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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT (FAMILY) FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

Boracol 15

Product type 08

Boric acid as included in the Union list of approved active substances

Case Number in R4BP: BC-PE052632-46

Evaluating Competent Authority: DK

Date: 09.06.2021

Table of Contents

1 CONCLUSION

The Applicant, KRS (Denmark) submitted on 05.07.2019 an application (R4BP-3 Case nr. BC-PE052632-46) under Regulation (EU) No 528/2012 (BPR), application type NA-MRP (rMS Denmark), for authorisation of Boracol 15 in PT8.

The rMS's assessment included consideration of the specific provisions in Commission Directive 2009/94/EC (of 31 July 2009) addressing inclusion of the active substance boric acid in Annex I to Direcive 98/8/EC as an active substance for use in Product Type 8 (PT8), wood preservatives, and consideration of the 'elements to be taken into account by Member States when authorising products' as stated in the Competent Authority Report (CAR) for boric acid (CA NL, 2009).

The Danish Competent Authority (DK CA) proposes authorisation of the biocidal product Boracol 15 for use by professionals only as a wood preservative (PT8) for *in situ* treatment of indoor/covered wood constructions such as roof trusses, braces, and floor separations (Use class 1 and 2) to which people, domestic animals and livestock do not come into direct contact. Boracol 15 can be used for preventive treatment of softwood and hardwood against brown rot fungi (*Coniophora puteana, Poria placenta, Gloeophyllum trabeum*, and *Serpula lacrymans*). 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. Boracol 15 can be used for preventive treatment of softwood and hardwood against wood-boring beetles (*Hylotrupes bajulus*, *Anobium punctatum*, and *Lyctus brunneus*).

Boracol 15 should be applied by superficial application (brushing) at an application rate of 182 g/m^2, equivalent to 157 mL/m^2. Boracol 15 may also be applied by non-pressurised injection into boreholes to treat those parts of *in situ* wooden structures that are not accessible for superficial treatment. Non-pressurised injection is supplementary to superficial application, such that where possible the accessible surface of wood treated by non-pressurised injection should also be treated by superficial application. The application rate for non-pressurised injection is the same as for superficial application. There are no standard application conditions. Professional judgement is required to establish the appropriate approach under the circumstances. The authorisation holder should be consulted on a case-by-case basis for guidance regarding conditions (requirements) for application via non-pressurised injection.

Boracol 15 contains the active substance boric acid (16.5% w/w). Boric acid meets the exclusion criteria under Article 5(1)c of the Biocidal Products Regulation (BPR) (528/2012) due to classification for reproductive toxicity (Repr. 1B, H360DF). Paragraph 10 of Annex VI (*Common principles for the evaluation of dossiers for biocidal products*) of the BPR states that in the case of biocidal products containing active substances covered by the exclusion criteria in Article 5(1), the competent authorities [or the Commission] shall also evaluate whether the conditions of Article 5(2) can be satisfied. Fungal- and wood-boring beetle infestation of wooden building constructions can be problematic in Denmark. The DK CA considers it necessary to have biocidal products against wood-destroying fungi (including dry rot) and wood-boring beetles on the Danish market, particularly for use in

the preservation of culturally important building such as churches and other buildings considered worthy of preservation. The Applicant has presented information regarding the suitability of the active substance (boric acid) in Boracol 15 for use in treating wooden building constructions, including when affected by elevated moisture content, and documented the efficacy of Boracol 15 for treatment of wood against wood-destroying fungi and wood-boring beetles. Evaluation of the claimed uses of Boracol 15 shows acceptable exposure for professionals (the only user category) at worst-case; exposure of the general public is limited to possible handling of contaminated work clothing prior to mechanical laundering, while exposure of pets and domestic animals, and emissions to the environment, are not expected. Thus Boracol 15 is considered to meet the conditions of 5(2)c of the BPR. According to Article 10(1)a of the BPR, an active substance that meets at least one of the exclusion criteria listed in Article 5(1) but which may be approved in accordance with Article 5(2) is considered a candidate for substitution, and according to Article 23 of the BPR a Comparative Assessment shall be performed for a biocidal product containing an active substance that is a candidate for substitution. A Comparative Assessment by DK CA of the proposed label claims of use against brown rot fungi (including *Serpula lacrymans*) and the wood-boring beetles *Hylotrupes bajulus*, *Anobium punctatum*, and *Lyctus brunneus* found, in the screening phase, only one biocidal product on the Danish market approved for preventative treatment of brown rot fungi and the three beetle species; the product contain propiconazole, tebuconazole, IPBC and cypermethrin as active substances. Thus, chemical diversity for the intended use is not adequate to minimise risk of resistance. Furthermore, the alternative biocidal product also contains an active substance classified for reproductive toxicity (Repr. 1B). In conclusion, there is not an adequate number of safer alternative biocidal products on the Danish market. Consequently, the DK CA finds it justifiable to approve Boracol 15.

Based on the assessment of Boracol 15 the following was noted for phys/chem, efficacy, human health and environment:

Analytical Methods and Physico-Chemical Properties

Boracol 15 is a solvent-based formulation packed in HDPE containers. Based on the physico-chemical properties, the product is not explosive, flammable or corrosive to metals, and does not require classification for physical hazards according to the CLP-regulation.

The majority of the endpoints have been adequately addressed by the applicant. The accelerated storage stability study (40°C, 8 weeks) indicates that the product is stable during storage with no variation in physical- or chemical properties after the study. Interim results (after 20 months) of the long-term stability study show acceptable stability of the active substance. In combination with the accelerated storage stability study, the Danish EPA preliminary accepts a shelf-life claim of 2 years.

The product will be approved with a post-authorisation requirement for submission of an acceptable long-term storage stability study, which must be submitted by 1 July 2021.

Efficacy

Boracol 15 has documented efficacy when the product is applied indoors (for wood: Use class 1 & 2) by superficial application (brushing) at a rate of 157 mL/m^2 to support claims for:

Preventive treatment of:

- wood against brown rot fungi (*Coniophora puteana, Poria placenta, Gloeophyllum trabeum*, and *Serpula lacrymans*) in Use class 2.
- masonry against the dry rot fungus *Serpula lacrymans* to prevent adjacent wood from being affected.
- wood against wood-boring beetles (*Hylotrupes bajulus*, *Anobium punctatum*, and *Lyctus brunneus*), larvae, in Use classes 1 and 2.

Curative treatment of:

- masonry against the dry rot fungus *Serpula lacrymans* to prevent adjacent wood from being affected.

No data tests for assessing the efficacy of application of Boracol 15 by non-pressurised injection were submitted as there are no standardised tests for assessing the efficacy of injection of wood preservatives. In the absence of relevant data the expected efficacy of this application method (when the product is applied at the same application rate recommended for superficial application, i.e. 182 g/m^2, equivalent to 157 mL/m^2) is based on the studies of efficacy on superficial application, and is as follows:

Preventive treatment of:

- wood against brown rot fungi (*Coniophora puteana, Poria placenta, Gloeophyllum trabeum*, and *Serpula lacrymans*) in Use class 2.
- wood against wood-boring beetles (*Hylotrupes bajulus*, *Anobium punctatum*, and *Lyctus brunneus*), larvae, in Use classes 1 and 2.

Human health

Professional use

Based on exposure- and risk assessment of the uses applied for, acceptable use of Boracol 15 by professionals using appropriate personal protective equipment (PPE) was identified for application* of the product by brushing or by non-pressurised injection (* including equipment- loading and cleaning activities associated with the application tasks). Other activities that could result in exposure of a professional to Boracol 15 did not result in unacceptable risk, including when their exposure contribution was added to those for the acceptable uses (i.e. in combined exposure scenarios). It can be concluded that professional use of Boracol 15, when used as recommended, does not pose an unacceptable risk to human health when appropriate risk mitigation measures (RMMs) are employed. The following RMMs are triggered:

- *Wear protective chemical-resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).*
- *A protective coverall (at least type 6, EN 13034) shall be worn.*
- *Use automatic dosage equipment instead of manual mixing and loading.*

General public

Based on the proposed situations of use, exposure of the general public to Boracol 15 is considered unlikely. However, as a significant risk for toddlers touching freshly treated wood and subsequently mouthing was identified, the following RMM is triggered:

- *Keep children and pets away from the product and treated wood during application and drying.*

No other risks for the general public were identified, however to protect human health and animal health (pets and domestic animals), the following labelling RMMs are considered appropriate:

- *Do not use on wood which may come in direct contact with food, feeding stuff and livestock animals.*
- *Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.*

Environment

No emissions to any environmental compartment are expected as the product is applied indoors and the service life is indoors, cf. the ESD for PT8. No environmental exposure or risk will therefore occur based on the authorised uses. In order to protect the soil and aquatic compartments, the following labelling RMMs are listed:

- *Do not treat wood that comes in direct contact with soil or water.*
- *Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer.*

As Boracol 15 can be harmful to protected organisms that may reside in treated structures, the following labelling RMM is considered appropriate:

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

Endocrine-disrupting properties

Boracol 15 has not been tested for potential endocrine-disrupting properties. Substances in the product do not have endocrine disruption indications based on current scientific knowledge and the available toxicological- and ecotoxicological information. Thus Boracol 15 is not considered to having endocrine-disrupting properties.

Summary

it is concluded that Boracol 15 meets the conditions of Article 19 of the BPR (Regulation (EU) no. 528/2012) and may authorised.

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 15	Denmark Estonia (cMS) Finland (cMS) Germany (cMS) Norway (cMS) 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-0026321-0000	
Date of the authorisation	09.06.2021	
Expiry date of the authorisation	09.06.2026	

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 substance

Active substance	Boric acid
Name of manufacturer	Rio Tinto Iron & Titanium GmbH
Address of manufacturer	Alfred-Herrhausen-Allee 3-5, 65760 Eschborn, Germany
Location of manufacturing sites	14486 Borax Road CA 93516-2000 Boron United States

Active substance	Boric acid
Name of manufacturer	Etimine S.A.

Address of manufacturer	Immeuble 67 204, Z.I. Scheleck 2 L-3225, Bettembourg, Luxemborg
Location of manufacturing sites	Emet, 43700 Kütahya, Turkey

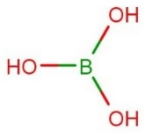
2.1.2 Product composition and formulation

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 substance

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	 $B(OH)_3$

2.1.2.2 Candidate(s) for substitution

Boracol 15 contains the active substance boric acid which meets the exclusion criteria of Article 5(1)c of the BPR, however according to paragraph 10 of Annex VI of the BPR, Article 5(2) of the BPR, and Article 10(1)a of the PBR, rMS DK considers boric acid to be a candidate for substitution. Find further information in the comparative assessment in section 2.2.11.

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

Only content of active substances are shown in the table below. A full composition can be found in the confidential annex.

Common name	IUPAC name	Function	CAS number	EC number	Content TC (% w/w)
Boric acid	Boric acid	Active substance	10043-35-3	233-139-2	16.5

2.1.2.4 Information on technical equivalence

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

2.1.2.5 Information on the substance(s) of concern

Human Health

Boracol 15 does not contain any substances of concern (SoCs) for human health 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[1]. See section 3.7.2 of the Confidential Annex for discussion of SoCs. A co-formulant is also considered a SoC if it has known or possible endocrine-disrupting properties; these criteria are not met by any of the co-forumulants in Boracol 15 (see under the heading *Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)* in Section 2.2.6.1, and in Section 3.7.3 of the Confidential Annex, for further information).

Environment

Boracol 15 does not have any SoC for the environment according to Article 3(f) of Regulation (EU) No. 528/2012, and 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-disrupting properties. The product does not have endocrine disruption indications based on current scientific knowledge, including available toxicological- and ecotoxicological information (see Confidential Annex Section 3.7.3 for full evaluation).

2.1.2.6 Type of formulation

AL – Any other liquid

1 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 Humana Health – Assessment & Evaluation (Parts B+C), Version 4.0, December 2017).

