	Amendment, major change

4.1 Background

In the present application, KRS Aps applies for a major change of the product Boracol 10_3Bd. The applicant wishes to replace one of the active substances in the product, namely disodium tetraborate, anhydrous (CAS nr. 1330-43-4), with boric acid (CAS nr. 10043-35-3) and a new co-formulant. See the 'Confidential annex to Addendum to PAR' for Boracol 10_3Bd for information regarding the new co-formulant).

Replacing disodium tetraborate, anhydrous with boric acid and the new co-formulant will essentially result in the same active substance after formulation of the product because boric acid plus the new co-formulant in solution, and disodium tetraborate in solution, both become a mix of the same ions and boric acid. By replacing disodium tetraborate in Boracol 10_3Bd with boric acid and the new co-formulant, such that the amounts of boron (B) and sodium (Na) are unchanged, the main difference between the two formulations is a slightly lower content of solvent. No other chemical difference is expected to occur after the change.

New data relevant for this application has been evaluated. Data that were evaluated within the scope of the previous product authorisation of Boracol 10_3Bd have not been re-evaluated. See Section 1.2 'Physical/chemical properties and storage stability' for further information.

4.2 Physical/chemical properties and storage stability

Replacement of disodium tetraborate, anhydrous with boric acid and the new co-formulant results in a product composition that is essentially the same as the original formulation of Boracol 10_3Bd. Refer to the 'Confidential annex to Addendum to PAR' for Boracol 10_3Bd for a detailed discussion of changes to the composition of the product.

Qualitative and quantitative information on the composition of the biocidal product

Information on the new quantitative and qualitative composition of Boracol 10_3Bd is given in the table below. Full details of the formulation of the product is provided in section 3.7.4.2 of the 'Confidential annex to Addendum to PAR'

Common name	IUPAC name	Function	CAS number	EC number	Content TC (%)
Boric acid	Boric acid	Active substance	10043-35-3	233-139-2	5.43
Didecyldimethylammonium chloride, DDAC*	Didecyldimethyl-ammonium chloride	Active substance	7173-51-5	230-525-2	2.45
Propan-2-ol	Propan-2-ol	Solvent	67-63-0	200-661-7	0.98

* Didecyldimethylammonium chloride (DDAC) is provided by BARDAC 22/IBC 907 KG BA, a mixture comprising 50% w/w DDAC.

Physical, chemical and technical properties

To support the read-across between Boracol 10_3Bd as originally formulated and the new formulation, in which disodium tetraborate, anhydrous is replaced with

boric acid and the co-formulant, the applicant has provided an accelerated storage stability test for the new formulation; see Table 1 for details.

Table 0: Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **accelerated storage**	CIPAC method 46.3 Storage at 54 ± 2 °C for 2 weeks in a 1 L HDPE bottle.	Test item: Boracol 10_3Bd Batch no. 2021-07-14 Nominal AS content: Boric acid: 5.43% w/w DDAC: 2.45% w/w AS content: See results	**Boric acid content** (ICP-OES)**:** T_0: 5.30% w/w $T_{2\ weeks}$: 5.44% w/w (+ 2.6%) **DDAC content** (LC-MS)**:** T_0: 2.36% w/w $T_{2\ weeks}$: 2.40% w/w (+ 1.7%) **Product appearance** (visual inspection)**:** T_0: Easy-flowing liquid, transparent. $T_{2\ weeks}$: Easy-flowing liquid, transparent. **pH** (CIPAC MT 75.3, neat)**:** T_0: 7.7 $T_{2\ weeks}$: 7.7 (No change)	Johannesen (2021) Report no. 989197 ACC Rev.1

Conclusion

The accelerated storage test of the new formulation of Boracol 10_3Bd demonstrated acceptable variation for the parameters active substance content, appearance, and pH. Thus indicating that the new formulation of the product is stable for storage. As the pH of the original formulation (pH 7.6) and the new formulation (pH 7.7) is similar, replacing disodium tetraborate, anhydrous with boric acid and the new co-formulant is expected to result in a final (new) formulation that is highly similar to the original formulation. The main chemical difference between the two formulations is a slightly lower content of solvent in the new formulation. Consequently, the read-across between the products is considered as acceptable and no additional data are required to assess this major change.

4.3 Classification and labelling

The change does not require revision of the classification and labelling.

4.4 Efficacy

The PT8 CAR for boric acid (NL CA, 2009) and the PT8 CAR for disodium tetraborate (NL CA, 2009) both state in chapter 2.2.1 that:

> "The toxicokinetics and toxicological effects of boric acid, disodium tetraborate, boric oxide (B_2O_3) and disodium octaborate tetrahydrate are likely to be similar on a boron equivalents basis. Therefore, the data obtained from studies with different borates can be read across in the human health assessment for each individual substance."

Both CARs have performed the efficacy assessment, and the risk assessments for human health and for the environment on the basis of boron equivalent (BAE).

According to EN 559-1, Annex 1, and Guidance document Volume II Efficacy. Part B+C: Assessment and Evaluation in Appendix 12, no new efficacy tests need to be performed.

4.5 Impact of change on human health

The change has no implications for the outcome of the Human Health Risk Assessment (HHRA). According to Section 4.1, replacing disodium tetraborate, anhydrous with boric acid and the new co-formulant will not alter the concentration of the active substance in terms of boron equivalents (BAE). As noted in Section 4.4, (toxicological) data obtained from studies with different borates can be read across in the human health assessment for each individual substance, and the CARs for disodium tetraborate and boric acid have performed the risk assessment on the basis of boron equivalent (BAE). The concentration of the active substance DDAC in the product is unaffected by the change. As noted in Section 4.1, the main difference between the original formulation and the new formulation is a slightly lower content of solvent (water) in the latter; no other chemical difference is expected.

The new co-formulant plus boric acid become, on solution, a mix of the same ions and boric acid as present in the original formulation of in Boracol 10_3Bd. However, the inclusion of a new co-formulant requires that it is evaluated as a potential Substance of Concern (SoC). This evaluation, presented in the 'Confidential Annex to Addendum to PAR' document, does not find the new co-formulant to be a SoC. Consequently, its inclusion (in combination with boric acid as a replacement for disodium tetraborate, anhydrous) has no effect on the human health risk assessment.

4.6 Impact of change on environmental risk assessment

The change has no implications for outcome of the Environmental Risk Assessment (ERA). According to Section 4.1, replacing disodium tetraborate, anhydrous with boric acid and the new co-formulant will not alter the concentration of the active substance in terms of boron. As noted in Section 4.4, (ecotoxicological) data obtained from studies with different borates can be read across for each individual substance, and the CARs for disodium tetraborate and boric acid have performed the risk assessment on the basis of boron. The concentration of the active substance DDAC in the product is unaffected by the change. As noted in Section 4.1, the main difference between the original formulation and the new formulation

is a slightly lower content of solvent in the latter; no other chemical difference is expected.

4.7 Change of label instructions

The change does not require revision of the label instructions.

4.8 Overall conclusion

Sufficient evidence was provided to demonstrate that the major change does not affect the physical and chemical properties, the risk assessments for human health and the environment, nor the conclusions with regard to efficacy. Based on the argumentation above, the major change can be authorised without changes to the intended use or classification of the biocidal product.

List of studies for the biocidal product:

IUCLID Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
Please refer to R4BP-3 case no. BC-GG069449-31	989197 ACC Rev.1	Danish Tech-nological Institute; Jonannesen, S. A.	2021	Test report. Accelerated storage stability study of Boracol 10_3Bd.	KRS ApS			X	

List of Appendices:

Appendix number	Year	Title	Data protection claimed	owner
1	2021	Boracol 10 3Bd with Boric Acid instead of Disodium Tetraborate Anhydrous	yes	KRS Aps
2	2021	Appendix 1_PAR_minor_major change	yes	KRS Aps

The appendices contains confidential information and are therefore presented in the 'Confidential annex to Addendum to PAR'.