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Repr. 1B
Hazard statement	H360FD: May damage fertility. May damage the unborn child.
Labelling	
Signal words	Danger
Pictogram	GHS08
Hazard statements	H360FD: May damage fertility. May damage the unborn child.
Precautionary statements[2]	P201: Obtain special instructions before use. P202: No not handle until all safety precautions have been read and understood. P280: Wear protective gloves/protective clothing/eye protection/face protection*. P308+P313: IF exposed or concerned: Get medical advice / attention. P405: Store locked up. P501: Dispose of contents/container to … in accordance with local/regional/national/international regulations (to be specified).
Note	* Manufacturer/supplier to specify the appropriate types of equipment.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Use # 1 Application by brushing to wood and adjacent masonry as a fungicide and insecticide, professional use

Product Type	PT8	Field code
Where relevant, an exact description of the authorised use	Fungicide and Insecticide	

[2] Based on established Danish practice, the following will be required on national authorisation: P101 (If medical advice is needed, have product container or label at hand.); P102 (Keep out of reach of children.), which will be combined with P405; P202 will not be required.

Target organism (including development stage)	Brown rot fungi (*Coniophora puteana, Poria placenta, Gloeophyllum trabeum*, and *Serpula lacrymans*), no data House longhorn beetle (*Hylotrupes bajulus*), larvae Common furniture beetle (*Anobium punctatum*), larvae Brown powderpost beetle (*Lyctus brunneus*), larvae	G.10 G.31 G.32 G.33
Field of use	Preventive treatment of wood against brown rot fungi in Use Class 2. Preventative and curative treatment of masonry against the dry rot fungus *Serpula lacrymans* to prevent adjacent wood from being affected. Preventive treatment of wood against wood-boring beetles in Use classes 1 and 2. Softwood and hardwood Masonry adjacent to treated wood Preventive treatment Curative treatment (for masonry against the dry rot fungus *Serpula lacrymans*) Use class 1 and 2 (for wood) Indoor.	 B.10, B.20 - D.40 D.50 E.10, E.20
Application method(s)	Brushing	F.10
Application rate(s) and frequency	182 g/m^2, equivalent to 157 mL/m^2 Once	
Category(ies) of users	Professional	A.30
Pack sizes and packaging material	Bottle: 1 L (HDPE), PP closure Can/tin: 2.5, 5, 10 and 20 L (HDPE), PP closure Drum: 200 L (HDPE), PP closure IBC: 1000 L (HDPE), PP closure Closure child-resistant on 1, 2.5 and 5 L pack sizes	

2.1.4.2 Use-specific instructions for use

See Section 2.1.5. In the case of the dry rot fungus, *Serpula lacrymans*, the product may be applied to masonry by brushing to prevent growth of the fungus into adjacent wood. The product should only be used on areas of masonry that are protected from precipitation.

When treating masonry it must be ensured that the application solution does not contaminate the environment.

2.1.4.3 Use-specific risk mitigation measures

See Section 2.1.5.

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 Section 2.1.5.

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

See Section 2.1.5.

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 Section 2.1.5.

2.1.4.7 Use description

Use # 2 Application by non-pressurised injection to wood as a fungicide and insecticide, professional use

Product Type	PT8	Field code
Where relevant, an exact description of the authorised use	Fungicide and Insecticide	
Target organism (including development stage)	Brown rot fungi (*Coniophora puteana, Poria placenta, Gloeophyllum trabeum*, and *Serpula lacrymans*), no data House longhorn beetle (*Hylotrupes bajulus*) larvae Common furniture beetle (*Anobium punctatum*) larvae Brown powderpost beetle (*Lyctus brunneus*) larvae	G.10 G.31 G.32 G.33

Field of use	Preventive treatment of wood against brown rot fungi in Use Class 2. Preventive treatment of wood against wood-boring beetles in Use classes 1 and 2. Softwood and hardwood Preventive treatment Use class 1 and 2 Indoor.	 B.10, B.20 D.40 E.10, E.20
Application method(s)	Non-pressurised injection into boreholes Non-pressurised injection is used to treat those parts of *in situ* wooden structures that are not accessible for superficial treatment. Non-pressurised injection is supplementary to superficial application, such that where possible, the accessible surface of wood treaded by non-pressurised injection should also be treated by superficial application. There are no standard application conditions. Professional judgement is required to establish the appropriate approach (including the positioning, spacing, diameter, depth, etc. of boreholes to receive the required quantity of the product) under the circumstances. The authorisation holder should be consulted on a case-by-case basis for guidance regarding conditions (requirements) for application via non-pressurised injection.	F.20
Application rate(s) and frequency	182 g/m^2, equivalent to 157 mL/m^2	
Category(ies) of users	Professional	A.30
Pack sizes and packaging material	Bottle: 1 L (HDPE), PP closure Can/tin: 2.5, 5, 10 and 20 L (HDPE), PP closure Drum: 200 L (HDPE), PP closure IBC: 1000 L (HDPE), PP closure Closure child-resistant on 1, 2.5 and 5 L pack sizes	

2.1.4.8 Use-specific instructions for use

See Section 2.1.5.

2.1.4.9 Use-specific risk mitigation measures

See Section 2.1.5.

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

See Section 2.1.5.

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

See Section 2.1.5.

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

See Section 2.1.5.

2.1.5 General directions for use

2.1.5.1 Instructions for use

For *in situ* treatment of covered wood constructions such as roof trusses, wood braces, and floor separations to which people, domestic animals and livestock do not come into direct contact. In the case of the dry rot fungus, *Serpula lacrymans*, the product may be applied to masonry by brushing to prevent growth of the fungus into adjacent wood.

If infestation by *Serpula lacrymans* is suspected, 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 product before use.

Do not dilute (ready-to-use).

Ensure adequate ventilation during the application.

Avoid contact with skin and eyes.

Wash hands after application and use of the product, and before eating, drinking or smoking.

Processing conditions: Temperature 5 – 40°C; Relative humidity below 90%.

Brush application: Application rate of 157 mL/m^2 (equivalent to 182 g/m^2) as a single application.

Non-pressurised injection: Application rate of 157 mL/m^2 (equivalent to 182 g/m^2).

2.1.5.2 Risk mitigation measures

Keep children and pets away from the product and treated wood during application and drying.

Wear protective chemical-resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

A protective coverall (at least type 6, EN 13034) shall be worn.

Use automatic dosage equipment instead of manual mixing and loading.

Do not use on wood which may come in direct contact with food, feeding stuff and livestock animals.

Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.

Do not treat wood that comes in direct contact with soil or water.

Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer.

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

Use of the product in residential areas is restricted to static wood constructions that do not have direct contact to the interior space.

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

First aid measures:

IF EXPOSED OR CONCERNED: Get medical advice/attention.

IF INHALED: Get medical advice / attention.

IF SWALLOWED: Get medical advice / attention.

IF ON SKIN: Wash skin with water. Get medical advice / attention.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

Methods and material for containment and cleaning up:

Contain and absorb spill with sand or other absorbent material and transfer to suitable waste containers. Disposed of safely as hazardous waste in accordance with local / regional / national / international regulations.

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.

It is recommended not to clean used materials (like brushes, contaminated covers and coveralls) with water, but reuse them 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.

Protect from light.

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.

Do not store near food, drink and animal feeding stuff.

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,	Compati-bility of the product with the

				non-professional)	**proposed packaging materials (Yes/No)**
Bottle	1 litre	Plastic: HDPE	Plastic: PP (Child resistant)	Professional	Yes
Can/tin	2.5, 5 litres	Plastic: HDPE	Plastic: PP (Child resistant)	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

Letter of access for the active substance is included in the product dossier (see IUCLID file).

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Intended use # 1 – brushing

Product Type(s)	8
Where relevant, an exact description of the authorised use	Wood preservative against wood-rotting fungi and wood-boring insects For soft- and hardwood and masonry Preventive and curative
Target organism (including development stage)	Wood rotting fungi (*Coniophora puteana, Poria placenta, Gloeophyllum trabeum, Trametes versicolor*, and the dry rot fungus, *Serpula lacrymans*) Wood-boring beetles (*Hylotrupes bajulus,* larvae; *Anobium punctatum*, larvae; *Lyctus brunneus,* larvae)

Field of use	Indoor – UC 1 and 2 Ready-to-use (RTU) product
Application method(s)	Brush treatment
Application rate(s) and frequency	182 g/m^2
Category(ies) of user(s)	Professional
Pack sizes and packaging material	Bottle: 1 L (HDPE) Can/tin: 2.5, 5, 10 and 20 L (HDPE) Drum: 200 L (HDPE) IBC: 1000 L (HDPE)

Intended use # 2 – Non-pressurised injection

Product Type(s)	8
Where relevant, an exact description of the authorised use	Wood preservative against wood-rotting fungi and wood-boring insects For soft- and hardwood and masonry Preventive and curative
Target organism (including development stage)	Wood rotting fungi (*Coniophora puteana, Poria placenta, Gloeophyllum trabeum, Trametes versicolor*, and the dry rot fungus *Serpula lacrymans*). Wood-boring beetles (*Hylotrupes bajulus,* larvae; *Anobium punctatum*, larvae; *Lyctus brunneus,* larvae)
Field of use	Indoor – UC 1 and 2 Ready-to-use (RTU) product
Application method(s)	Non-pressurised injection
Application rate(s) and frequency	See Guidance for non-pressurised injection
Category(ies) of user(s)	Professional
Pack sizes and packaging material	Bottle: 1 L (HDPE) Can/tin: 2.5, 5, 10 and 20 L (HDPE) Drum: 200 L (HDPE) IBC: 1000 L (HDPE)

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20°C and 101.3 kPa	Visual inspection ECHA Guidance, section 3.1, p. 67.	16.5% boric acid	Liquid	Danish Technological Institute, Report No. 852037 ACC rev 5.
Colour at 20°C and 101.3 kPa	Visual inspection ECHA Guidance, section 3.1, p. 67.	16.5% boric acid	Clear colourless	Danish Technological Institute, Report No. 852037 ACC rev 5.
Odour at 20°C and 101.3 kPa	ECHA Guidance, section 3.1, p. 67	16.5% boric acid	Light soapy odour.	Danish Technological Institute, Report No. 852037 ACC rev 5.
Acidity / alkalinity	UA-310 equivalent to CIPAC MT 75.3	16.5% boric acid	pH (neat) measured at 23°C: 6.3	Danish Technological Institute, Report No. 852037 ACC rev 5.
Relative density	CIPAC MT 3.2 and OECD 109	16.5% boric acid	Density at 20°C: 1.1612	Danish Technological Institute, Report No. 852037 ACC rev 5.
Storage stability test – **accelerated storage**	CIPAC MT 46.3. Storage in a 1 L HDPE container at 40 °C for 8 weeks.	See results	The stability of the product was tested after storage for 8 weeks at 40°C. Appearance: Before storage: Clear colourless liquid. After storage: Clear colourless liquid.	Danish Technological Institute, Report No. 852037 ACC rev 5.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			AS content: Before storage: 16.2 w/w% After storage: 16.2 w/w%. Variation: 0% pH (neat): Before storage: 6.3. After storage: 6.3. After storage, no changes in colour, AS content and pH were observed. The product should not be stored at temperatures above 40°C.	
Storage stability test – **long term storage at ambient temperature**	GIFAP (CropLife International) monograph No. 17. Storage in a 1 L HDPE container at ambient temperature with temperature monitoring for 20 months (**Interim results**). The study deviates from guideline, as the temperature	See results	The stability of the product was tested after storage for 20 months at ambient temperature. AS content: Before storage: 16.2 %(w/w) After storage: 16.7 %(w/w) Variation: +3%. Packaging material: 0.03% weight change, no visual damage observed after the study. eCA evaluation: The deviation from guideline regarding temperature is considered acceptable since both the AS content and the packaging	Danish Technological Institute, Report No. 845540 20M Rev.1

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	varies from 17.2-24.8 °C during the study.		material was demonstrated to be stable. Further, the average temperature of the study was held at the required 20 °C through the 20 month ambient storage stability study.	
	GIFAP (CropLife International) monograph No. 17.	See results	Study on-going at the Danish Technological Institute. Two years stability study is available by 1 July 2021.	Danish Technological Institute, Report No.
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 'Protect from light' 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 and packaging were stable during the 20 month storage stability study at ambient temperature. No visual damage to the HDPE container was observed.	Danish Technological Institute, Report No. 845540 20M Rev.1
Wettability			Not applicable – Boracol 15 is a liquid formulation	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Suspensibility, spontaneity and dispersion stability			Not applicable – Boracol 15 is a liquid formulation	
Wet sieve analysis and dry sieve test			Not applicable – Boracol 15 is a liquid formulation	
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable – Boracol 15 is a liquid formulation	
Disintegration time			Not applicable – Boracol 15 is a liquid formulation	
Particle size distribution, content of dust/fines, attrition, friability			Not applicable – Boracol 15 is a liquid solution	
Persistent foaming			Not applicable – Boracol 15 is a RTU (Ready To Use) liquid formulation	
Flowability/Pourability/Dustability	CIPAC MT 148	16.5% boric acid	The pourability was measured before and after accelerated storage for 8 weeks. Residue: Before storage: 0.38% After storage: 0.48% Rinsed residue: Before storage: 0.17% After storage: 0.17% The residue measured for the test material, Boracol 15, does not exceed 5%, and the rinsed residue does not exceed 0.25%.	Danish Technological Institute, Report No. 852037 ACC rev 5.
Burning rate — smoke generators			Not applicable – Boracol 15 is a liquid formulation	
Burning completeness — smoke generators			Not applicable – Boracol 15 is a liquid formulation	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Composition of smoke — smoke generators			Not applicable – Boracol 15 is a liquid formulation	
Spraying pattern — aerosols			Not applicable – Boracol 15 is a liquid formulation intended for brushing and non-pressurised injection into boreholes.	
Physical compatibility			Not applicable – Boracol 15 is not to be used in combination with other products.	
Chemical compatibility			Not applicable – Boracol 15 is not to be used in combination with other	
Degree of dissolution and dilution stability			Not applicable – Boracol 15 is a ready-to-use (RTU) liquid.	
Surface tension	EC method A.5 and OECD 115. Test conducted at 25°C using a ring tensiometer.	16.5% boric acid	164.5 mN/m	Danish Technological Institute, Report No. 852037 ACC rev 5.
Viscosity	CIPAC MT 192 and OECD 114 using a rotational viscosimeter	16.5% boric acid	The viscosity[3] was measured at 6 different shear rates between 20 s^{-1} and 100 s^{-1}. <u>Before storage:</u> Dynamic viscosity at 20°C: 16.2 mPa*s – 16.3 mPa*s Dynamic viscosity at 40°C: 7.5 mPa*s – 7.8 mPa*s	Danish Technological Institute, Report No. 852037 ACC rev 5.

[3] Kinematic viscosity at 40°C was not calculated for the product, as the product does not contain > 10% hydrocarbons or other components classified with H304, thus, the product will not be classified with H304.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			<u>After storage (8 weeks at 40°C):</u> Dynamic viscosity at 20°C: 16.2 mPa*s - 16.3 mPa*s Dynamic viscosity at 40°C: 7.6 mPa*s - 7.8 mPa*s	

Conclusion on the physical, chemical and technical properties of the product

The submitted studies for the physical, chemical and technical properties of the product Boracol 15 have been evaluated and are considered acceptable.
The product is a colourless liquid with a soapy odour.
The results from the accelerated stability study were acceptable, as no variations were observed for the parameters active substance content, pH and appearance of the product after storage at 40°C for 8 weeks. The submitted interim results for the long term storage stability study demonstrated an acceptable variation in active substance content and that the packaging material was stable after storage for 20 months at ambient temperature. The viscosity of the product does not affect the toxicological classification of the product.

The following information concerning storage should be stated on the product label:

- Store below 40°C.
- Protect from frost.
- Protect from light.

On the background of the accelerated stability test and the submitted interim results of the long term storage stability test, rMS DK preliminary accepts the shelf-life claim of two years; however, with a post-authorization requirement for an acceptable long-term stability study of two years. The 24 months storage stability results will be integrated in the report when available by 1 July 2021.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Statement	-	The explosive properties of each substance in the formulation has been evaluated: Boric acid has no explosive properties according to the CLH report for boric acid: Explosive properties are indicated by the presence of certain reactive groups in the molecule. The molecular structure of boric acid indicates that such groups are not present. No reactive or unstable groups are present, and it does not contain any functional groups quoted in the "Manual of Tests and Criteria" (fourth revised edition, appendix 6, table A6.1) or in Bretherick's-Handbook (6th Edition, Volume 2) as indicative of explosive properties. It can therefore be concluded by expert judgment that the molecular structure does not indicate that this substance will explode under the conditions of the test as described in Test Guideline A.14 of EC Directive 92/69/EEC and therefore testing is not required. The remaining ingredients of the formulation do not contain any	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			chemical groups associated with explosive properties.[4] Since none of the substances have explosive properties, a mixture of the substances is considered not to have explosive properties.	
Flammable gases			Not applicable – Boracol 15 is a liquid formulation	
Flammable aerosols			Not applicable – Boracol 15 is a liquid formulation not an aerosol	
Oxidising gases			Not applicable – Boracol 15 is a liquid formulation	
Gases under pressure			Not applicable – Boracol 15 is a liquid formulation	
Flammable liquids	EC method A.9	16.5% boric acid	No flash point was observed until the flame was extinguished	Danish Technological Institute, Report No. 852037 ACC rev 5.
Flammable solids			Not applicable – Boracol 15 is a liquid formulation.	
Self-reactive substances and mixtures			Boracol 15 does not contain any ingredients that contain chemical groups associated with explosive or self-reactive properties according to	

4 Please refer to section 3.7.1.2 of the confidential annex for details regarding the evaluation of explosive, self-reactive and oxidising properties of the remaining ingredients of the biocidal product.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the UN-MTC.[5] Thus, Boracol 15 is not considered a self-reactive mixture.	
Pyrophoric liquids			Study scientifically unjustified. Based on experience in handling and manufacture of the product, Boracol 15 is not a pyrophoric formulation. Furthermore, no flash point could be recorded for the product according to EC method A.9.	
Pyrophoric solids			Not applicable – Boracol 15 is a liquid formulation.	
Self-heating substances and mixtures			Self-heating properties only apply to solids or liquids adsorbed to a large surface. Since Boracol 15 is a liquid formulation, which is not adsorbed to a surface, Boracol 15 is not self-heating.	
Substances and mixtures which in contact with water emit flammable gases			Testing not required since the biocidal product contains water as part of the formulation.	
Oxidising liquids			The oxidising properties of each substance of the formulation has been evaluated: Boric acid contains oxygen, fluorine or chlorine that are chemically bound	

5 Boric acid (CAS No. 10043-35-3): According to the CLH report no classification is proposed in the hazard class Self-reactive substance and mixtures. Besides this no reactive or unstable groups are present and it does not contain any functional groups quoted in the "Manual of Tests and Criteria" (fourth revised edition, appendix 6, table A6.1, table A6.3). Please refer to section 3.7.1.2 of the confidential annex for details regarding the evaluation of explosive, self-reactive and oxidising properties of the remaining ingredients of the biocidal product.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			to atoms besides carbon or hydrogen. However, boric acid has no oxidising properties according to the CAR. The remaining ingredients either do not contain oxygen, chlorine or fluorine that are chemically bound to atoms besides carbon or hydrogen, or do not display oxidising properties.[6] Thus, Boracol 15 does not contain any oxidising ingredients and is therefore not considered an oxidising liquid.	
Oxidising solids			Not applicable – Boracol 15 is a liquid formulation	
Organic peroxides			Boracol 15 does not contain any organic peroxides.	
Corrosive to metals	UN Section 37:2015, Test C.1 Test time: 7 days.		Mass loss: Aluminium: Non-immersed: 0% Partly immersed: 0% Fully immersed: 0% Steel: Non-immersed: 0.1% Partly immersed: 0% Fully immersed: 0%	Danish Technological Institute, Report No. 938346 rev 1.

6 Please refer to section 3.7.1.2 of the confidential annex for details regarding the evaluation of explosive, self-reactive and oxidising properties of the remaining ingredients of the biocidal product.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			No intrusion was observed. As the mass loss is < 13.5% and the intrusion is < 6.25 mm/year, Boracol 15 is not corrosive to metals.	
Auto-ignition temperatures of products (liquids and gases)	European Commission Regulation (EC) No. 440/2008, Method 4.15		The auto-ignition temperature of Boracol 15 according to the auto-ignition test conditions was 405 C.	Siemens report no. PS20190438-1
Relative self-ignition temperature for solids			Not applicable – Boracol 15 is a liquid formulation	
Dust explosion hazard			Not applicable – Boracol 15 is a liquid formulation	

Conclusion on the physical hazards and respective characteristics of the product
The submitted information on physical hazards and respective characteristics for the product Boracol 15 has been evaluated. These data do not lead to classification of the product according to the CLP Regulation (EC) No 1272/2008.

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 PT8 CAR for 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 (%)[7]**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Determination of the active substance Boric Acid (CAS no. 10043-35-3)	Boric acid content determined by calculation from the boron content of a sample. Boron content is determined using ICP-OES. Quantification was carried out with external standards of boron. The method was developed for determinat-	Fortified at 0.96 µg/mL n = 5 determinat-ions Using matrix without component of interest *Repeatability:* Nominal value: 5.43% n = 5 Measured range: 5.17-5.69% w/w Mean: 5.49 %RSD: 3.6 %Recovery: 101	Linear for determinat-ion of boron content in the measured range 0 – 20 µg/mL Linear regression: y = 693742 x – 24258 y = intensity, x = c (boron) in mg/L r^2 = 0.9996 n = 6 calibration standards	The contribut-ion from the technical materials (matrix without component of interest) to the detection of boron is 0.028 µg/mL (n = 5 determinat-ions) less than 6% of LOQ. The contributio n from the method blank is 0.06 µg/mL	89.7 – 98.5 n = 5 determinat-ions	95.3	3.5	LOQ = 0.5 µg/mL	Danish Technolog-ical Institute, Report No. 740675

[7] The recovery for Boracol 15 is supported by the supplementary report (Danish Technological Institute, Report no. 845540-1).

	ion of Boric acid in Boracol 10_3Bd, which is of comparable formulation to Boracol 15.			(n = 5 determinat-ions), less than 12% of LOQ.					
Determinat-ion of the active substance Boric Acid (CAS no. 10043-35-3)	Boric acid content determined by calculation from the boron content of a sample. Boron content is determined using ICP-OES. Quantificat-ion was carried out with external standards of boron.	Fortified at 2.8 %(w/w) (correspond-ing to a concentration of 6.50 µg/mL boron) n = 2 determinat-ions	Not determined	Not determined	98.1 - 98.1% n=2 determinat-ions	98.1 %	No stand-ard deviat-ion obser-ved from the two sample s tested.	Not determined	Danish Technologi-cal Institute, Report No. 845540-1 *Supplemen t to test report no. 740675*

Justification for bridging the analytical method for Boracol 10_3Bd to Boracol 15:

The composition of the products Boracol 10_3Bd and Boracol 15 are comparable. In addition, the analytical technique used to determine the active (boron) is destructive to the material prior detection by OES. Therefore, since the validation of the analytical method for Boracol 10_3Bd meets the requirements of the parameters tested, this is also valid for the product Boracol 15. The placebo is of most importance to the test of interference (specificity), which needs to be less than 3%. The placebo of Boracol 10_3Bd showed a signal which is caused by trace amount of boron (identified by analysis). Trace amount of boron in the placebo does not affect the result of the recovery test when analyzed solution are within the calibration of the method. Similarly, when no trace amount of boron is seen in Boracol 15, the recovery is unaffected using the calibration of the same analytical method.

eCA note: The analytical method ICP-OES detects only the content of separate elements in a test item. In this case the content of boron. Although Boracol 15 and Boracol 10_3Bd are not identical, they can be seen as comparable concerning the analytical method, since the method targets only boron in the test sample. The method is developed to determine the boric acid equivalents in Boracol 10_3Bd and for both biocidal products, only the active substance(s) contain boron. Furthermore, the same solvents are present in both products. Thus, the DK rMS considers the bridging for the method validation as acceptable. In the case of Boracol 10_3Bd, a signal corresponding to 5.6% of LOQ was detected in the placebo sample. However, as determined as part of the accelerated storage stability study (Danish Technological Institute, Report No. 852037 ACC rev 5), the placebo sample of Boracol 15 contains a boron signal <LOD for the analytical method. Since the interference is < 3% for Boracol 15, the specificity is considered as acceptable according to SANCO 3030/99. Therefore, the DK CA considers the method and bridging between Boracol 10_3Bd and Boracol 15 as acceptable.

Conclusion on the methods for detection and identification of the product
The analytical method allows for determination of boron content and calculation of the content of boric acid in Boracol 15. The provided results show that the method is linear, precise, accurate and specific for determining the content of boron. Therefore, the method is considered acceptable for determination of boric acid content in Boracol 15. Analytical methods for the determination of boric acid 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 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 and hardwood.
Masonry adjacent to treated wood.
Preventive treatment.
Curative treatment (masonry against the dry rot fungus, *Serpula lacrymans*) to prevent adjacent wood from being affected)
Use class 1 and 2 (for wood).

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

Brown rot fungi (*Coniophora puteana, Poria placenta, Gloeophyllum trabeum*, and *Serpula lacrymans*) in Use class 2.

Wood-boring beetles (*Hylotrupes bajulus*, larvae; *Anobium punctatum*, larvae; and *Lyctus brunneus*, larvae) in use Classes 1 and 2.

In situ treatment of indoor/covered wood constructions such as roof trusses, braces, and floor separations to which people, domestic animals and livestock do not come into direct contact.

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

The primary mode of action of borates (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, borates act 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).

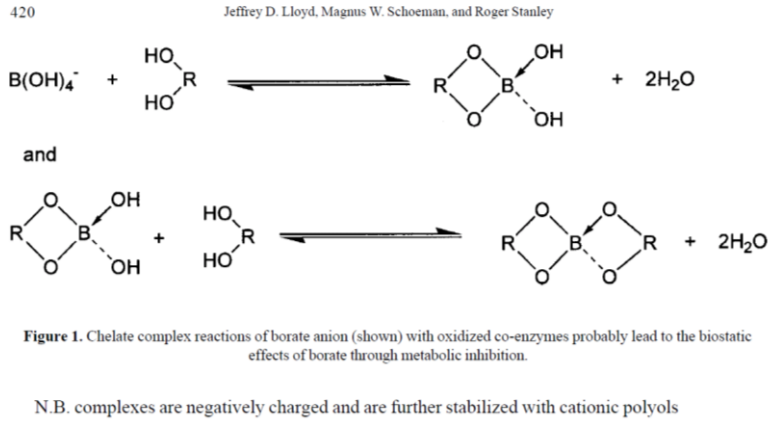


Figure 1. Chelate complex reactions of borate anion (shown) with oxidized co-enzymes probably lead to the biostatic effects of borate through metabolic inhibition.

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, borates 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.

2.2.5.5 Efficacy data

Introduction

Three test reports were submitted to support the label claim against fungi, namely study *825979-T1*, which assessed efficacy against *Coniophora puteana*, *Poria placenta*, *Gloeophyllum trabeum*, and *Trametes versicolor* according to EN 839 after EN 73, study *825979-T2*, which assessed efficacy against *Serpula lacrymans* according to EN 839 after EN 73, and study *825984* which assessed efficacy against *Serpula lacrymans* according CEN/TS 12404. The tests were conducted by the Danish Technological Institute (DTI, Denmark). The test reports have been reviewed by rMS DK, which also commissioned their evaluation by the Institut Technologique FCBA (FCBA, France); their *Assessment report no. 401/20/054Z V2* (of 28 July 2020) is included in the annotation for each of the three test reports.

Three tests were submitted to support the label claim against wood-boring beetles, namely: study *DTI 826016-1, rev.1*, which assessed efficacy against *Lyctus brunneus* according to EN 20-1 after EN 73; study *DTI 826020-1*, which addressed efficacy against *Hylotrupes bajulus* according to EN 46-1 after EN 73; and study *DTI 826029-1*, which addressed efficacy against *Anobium punctatum* according to EN 49-1 after EN 73. The tests were conducted by the FCBA (France). The test reports have been reviewed by rMS

DK, which also commissioned evaluation, by the DTI (Denmark), of the reports for *L. brunneus* and *H. bajulus*; their *Evaluation of FCBA test reports 401/18/188F/1/c v.2 and 401/18/188F/2/a* (of 20.02.2020) is included in the annotation for both of the test reports. The test report for the third beetle species (*A. punctatum*) was evaluated by the rMS; its *Evaluation of FCBA test report 401/18/188F/1/b* (of 25.11.2020) is included in the annotation for the test report.

An overview of the efficacy tests for Boracol 15 is provided in the table below.

Overview of the efficacy test for Boracol 15				
Study ID	**Test method**	**Organisation conducting study**	**Organisation evaluating study**	**Reference for evaluation report**
Fungi				
825979-T1	EN 839 + EN 73	DTI, Denmark	FCBA, France	*Assessment report no. 401/20/054Z V2* (of 28 July 2020)
825979-T2	EN 839 + EN 73			
825984	CEN/TS 12404			
Wood-boring beetles				
DTI 826016-1, rev.1	EN 20-1 + EN 73	FCBA, France	DTI, Denmark	*Evaluation of FCBA test reports 401/18/188F/1/c v.2 and 401/18/188F/2/a* (of 20.02.2020)
DTI 826020-1	EN 46-1 + EN 73			
DTI 826029-1	EN 49-1 + EN 73		Danish EPA	*Evaluation of FCBA test report 401/18/188F/1/b* (of 25.11.2020)

In the efficacy tests, the test substance (solution) applied to wood or mortar was a 'Boracol 15' formulation containing 15.00% w/w boric acid that was obtained by diluting (with distilled water) a Boracol 15 concentrate (supplied by the Applicant) containing 20.00% w/w boric acid. Dilution (with distilled water) of the concentrate to a boric acid concentration of 16.50% w/w yields a solution qualitatively and quantitatively identical to the biocidal product Boracol 15 (see Section 3.7.1 of the confidential annex). It is considered that the quantitative differences in the levels of co-formulants in the 'Boracol 15' formulation tested in the efficacy tests compared to those in the biocidal product Boracol 15 are unlikely to significantly alter (enhance or attenuate) the toxicity of boric acid in the test substance relative to the biocidal product itself[8]. Consequently,

[8] The presence of propane-1,2-diol can result in formation of borate ester species and derivatives thereof. The effect of the presence of propane-1,2-diol is expected to be proportional to the ratio between boric acid and propane-1,2-diol, and this ratio is not affected by dilution (with water) of the product or a concentrate of the product. The formation of polynuclear anions of boron in

extrapolation of the findings of the efficacy tests, and pro-rata correction of the quantity of Boracol 15 biocidal product to be applied based on the application rate of the 'Boracol 15' test formulation in the efficacy tests, is considered acceptable. Pro-rata correction of the application rate for the 'Boracol 15' test formulation to yield the corresponding application rate for Boracol 15 biocidal product is: application rate x ([`Boracol 15' test formulation] / [Boracol 15 biocidal product]). Thus an application rate of 200 g/m^2) 'Boracol 15' test formulation corresponds to an application rate of 182 g/m^2 Boracol 15 biocidal product, i.e. 200 g/m^2 x 15.0%/16.5% = 182 g/m^2.

aqueous solution, is not expected to be significantly affected by the additional dilution (from 16.5% to 15.0% w/w boron) due to the availability of hydroxyl groups in solution.

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 protective effectiveness against wood destroying basidiomycetes – Application by surface treatment	Preventive treatment, Use class 2	A 'Boracol 15' test formulation containing 15% w/w boric acid.	*Coniophora puteana*, *Poria placenta*, *Gloeophyllum trabeum, Trametes versicolor** (*This species was tested in the study, though as it is a white rot fungus, (which are not relevant for Use classes 1 and 2) it is not relevant for the current application.)	EN 839 + EN 73	Scots pine, sapwood 200, 400 & 600 g/m^2	Effective at an application rate < 200 g/m^2 (corresponding to < 182 g/m^2 for the biocidal product) The test was not valid regarding the untreated control specimens exposed together with the test specimens. This was especially evident for higher application rates. The effect is attributed to diffusion of boron into the growth medium, since degradation was observed in the virulence control specimens. Therefore, it is reasonable to conclude that the formulation tested was effective at the lowest application rate	Danish Technological Institute, Report No. 825979-T1 This report has been evaluated by the FCBA; see *Assessment report no. 401/20/054Z V2* (of 28 July 2020)
Determination of the protective effectiveness against wood destroying basidiomycetes – Application by surface treatment	Preventive treatment, Use class 2	A 'Boracol 15' test formulation containing 15% w/w boric acid.	*Serpula lacrymans*	EN 839 + EN 73	Scots pine, sapwood 200, 400 & 600 g/m^2	Effective at an application rate < 200 g/m^2 (corresponding to < 182 g/m^2 for the biocidal product)	Danish Technological Institute, Report No. 825979-T2 This report has been evaluated by the FCBA; see

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**
							Assessment report no. 401/20/054Z V2 (of 28 July 2020)
Determination of the curative efficacy against *Serpula Lacrymans* – Application by surface treatment	Remedial treatment, Use class 2	A 'Boracol 15' formulation containing 15% w/w boric acid.	*Serpula lacrymans*	ENV 12404	Mortar 200 g/m^2	Effective against penetration of *S. lacrymans* through mortar at an application rate of 200 g/m^2 (corresponding to 182 g/m^2 for the biocidal product) (The test preservative or a dilution of the test preservative is considered to be effective at the application rate used in the test provided that none of the replicates has a rating exceeding 1: *Only growth on the underside of the mortar test specimen and no growth on the wood test specimen*.)	Danish Technological Institute, Report No. 825984 This report has been evaluated by the FCBA; *Assessment report no. 401/20/054Z V2* (of 28 July 2020)
Determination of the protective effectiveness against *Lyctus brunneus* (Stephens) – Part 1: Application by surface treatment	Preventive treatment, Use class 1 & 2	A 'Boracol 15' formulation containing 15% w/w boric acid.	*Lyctus brunneus*	EN 20-1 + EN 73	*Quercus* spp., sapwood Tested with 200 g/m^2	Effective against *L. brunneus* at an application rate of 200 g/m^2 (corresponding to 182 g/m^2 for the biocidal product)	DTI 826016-1, rev.1 This report has been evaluated by the DTI; see *Evaluation of*

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**
(laboratory method)							*FCBA test reports 401/18/188F/ 1/c v.2 and 401/18/188F/ 2/a* (of 20.02.2020)
Determination of the preventive action against recently hatched larvae of *Hylotrupes bajulus* (Linnaeus) – Part 1: Application by surface treatment (laboratory method)	Preventive treatment, Use class 1 & 2	A 'Boracol 15' formulation containing 15% w/w boric acid	*Hylotrupes bajulus*	EN 46-1 + EN 73	Scots pine, sapwood Tested with 200 g/m^2	Effective against *H. bajulus* at an application rate of 200 g/m^2 (corresponding to 182 g/m^2 for the biocidal product)	DTI 826020-1 This report has been evaluated by the DTI; see *Evaluation of FCBA test reports 401/18/188F/ 1/c v.2 and 401/18/188F/ 2/a* (of 20.02.2020))
Determination of the protective effectiveness against *Anobium punctatum* (De Geer) by egg-laying and larval survival - Part 1: Application by surface treatment (laboratory method).	Preventive treatment, use class 1 & 2	A 'Boracol 15' formulation containing 15% w/w boric acid	*Anobium punctatum*	EN 49-1 + EN 73	*Quercus* spp., sapwood Tested with 200 and 400 g/m^2	Effective against *A. punctatum* at an application rate of 200 g/m^2 (corresponding to 182 g/m^2 for the biocidal product)	DTI 826029-1 This report has been evaluated by the rMS; see *Evaluation of FCBA test report 401/18/188F/ 1/b* (of 25.11.2020)

Efficacy of application via non-pressurised injection

Application of a wood preservative by injection methods is used to treat parts or surfaces of *in situ* wooden structures that are not accessible for superficial treatment (e.g. by brushing, rolling or spraying). There are no standardised tests for assessing the efficacy of injection of wood preservatives. In the absence of relevant tests, the expected efficacy of such methods can be evaluated based on the findings of studies of efficacy of the product when applied by surface treatment, and considering the application conditions[9]. *Appendix II: List of Intended Uses* of the PT8 CAR for boric acid (CA NL, 2009) identifies professional, *in situ* injection of boric acid as a remedial (curative) treatment for decay fungi and wood-boring beetles.

EN 14128:2004 *Durability of wood and wood-based products - Performance criteria for curative wood preservatives as determined by biological tests* does not recommend or require specific tests for the injection application method. The guidance addresses (section 8.5) curative treatment by injection methods, though its criteria for acceptance are solely based on surface treatment. EN 599-1:2009+ A1:2013 *Durability of wood and wood-based products – Efficacy of preventive wood preservatives as determined by biological tests – Part 1: Specification according to use class* only considers superficial and penetrating processes, and injection (or diffusion) is considered together with penetrating processes.

Application conditions for non-pressurised injection of Boracol 15 include – and vary with – the accessibility of the treated wood, the dimensions of the wood, the wood species, the target organisms(s), and the extent of infestation. Consequently, there are no standard application conditions. Professional judgement is required to establish the appropriate approach (including the positioning, spacing, diameter, depth, etc. of boreholes to receive the required quantity of the preservative) under the circumstances. The authorisation holder should be consulted on a case-by-case basis for guidance regarding conditions (requirements) for application via non-pressurised injection. An example of an application approach provided by the Applicant is presented in the document *Boracol_15_Injection* (see IUCLID Section 13). Non-pressurised injection of Boracol 15 is supplementary to superficial application, such that where possible, the accessible surface of wood treaded by non-pressurised injection should also be treated by superficial application.

Conclusion on efficacy of application via non-pressurised injection

Evidence of efficacy of Boracol 15 when applied by non-pressurised injection is gained from the tests of its efficacy on superficial application. As there are no standard conditions for application by non-pressurised injection, professional judgement is required to establish the appropriate approach to deliver the recommended quantity of the preservative under the circumstances. An application rate of 182 g/m^2, equivalent to 157

9 Application conditions for injection treatment include accessibility of the treated wood, dimensions of the wood, wood species, target organism(s), and extent of infestation.

mL/m^2, (i.e. the application rate recommended for superficial application) is recommended when Boracol 15 is applied by non-pressurised injection.

Conclusion on the efficacy of the product

Application by superficial treatment

Efficacy tests of Boracol 15 support the following claims when the product is applied indoors by superficial application at a rate of 182 g/m^2, equivalent to 157 mL/m^2:

Preventive treatment of:

- wood against brown rot fungi (*Coniophora puteana, Poria placenta, Gloeophyllum trabeum*, and *Serpula lacrymans*) in Use class 2
- masonry against the dry rot fungus *Serpula lacrymans* to prevent adjacent wood from being affected.
- wood against wood-boring beetles (*Hylotrupes bajulus*, larvae; *Anobium punctatum*, larvae; and *Lyctus brunneus*, larvae), in Use Classes 1 and 2.

Curative treatment of:

- masonry against the dry rot fungus *Serpula lacrymans* to prevent adjacent wood from being affected.

Application by non-pressurised injection

No data tests for assessing the efficacy of application of Boracol 15 by non-pressurised injection were submitted as there are no standardised tests for assessing the efficacy of injection of wood preservatives. In the absence of relevant data the expected efficacy of this application method (when the product is applied at the same application rate recommended for superficial application, i.e. 182 g/m^2, equivalent to 157 mL/m^2) is based on the studies of efficacy on superficial application, and is as follows:

Preventive treatment of:

- wood against brown rot fungi (*Coniophora puteana, Poria placenta, Gloeophyllum trabeum*, and *Serpula lacrymans*) in Use class 1.
- wood against wood-boring beetles (*Hylotrupes bajulus*, larvae; *Anobium punctatum*, larvae; and *Lyctus brunneus*, larvae) in Use Classes 1 and 2.

2.2.5.6 Occurrence of resistance and resistance management

Due to the mode of action of boric acid, development of resistance to Boracol 15 is not expected. Resistance to boric acid as a wood preservative has not been reported.

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.

2.2.5.7 Known limitations

No observations of undesirable or unintended effects of Boracol 15 are addressed in the efficacy studies.

2.2.5.8 Evaluation of the label claims

The label claims as applied for (see Section 2.2.1 *Intended use(s) as applied for by the applicant*) are not fully aligned with the intended uses or fully supported by the efficacy data presented. The overall claim 'Wood preservative against wood-rotting fungi and wood-boring insects' is not fully supported for the following reasons. In relation to anti-fungal activity, the term 'wood-rotting fungi' is considered to cover both brown rot fungi and white rot fungi. While a study showing efficacy against the white rot fungus *Trametes* (*Coriolus*) *versicolor* was presented, white rot fungi are not relevant target organisms in Use class 1 or 2, and a more specific claim against brown rot fungi is considered more appropriate. In relation to insecticidal activity, the data requirements[10] for a claim against wood-boring insects in general have not been met, however efficacy against wood-boring beetles (*Hylotrupes bajulus*, *Anobium punctatum*, and *Lyctus brunneus*) has been demonstrated.

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Boracol 15 is not intended for use with other biocidal products.

2.2.6 Risk assessment for human health

The toxicology of the active substance boric acid was examined according to the standard requirements under the *Biocidal Products Directive (BPD) 98/8/EC*. The toxicological properties of the active substance are summarized in the PT8 Competent Authority Report (CAR): Boric acid – rMS Netherlands (February 2009).

[10] Guidance on the BPR: Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 3.0 (April 2018), p. 170.

Boracol 15 is not sufficiently similar to the model products for the active substance to permit its use as reference product in this application (see *Annex I of Directive 98/8/EC*). No toxicity studies of Boracol 15 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)*[11], on the basis that there is sufficient toxicological data on the active substance and co-formulants to allow classification of Boracol 15 according to *Regulation (EC) No 1272/2008 (CLP)*, and no synergistic effects between any of the components are expected.

According to the PT8 CAR for boric acid (p. 8), the toxicokinetics and toxicological effects of boric acid are likely to be similar on a boron equivalent basis, thus data obtained from studies with different borates can be read across in the human health assessment for the individual substances.

Boric acid is classified for reproductive toxicity (Repr. 1B, H360FD: May damage fertility. May damage the unborn child)[12] with a Specific Concentration Limit (SCL) of ≥ 5.5%[13] (see Annex VI (ATP10) of *Regulation (EC) No 1272/2008*). Thus, following the requirements of *Regulation (EC) No 1272/2008*, Boracol 15 should be classified for Repr. 1B, H360 FD 'May damage fertility. May damage the unborn child'.

The active substance in Boracol 15 (boric acid) is currently not considered[14] to have endocrine-disrupting (ED) properties according to *Regulation (EU) 528/2012*. It has not

11 Guidance on the BPR: Volume III: Human health, Part A: Information Requirements, Version 1.2 (May 2018) states (e.g. p. 78): "*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.*"

12 The PT8 CAR for boric acid (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.*"

13 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. It 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. At its meeting of 16.09.2019, RAC (Risk Assessment Committee, ECHA) was in favour of the proposal ('Opinion adopted'). If the reclassification is adopted it will not have implications for the classification of Boracol 15.

14 The PT8 CAR for boric acid does 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*".

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) 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	Not corrosive or irritant to the skin.
Justification for the value/conclusion	No studies of skin corrosion or irritation have been performed with Boracol 15. Testing of the a.s. boric acid revealed no skin corrosion or skin irritation potential. Boracol 15 is formulated with a co-formulant classified for skin corrosion/irritation, though it has been disregarded in the risk assessment for skin corrosion/irritation; see Section 3.7.1.1 of the Confidential Annex for further information. Consequently, classification of Boracol 15 for skin corrosion or irritation is not considered warranted.
Classification of the product according to CLP and DSD	Classification for skin irritation is not required according to Regulation (EC) No 1272/2008.

Data waiving	
Information requirement	According to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements), Chapter 3, sub-section 3.1.1 Skin corrosion or skin irritation* (version 1.2, May 2018) 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 the any of the components are not expected.
Justification	The toxicities of the a.s. and of the co-formulants are known, no synergistic effects are expected, and antagonistic effects have been taken into consideration. Thus, toxicological properties and classification of Boracol 15 can be deduced from the intrinsic properties of its individual components using the guidance for classification of mixtures under Regulation (EC) No 1272/2008 (CLP).

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritant to the eye.
Justification for the value/conclusion	No studies of eye irritation have been performed with Boracol 15. Testing on the a.s. boric acid revealed no eye irritation potential. Boracol 15 is formulated with a co-formulant classified for skin corrosion/irritation and eye irritation, though it has been disregarded in the risk assessment for skin corrosion/irritation; see Section 3.7.1.1 of the Confidential Annex for further information. Consequently, classification of Boracol 15 for eye irritation is not considered warranted.
Classification of the product according to CLP and DSD	Classification for eye irritation is not required according to Regulation (EC) No 1272/2008.

Data waiving	
Information requirement	According to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements), Chapter 3, sub-section 3.1.2 Eye irritation* (version 1.2, May 2018) 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 the any of the components are not expected.
Justification	The toxicities of the a.s. and of the co-formulants are known, no synergistic effects are expected, and antagonistic effects have been taken into consideration. Thus, toxicological properties and classification of Boracol 15 can be deduced from the intrinsic properties of its individual components using the guidance for classification of mixtures under Regulation (EC) No 1272/2008 (CLP).

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the conclusion	No studies of respiratory irritation have been performed with Boracol 15. Testing of the a.s. boric acid revealed no respiratory tract irritation potential. None of the co-formulants 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.
Justification	The toxicities of the a.s. and of the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and classification of Boracol 15 can be deduced from the intrinsic properties of its individual components using the guidance for classification of mixtures under Regulation (EC) No 1272/2008 (CLP).

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not a skin sensitiser.
Justification for the value/conclusion	No skin sensitisation studies have been performed with Boracol 15. Testing of the a.s. boric acid revealed no skin sensitisation potential. None of the co-formulants are classified for skin sensitisation.
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	According to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements), Chapter 3, sub-section 3.1.3 Skin sensitisation* (version 1.2, May 2018) 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 the any of the components are not expected.
Justification	The toxicities of the a.s. and of the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and classification of Boracol 15 can be deduced from the intrinsic properties of its individual components using the guidance for classification of mixtures under Regulation (EC) No 1272/2008 (CLP).

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not a respiratory sensitiser.
Justification for the value/conclusion	The a.s. boric acid has not been tested for respiratory sensitisation, though as it does not show skin sensitising potential (Buehler test and human occupational exposure; PT8 CAR for boric acid (NL CA, 2009)) it is not predicted to be a respiratory sensitiser. None of the co-formulants are classified for respiratory sensitisation.

Classification of the product according to CLP and DSD	Classification for respiratory sensitisation is not required according to Regulation (EC) No 1272/2008.

Data waiving	
Information requirement	According to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements), Chapter 3, sub-section 3.1.4 Respiratory sensitisation* (version 1.2, May 2018) 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 the any of the components are not expected. See also sub-section 2.1.4 of the aforementioned guidance document.
Justification	The toxicity of the a.s. and the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and classification of Boracol 15 can be deduced from the intrinsic properties of its individual components using the guidance for classification of mixtures under Regulation (EC) No 1272/2008 (CLP).

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route.
Justification for the selected value	No acute oral toxicity studies have been performed with Boracol 15. Testing of the a.s. boric acid revealed no acute toxicity: LD_{50} (rat) > 2000 mg/kg bw. None of the co-formulants are classified for acute oral toxicity. Consequently, the acute oral toxicity of Boracol 15 is predicted to be > 2000 mg/kg bw (cut-off value for classification for acute oral toxicity).
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 required. According to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements), Chapter 3, sub-section 3.1.5 Acute toxicity* (version 1.2, May 2018), 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 the any of the components are not expected.

Justification	The toxicity of the a.s. and the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and classification of Boracol 15 can be deduced from the intrinsic properties of its individual components using the guidance for classification of mixtures under Regulation (EC) No 1272/2008 (CLP).

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route.
Justification for the selected value	No acute inhalation toxicity studies have been performed with of Boracol 15. Testing of the a.s. boric acid revealed no acute inhalation toxicity: LC_{50} (rat) > 2.12 mg/L (aerosol, highest attainable concentration). None of the co-formulants are classified for acute inhalation toxicity. Consequently, the acute inhalation toxicity of Boracol 15 vapour is predicted to be > 20 mg/L/4t (cut-off value for classification for acute inhalation toxicity a vapour).
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	According to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements), Chapter 3, sub-section 3.1.5 Acute toxicity* (version 1.2, May 2018), 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 the any of the components are not expected.
Justification	The toxicity of the a.s. and the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and classification of Boracol 15 can be deduced from the intrinsic properties of its individual components using the guidance for classification of mixtures under Regulation (EC) No 1272/2008 (CLP).

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	No acute dermal toxicity studies have been performed with Boracol 15. Testing of the a.s. boric acid revealed no acute dermal toxicity: LD_{50} (rat) > 2000 mg/kg bw. None of the co-formulants are classified for acute dermal toxicity. Consequently, the acute dermal toxicity of

	Boracol 15 is predicted to be > 2000 mg/kg bw (cut-off value for classification 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 required. According to the *Guidance on the Biocidal Products Regulation: Volume III (Human Health), Part A (Information Requirements), Chapter 3, sub-section 3.1.5 Acute toxicity* (version 1.2, May 2018), 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 the any of the components are not expected.
Justification	The toxicity of the a.s. and the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and classification of Boracol 15 can be deduced from the intrinsic properties of its individual components using the guidance for classification of mixtures under Regulation (EC) No 1272/2008 (CLP).

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*[15]. The first choice source of data is a dermal absorption study for the biocidal product. This is not an option for Boracol 15, 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(s) for the active substance(s) should be considered. This also is not an option for Boracol 15 as its qualitative and quantitative composition differs from the reference product(s) in the PT8 CAR (NL CA, 2009) for boric acid to an extent that read-across is not permissible according to the 2017 version of EFSA's *Guidance on dermal absorption*[16], the version applicable to this application based on its submission date.

As an alternative to read across, document *CA-July13-Doc.6.2.b* proposes using the EFSA (2012) guidance (as of this time, the 2017 version of the guidance) to select a default value for dermal absorption. An alternative to using a default value is to apply expert judgement to identify a reasonable worst-case value for dermal absorption of boric acid from Boracol 15. This approach has previously been taken for a products containing boric acid authorised for use in PT8.

In this PAR, the default dermal absorption value stipulated in the *Guidance on dermal absorption* (EFSA 2017) on the basis of the concentration of boric acid in Boracol 15 and the formulation of the product has been selected for boric acid. Justification for selection of this value is provided in the table below.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Boric acid
Value(s)	25%
Justification for the selected value(s)	No dermal absorption studies with Boracol 15 have been conducted. The PT8 CAR for boric acid does not present data for dermal absorption of boric acid at a concentration and in a matrix considered comparable to the formulation of Boracol 15. Based on EFSA's 2017 *Guidance on dermal absorption*, a dermal absorption default value of 25% should be applied to boric acid as it

[15] *Guidance on Dermal Absorption*. EFSA Panel on Plant Protection Products and their Residues (PPR). Parma, Italy. EFSA Journal 2012; 10(4): 2665. Updated: EFSA Journal 2017; 15(6): 4873.

[16] *Guidance on dermal absorption*. EFSA Panel on Plant Protection Products and their Residues (PPR). Parma, Italy. EFSA Journal 2017; 15(6): 4873.

	is present at a concentration (16.5% w/w) > 5% (i.e. Boracol 15 is considered a 'concentrate') in an organic solvent-based/dispersed formulation. See section 3.7.2 of the Confidential Annex for evaluation of the potential of co-formulants in Boracol 15 to affect dermal absorption of boric acid from the product. Previously, expert judgement has been used to identify a reasonable worst-case value for dermal absorption of boric acid from PT8 products. rMS (DE CA) used expert judgement[17] to identify a worst-case estimate for dermal absorption of 20% for a product due to the absence of product-specific data on dermal absorption, inapplicability of read-across to a model product, and no validated methods available for quantitative prediction of the effect of penetration enhancers. DE CA subsequently noted that derivation of the value of 20% was not in accordance with guidance current at the time of authorisation[18], but that the issue had been discussed at several Co-ordination Group (CG) meetings and was accepted by Member States and the Commission. However, DE CA noted that the appropriateness of this value should be reviewed at the time of renewal of the authorisation. Due to the uncertainties inherent in expert judgment, the 'default value approach' (using EFSA's 2017 *Guidance on dermal absorption* has been used to derive a dermal absorption value (25%) for boric acid/boron from Boracol 15.

[17] 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 PT8 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).

[18] EFSA *Guidance on Dermal Absorption* (2012); OECD *Guidance Notes on Dermal Absorption* (2011).

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

Boracol 15 does not contain any substance of concern (SoC) for human health; see *Section 3.7.2* of the *Confidential Annex* for discussion of SoCs.

One for the criteria that results in a co-formulant being considered a SoC if it has known or possible endocrine-disrupting (ED) properties. The guidance for application of ED criteria (*CA March18 Doc.7.3b-final*[19]) 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[20] 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 15; none were found to have known ED properties or were judged to have possible ED properties.

Available toxicological data relating to a mixture

No information additional to that in SDSs was provided.

Other information

No additional information.

2.2.6.2 Exposure assessment

Boracol 15 is a ready-to-use (RTU) biocidal product intended for the preservation of wood (PT8) – preventive and curative treatment against fungal and insect attack – via *in situ* brush application or non-pressurised injection. The product is intended for indoor/covered wood constructions such as roof trusses, wood braces, and floor separations (Use class 1 and 2) to which people, domestic animals and livestock do not come into direct contact and, in specific cases, adjacent masonry. Non-pressurised injection is used to treat parts of *in-situ* wooden structures that are not accessible for surface treatment. Boracol 15 is a

19 Applicable as of 7 June 2018 to co-formulants in products under assessment.

20 Described in the guidance document *Assessment of endocrine disruption (ED) properties of co-formulants in biocidal products – instructions for applicants* (referred to in CA March18 Doc.7.3b-final).

solvent-based product, though the primary solvent is miscible in water, and water is a co-solvent.

The human exposure assessment relates to the use phases of the product, and addresses primary- and secondary exposure, with exposure of professionals (the only user group) 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 labelling of biocidal products. They are expected to be trained and skilled in the main activities of their occupation and have experience and skills in the use of personal protective equipment (PPE) if such equipment is required for their work.

The main paths of human exposure to the biocidal product are presented in the following table.

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Indust-rial use	**Profess-ional use**	**Non-profess-ional use**	**Indust-rial use**	**Profess-ional use**	**General public**	**Via food**
Inhalation	n.a.	Yes	n.a.	n.a.	Yes	No[1]	n.a.
Dermal	n.a.	Yes	n.a.	n.a.	Yes	Yes	n.a.
Oral	n.a.	No	n.a.	n.a.	No	Yes[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 active substance is expected to result in negligible exposure of the general public via inhalation.

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

Considerations for boric acid in relation to exposure assessment

Exposure/dose rates for boric acid presented in this PAR are expressed as boron equivalents, permitting comparison with the AEL for boric acid, which is expressed as weight units of boron (B) per kg body weight per day (i.e. 0.1 mg B/kg bw/day[21]) in the PT 8 CAR (NL CA, 2009).

Conversion factors for boron-equivalent doses are calculated using the formula:

21 The $AEL_{short\text{-}term}$, $AEL_{medium\text{-}term}$ and $AEL_{long\text{-}term}$ for boric acid are identical.

$N \times (MW_{boron}/MW_{as})$

In this formula, N is the number of boron atoms in the active substance (1 in the case of boric acid; molecular formula: H_3BO_3) and MW is the molecular weight of boron (MW = 10.811 g/mol) or the active substance, boric acid (61.833 g/mol). The conversion factor for boric acid to the equivalent dose of boron is thus:

1 x 10.811/61.833 = 0.175

List of exposure scenarios

Scenarios considered relevant for assessing primary- and secondary exposure of professionals are evaluated. Boracol 15 is intended for *in situ* treatment of indoor/covered wood construction such as roof trusses, wood braces, and floor separations (Use class 1 and 2) to which people, domestic animals and livestock do not come into direct contact and, in specific cases, masonry adjacent to these building elements. According to the *Technical Agreements for Biocides – Human Health (TOX)* v.2.0 (of 09.11.2018), Point 'TOX 36' for PT8, "*secondary exposure of professionals handling treated dried wood does not need to be assessed as it is covered by the exposure during the handling of wet wood after the application of the biocidal product. However, other types of secondary exposure to professionals (e.g. sanding treated wood) should still be assessed*". The building elements to which Boracol 15 is to be applied are generally not expected to be handled (e.g. moved or mounted) or worked (e.g. sawed or sanded), however a scenario for a professional sanding treated wood has been included in order to obtain an indication of the extent of such exposure.

Exposure of the general public is assessed via laundering of work clothes at home. As the product is intended to be applied by professionals only and *in situ* to structures to which the general public has limited access during both the application and post-application phases, exposure of the general public – and especially infants, toddlers and children – is considered unlikely during both the application and post-application phases. Consequently, the PT8 exposure scenarios '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 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 potential incidental exposure. A scenario addressing inhalation of volatile residues indoors is not warranted as the vapour pressure of boric acid is predicted to be less than 10^{-5} Pa at ambient temperature[22], thus inhalation of volatile residues indoors is considered negligible.

Appropriate combined exposure scenarios are identified.

22 See Appendix 1 of the CAR for boric acid (NL CA, 2009).

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1	Mixing and loading	Primary exposure, chronic. Transfer (semi-automatic) of the product to a painting pot or injection equipment.	Professionals
2.	Application by brushing	Primary exposure, chronic. Professionals applying the product using a brush.	Professionals
3.	Application by non-pressurised injection	Primary exposure, chronic. Professionals applying the product by non-pressurised injection.	Professionals
4.	Cleaning the brush	Primary exposure, chronic. Professionals cleaning the brush after application.	Professionals
5.	Cleaning non-pressurised injection equipment	Primary exposure, chronic Professionals cleaning the non-pressurised injection equipment after application.	Professionals
6.	Sanding treated wood	Secondary exposure, chronic. Professional sanding of the surface of treated wood.	Professionals
7.	Laundering work clothes	Secondary exposure, acute, intermediary. Contaminated work clothing is handled prior to mechanical laundering.	General public Professionals
8	Toddler touching freshly treated wood	Secondary exposure, acute, incidental. Toddler touching freshly treated wood with subsequent mouthing of fingers.	General public

Industrial exposure

Not relevant. Boracol 15 is not intended for use in industrial settings.

Professional exposure

Scenario 1 – Mixing and loading

Description of Scenario 1 – Mixing and loading (professionals)

Boracol 15 is a ready-to-use (RTU) product and does not require mixing, however exposure during transfer of the product from the container(s) it is supplied in to a painting pot and/or non-pressurised injection equipment 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. As the intended pack sizes include sizes that cannot be handled manually, a semi-automated or automated loading model is, at minimum, required to model loading of the product. A semi-automated transfer/pumping model is considered more relevant for professional users, and can also be employed with smaller pack sizes of the product. The RISKOFDERM *Potential Dermal Exposure Model* calculator was used to estimate exposure to the product using the RISKOFDERM dermal exposure model *Loading liquid, automated or semi-automated* (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 not expected. Assuming a daily exposure (task) duration of 1.5 minutes and a product transfer rate of 10 L/min (giving a daily transfer of 15 L product), a hand exposure of 13 mg/min (total loading 20 mg) was calculated (refer to Appendix 3.2 for details). Transfer of 15 L product covers loading in preparation for application by brushing and by non-pressurised injection on the same day. It is a conservative value, as application of Boracol 15 at the recommended rate for brushing/rolling (157 mL/m^2) to the maximum of 31.6 m^2 wood treated by this application method on a daily basis (see Scenario 2) requires the use of ~ 5 L product (157 mL/m^2 x 31.6 m^2 = 4.96 L), and application via non-pressured injection to the maximum of 100 boreholes treated by this application method on a daily basis (see Scenario 3) requires the use of ~ 1 L product (10 mg (8.6 mL at a product density of 1.16 g/cm^3) x 100 = 860 mL), yielding a total requirement of ~ 6 L.

Professionals are expected to wear gloves, reducing exposure of the hands (Tier 2 assessment).

For details on the exposure calculation refer to Appendix 3.2.

Tier 1	**Parameter**	**Value**
	Active substance (boric acid) conc.	16.5% w/w
	Dermal exposure, hands (90% percentile)[1]	13 mg/min
	Indicative dermal exposure, body[1]	No exposure foreseen
	Indicative inhalation exposure[1]	Negligible; normal or good ventilation
	Exposure duration	1.5 min
	Transfer rate of product[1]	10 L/min
	Body weight, adult[2]	60 kg

Description of Scenario 1 – Mixing and loading (professionals)		
	Dermal absorption, boric acid	25%
Tier 2	Glove penetration[3]	10%

1 RISKOFDERM dermal exposure model *Loading liquid, automated or semi-automated*.

2 HEAdhoc Recommendation no. 14 *Default human factor values for use in exposure assessments for biocidal products* (HH WG-III-2017).

3 HEEG Opinion No. 9 *Default protection factors for protective clothing and gloves* (TM-I-2010).

Calculations for Scenario 1 – Mixing and loading

Summary table: estimated exposure* from professional use					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake** (mg B/kg bw/d)	**Estimated dermal uptake** (mg B/kg bw/d)	**Estimated oral uptake** (mg B/kg bw/d)	**Estimated total uptake** (mg B/kg bw/d)
Scenario 1	1	-	0.0024	-	0.0024
	2	-	0.0002	-	0.0002

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

Further information and considerations on scenario 1 – Mixing and loading

No further information.

Scenario 2 – Application by brushing

Description of Scenario 2 – Application by brushing

Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure (point 23) and the *Biocides Human Health Exposure Methodology* (October 2015) document's scenario *Professional brush treatment* (p. 120) provide values for use in calculation of dermal and inhalation exposure to a wood preservative during professional brush treatment. The indicative values are normalized to 1% active substance. As the vapour pressure of boric acid is predicted to be less than 10^{-5} Pa at ambient temperature [23], the indicative inhalation exposure for non-volatile substances is used.

Professionals are expected to wear coated coveralls, reducing exposure of the body, and to wear gloves, reducing exposure of the hands (Tier 2 assessment).

The application area (31.6 m^2) modelled in this scenario is considered to cover an expected limit area of masonry treated by brush application in order to prevent adjacent wood from being affected by dry rot fungus, *Serpula lacrymans*. Appliaction to masonry is restricted to this situation and target organism.

For details on the exposure calculation refer to Appendix 3.2.

	Parameters	**Value**
Tier 1	Active substance (boric acid) conc.	16.5% w/w
	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] (non-volatile substances)	0.0016 mg/m^2 (normalized to 1% a.s.)
	Exposure duration[1]	240 min
	Application area[1]	31.6 m^2
	Body weight, adult[2]	60 kg
	Dermal absorption, boric acid	25%
Tier 2	Glove penetration[3]	10%
	Coated overalls penetration[3]	10%

1 *Consumer painting Model 3/Professional brush treatment scenario*, in *Biocides Human Health Exposure Methodology* (version 1, October 2015, p. 120); HEAdhoc Recommendation no. 6 *Methods and models to assess exposure to biocidal products in different product types* (version 3, 2017).

2 HEAdhoc Recommendation no. 14 *Default human factor values for use in exposure assessments for biocidal products* (HH WG-III-2017).

3 HEEG Opinion No. 9 *Default protection factors for protective clothing and gloves* (TM-I-2010).

Calculations for Scenario 2 – Application by brushing

23 See *Appendix 1* of the CAR for boric acid (NL CA, 2009).

Summary table: estimated exposure* from professional use					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake** (mg B/kg bw/d)	**Estimated dermal uptake** (mg B/kg bw/d)	**Estimated oral uptake** (mg B/kg bw/d)	**Estimated total uptake** (mg B/kg bw/d)
Scenario 2	1	0.0024	0.2965	-	0.2989
	2	0.0024	0.0297	-	0.0321

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

Further information and considerations on scenario 2 – Application by brushing

No further information.

Scenario 3 – Application by non-pressurised injection

Description of Scenario 3 – Application by non-pressurised injection		
Mixing & Loading model 4 in the *Biocides Human Health Exposure Methodology* (October 2015, p. 121) provides values for exposure to a biocidal product during professional borehole impregnation with a liquid (i.e. non-pressurised injection). The model assumes a hand exposure of 10 mg product/loading with 100 loadings per day; the latter is considered conservative with respect to the intended uses of Boracol 15. No exposure of areas of the body other than the hands is assumed to occur. As the vapour pressure of boric acid is predicted to be less than 10^{-5} Pa at ambient temperature[24], inhalation exposure is considered negligible. Professionals are expected to wear gloves, reducing exposure of the hands (Tier 2 assessment). For details on the exposure calculation refer to Appendix 3.2.		
Tier 1	**Parameters**	**Value**
	Active substance (boric acid) conc.	16.5% w/w
	Indicative dermal exposure, hands[1]	10 mg/loading
	Loadings per day[1]	100
	Body weight, adult[2]	60 kg
	Dermal absorption, boric acid	25%
Tier 2	Glove penetration[3]	10%

24 See *Appendix* 1 of the CAR for boric acid (NL CA, 2009).

1 *Mixing & Loading model 4* in *Biocides Human Health Exposure Methodology* (version 1, October 2015, p. 121).

2 HEAdhoc Recommendation no. 14 *Default human factor values for use in exposure assessments for biocidal products* (HH WG-III-2017).

3 HEEG Opinion No. 9 *Default protection factors for protective clothing and gloves* (TM-I- 2010).

Calculations for Scenario 3 – Application by non-pressurised injection

Summary table: estimated exposure* from professional use					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake** (mg B/kg bw/d)	**Estimated dermal uptake** (mg B/kg bw/d)	**Estimated oral uptake** (mg B/kg bw/d)	**Estimated total uptake** (mg B/kg bw/d)
Scenario 3	1	-	0.1203	-	0.1203
	2	-	0.0120	-	0.0120

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

Further information and considerations on scenario 3 – Application by injection

No further information.

Scenario 4 – Cleaning the brush

Description of Scenario 4 – cleaning the brush
A post-application task which may lead to some degree of exposure is cleaning the brush used to apply Boracol 15. 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. The brush used to apply a water-based formulation maybe washed under a stream of water (e.g. from a tap), a process that can be expected to result in negligible dermal exposure. Boracol 15 is a solvent-based product, though as the primary solvent is miscible in water (and water is a co-solvent) a brush used to apply the product might be washed under a stream of water. However, as a worst-case scenario, exposure of professionals to Boracol 15 during brush cleaning is assessed using the *General Exposure Calculator for Washing out Of Brushes* of the annex to HEEG Opinion 11. The above model assumes that cleaning a brush used to apply a water-based formulation may be done by repeated dipping and swaying it in a vessel containing clean water. A large brush has a size of 10 x 10 x 2 cm, corresponding to a volume of 200 mL. The brush is cleaned (dipped and swayed) three times, using fresh water on each occasion (step). The volume of water should be large enough to allow enough 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 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 absorbs ~ 90% of the released liquid. Washing and squeezing is done a maximum of three times. No exposure of areas of the body other than the hands is assumed to occur. Exposure via inhalation is considered negligible.

During brush cleaning, professionals may retain gloves worn during brush application of the b.p. (Tier 2 assessment).

For details on the exposure calculation refer to Appendix 3.2.

	Parameters	**Value**
Tier 1	Active substance (boric acid) conc.	16.5% w/w
	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
	Dermal absorption, boric acid	25%
Tier 2	Glove penetration[3]	10%

1 HEEG Opinion No. 11 *Exposure model: Primary exposure scenario – washing out of a brush which has been used to apply a paint* (TM-III-2010).

2 HEAdhoc Recommendation no. 14 *Default human factor values for use in exposure assessments for biocidal products* (HH WG-III-2017).

3 HEEG Opinion No. 9 *Default protection factors for protective clothing and gloves* (TM-I-2010).

Calculations for Scenario 4 – cleaning the brush

Summary table: estimated exposure* from professional use 'cleaning the brush'					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake** (mg B/kg bw/d)	**Estimated dermal uptake** (mg B/kg bw/d)	**Estimated oral uptake** (mg B/kg bw/d)	**Estimated total uptake** (mg B/kg bw/d)
Scenario 4	1	-	0.0184	-	0.0184
	2	-	0.0018	-	0.0018

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d,

Further information and considerations on scenario 4 – cleaning the brush

No further information.

Scenario 5 – Cleaning non-pressurised injection equipment

Description of Scenario 5 – Cleaning non-pressurised injection equipment		
The RISKOFDERM scenario for cleaning of spray equipment (Marquart *et al*. 2006), described in HEAdhoc Recommendation no. 4 *Cleaning of spray equipment in antifouling use (PT21)*, is considered appropriate for modelling exposure during cleaning of non-pressurised injection equipment used to apply Boracol 15. Boracol 15 is less viscous than antifouling paint (given a density of 1.6 g/cm^3 in Recommendation no. 4), and the equipment used to apply it is expected to be cleaned only once a day (at the end of the day) as opposed to potentially several times during the work day in the case of antifouling paint. Consequently, the relatively brief (3.69 minutes) one-time hand exposure data of Delgado *et al*. (2004) that Marquant *et al.* (2006) used to derive a reasonable worst-case hand exposure of 210 mg paint (typical exposure 50 mg paint) is considered appropriate. The scenario of Marquart *et al*. focuses on hand exposure, as it is based on the study of Delgado *et al*. which noted that "the main body regions exposed during the cleaning of the spray gun are the hands, though there might be splashes to other parts of the body". As exposure of the body during cleaning of non-pressurised injection equipment used to apply to Boracol 15 is expected to be incidental, exposure of areas of the body other than the hands is assumed to be negligible. Exposure via inhalation is considered negligible. Professionals are expected to wear gloves, reducing exposure of the hands (Tier 2 assessment). For details on the exposure calculation refer to Appendix 3.2.		
Tier 1	**Parameters**	**Value**
	Boric acid	16.5% w/w
	Hands, b.p. loading[1]	210 mg

	Body weight, adult[2]	60 kg
	Dermal absorption, boric acid	25%
Tier 2	Glove penetration[3]	10%

1 HEAdhoc Recommendation no. 4 *Cleaning of spray equipment in antifouling use (PT21)* (HH WG-IV-2014).

2 HEAdhoc Recommendation no. 14 *Default human factor values for use in exposure assessments for biocidal products* (HH WG-III-2017).

3 HEEG Opinion No. 9 *Default protection factors for protective clothing and gloves* (TM-I-2010).

Calculations for Scenario 5 – Cleaning non-pressurised injection equipment

Summary table: estimated exposure* from professional use 'Cleaning non-pressurised injection equipment'					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake** (mg B/kg bw/d)	**Estimated dermal uptake** (mg B/kg bw/d)	**Estimated oral uptake** (mg B/kg bw/d)	**Estimated total uptake** (mg B/kg bw/d)
Scenario 5	1	-	0.0253	-	0.0253
	2	-	0.0025	-	0.0025

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

Further information and considerations on scenario 5 – Cleaning non-pressurised injection equipment

No further information.

Scenario 6 – Sanding treated wood

Description of Scenario 6 – Sanding treated wood
The cutting and sanding scenario (acute exposure) for non-professionals described in TNsG 2002, User Guidance, pp. 51-52 is extrapolated to a scenario for professionals (chronic exposure) by increasing the exposure time from 1 to 6 hours per day. *Inhalation route:* A person is sanding (power sander) the surface of treated wood (4 cm x 4 cm x 2.5 m, surface area 4,032 cm²). The active substance is in the outer 1 cm. The product has been applied at a rate of ~ 157 mL/m² (at a relative b.p. density of 1.16 g/cm³ this is equivalent to 182 g/m²). If 100% retention of the b.p. by the wood is assumed as the ultimate worst case, the wood contains: Boric acid: 182 g/m^2 × 16.5% = 30.03 g/m^2 (3.003 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 both palms of hands is 410 cm² and 20% of this area is the assumed contaminated. 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.

Professionals are expected to wear gloves when using a power sander, reducing exposure of the hands (Tier 2 assessment). 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 is assumed.

For details on the exposure calculation refer to Appendix 3.2.

	Parameters	**Value**
Tier 1	Concentration of a.s. on the wood surface (outer 1 cm)[1] (calculated)	3.003 mg/cm^2
	Density of wood[2]	0.4 g/cm^3
	Wood dust concentration[1]	5 mg/m^3
	Task duration[1] (extrapolated)	6 h
	Inhalation rate[3]	1.25 m^3/h
	Surface area of palms of hands[3]	410 cm^2
	Contaminated area of palms[1]	20%
	Transfer efficiency[4]	2%
	Dermal absorption, boric acid	25%
Tier 2	Glove penetration[5]	10%

1 HUMAN EXPOSURE TO BIOCIDAL PRODUCTS (TNsG June 2002), USER GUIDANCE, version 1, p. 51-52.

2 Point 'TOX35' of the *Technical Agreements for Biocides – Human Health (TOX)* v.2.0 (November 2018).

3 HEAdhoc Recommendation no. 14 *Default human factor values for use in exposure assessments for biocidal products* (HH WG-III-2017).

4 *Biocides Human Health Exposure Methodology* 2015, p. 171, taking the value for rough wood sawn / sanded based on the intended use of the product.

5 HEEG Opinion No. 9 *Default protection factors for protective clothing and gloves* (TM-I-2010).

Calculations for Scenario 6 – Sanding treated wood

Summary table: estimated exposure* from professional use 'sanding treated wood'					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake** (mg B/kg bw/d)	**Estimated dermal uptake** (mg B/kg bw/d)	**Estimated oral uptake** (mg B/kg bw/d)	**Estimated total uptake** (mg B/kg bw/d)
Scenario 6	1	0.0011	0.0036	-	0.0047
	2	0.0011	0.0004	-	0.0015

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

Further information and considerations on scenario 6 – Sanding treated wood

No further information.

Combined scenarios

It is possible that a professional may apply Boracol 15 by both application methods (brushing, non-pressurised injection) during the same working day. This would not permit time to also perform the task 'sanding treated wood' (Scenario 6), set to a duration of 6 hours for the professional. Consequently, Scenario 6 is not included in the worst-case combined scenario. Scenario 7, 'laundering work clothes' (Tier 1) (see descriptions under general public) is included in the worst-case exposure scenario for professional users as a professional may also launder their work clothes. According to the *Technical Agreements for Biocides – Human Health (TOX)* v.2.0 (of 09.11.2018), Point 'TOX 37' "*exposure during the application and post application tasks should be assessed but not combined in those cases where the post-application scenario is not a long-term exposure scenario.*" Laundering work clothes is characterised as an acute, intermediate scenario as it is not a daily activity (assumed to be performed once a week) but may be performed on a long-term basis. However, as the acute- medium- and long-term AEL for boric acid is the same value, it is possible to include the exposure associated with laundering work clothes in a combined exposure scenario otherwise comprised of chronic exposures, and compare the resulting total systemic exposure to the $AEL_{long\text{-}term}$. Never-the-less, the combined scenario that does not include Scenario 7 (or Scenario 6) is considered the most representative as it is applicable for 4 of 5 work days. A combined scenario in which Scenario 6 'sanding treated wood' is added to the worst-case combined scenario has also been calculated, though it is unrealistic as the time required to perform all the activities greatly exceeds the duration (8 h) of a work day. In the combined scenarios, Tier 2 exposure values for the application tasks (brushing, non-pressurised injection) and associate activities (product loading, equipment cleaning) and for sanding (i.e. scenarios 1, 2, 3, 4, 5, 6) have been used. For Scenario 7 (laundry) only Tier 1 exposure was estimated.

Summary table: combined systemic exposure* from professional uses				
Scenarios combined	**Estimated inhalation uptake** (mg/kg bw/d)	**Estimated dermal uptake** (mg/kg bw/d)	**Estimated oral uptake** (mg/kg bw/d)	**Estimated total uptake** (mg/kg bw/d)
Most representative Brush & injection application & associated activities (1[1]+2+3+4+5), all at Tier 2	0.0024	0.0463	–	0.0487
Worst case Brush & injection application & associated activities, plus laundry (1[1]+2+3+4+5+7), all at Tier 2 except laundry (Tier 1 only)	0.0024	0.0610	–	0.0634
Unrealistic Brush & injection application & associated activities, plus sanding & laundry (1[1]+2+3+4+5+6+7), all at Tier 2 except laundry (Tier 1 only)	0.0035	0.0614	–	0.0649

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

1 The value for Scenario 1 (Mixing and loading) is included once as it covers the combined exposure associated with the loading task for both application scenarios (brushing, non-pressurised injection).

Non-professional exposure

Boracol 15 is for professional use only. Thus, no exposure to the non-professional user is expected.

Exposure of the general public

Scenario 7 – Laundering of work clothes

Description of Scenario 7 – Laundering of work clothes
An activity that may result in exposure to Boracol 15 is the laundering of contaminated work clothing. Persons at risk are adults (general public and professionals). The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term. Laundering is assumed to occur mechanically; the only likely exposure is dermal exposure during handling of contaminated clothing while preparing it for laundry. Exposure is restricted to the hands and is dependent on their area, the concentration of dislodgeable residues on the surface of the work clothing, and the transfer coefficient to skin. The work clothing to be washed is the coated coverall worn by a professional in Scenario 2. It is assumed that the coverall is washed after one working week (corresponding to five

working days), and that the total residues accumulating during this time is 5-times the daily deposition due to application by brushing (Scenario 2). Contamination of the coverall during the other tasks resulting in primary exposure to Boracol 15 is not considered as exposure of the body is assumed to be negligible in the relevant scenarios.

The sum transfer area is determined by estimating how many times the coverall is touched by the hands while preparing it for laundering. For Tier 1, it is assumed that this happens 3 times, twice with the palms both hands and once with the total hands surface, giving a total transfer area of 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 PT8 CAR for propiconazole (FI CA, 2007).

For details on the exposure calculation, please refer to Appendix 3.2.

	Parameters	**Value**
Tier 1	Clothing a.s. contamination[1]	111.78 mg/cm^2
	Days before washing	5 days
	Percentage dislodgeable (Transfer coefficient, TC)	50%
	Surface of medium coated coverall[2]	22700 cm^2
	Sum transfer area[3]	1640 cm^2
	Dermal absorption, boric acid	25%

1 Clothing contamination equals the body exposure calculated in Scenario 2 minus the amount (10%) that penetrates the coated coveralls considered in that scenario.

2 See the PT8 CAR for propiconazole (FI CA, 2007). Body exposure from Scenario 2 is assumed to be equally distributed over this area.

3 Based on a surface area of both palms of 410 cm^2 and total surface of both hands of 820 cm^2 from HEAdhoc Recommendation no. 14 *Default human factors values for use in exposure assessment for biocidal products* (HH WG-III-2017).

Calculations for Scenario 7 - Laundering work clothes

Summary table: systemic exposure* of general public 'laundering work clothes'					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake** (mg B/kg bw/d)	**Estimated dermal uptake** (mg B/kg bw/d)	**Estimated oral uptake** (mg B/kg bw/d)	**Estimated total uptake** (mg B/kg bw/d)
Scenario 7	1	-	0.0147	-	0.0147

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

Further information and considerations on scenario 7– Laundering of work clothes

No further information.

Scenario 8 – Toddler touching freshly treated wood

Description of Scenario 8 – Toddler touching freshly treated wood (general public)		
Although it is expected that organizational measures are in place when professionals apply wood preservatives, it is possible that a toddler or child may come into contact with Boracol 15 being applied by a professional. 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. Harmonised input values are given in HEAdhoc Recommendation no. 5. 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 15 is intended to penetrate 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 toddler is used as a risk envelope for all relevant child groups; the scenario is not considered relevant for infants. For details on the exposure calculations please refer to Appendix 3.2.		
	Parameter	**Value**
Tier 1	Concentration of a.s. on the surface[1]	3.003 mg/cm^2
	Toddler hand surface area (both palms)[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
	Dermal absorption, boric acid	25%
	Oral absorption, boric acid[4]	100%

1 Calculated in *Description of Scenario 6 – Sanding treated wood*.

2 HEAdhoc Recommendation no. 14 *Default human factors values for use in exposure assessment for biocidal products* (HH WG-III-2017).

3 HEAdhoc Recommendation no. 5 *Non-professional use of antifouling paints: exposure assessment for a toddler*. (HH WG-I-2015).

4 PT8 CAR for boric acid (NL CA, 2009).

Calculations for Scenario 8 - Toddler touching freshly treated wood

Summary table: systemic exposure* of general public 'toddler touching freshly treated wood'					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake** (mg B/kg bw/d)	**Estimated dermal uptake** (mg B/kg bw/d)	**Estimated oral uptake** (mg B/kg bw/d)	**Estimated total uptake** (mg B/kg bw/d)
Scenario 8	1	-	0.7568	0.3027	1.0595

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

Further information and considerations on scenario 8– Toddler touching freshly treated wood

No further information

Combined scenarios

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 15 or a surrogate are available.

Dietary exposure

Exposure of food or drinking water to the active substance in Boracol 15 (boric acid) can be excluded when it is applied according to the recommended uses and relevant RMMs specified.

Information of non-biocidal use of the active substance

Boric acid is not 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 study. Natural boron is composed of two stable isotopes, one of which (boron-10) has a number of uses as a neutron-capturing agent.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Livestock exposure to the active substance in Boracol 15 can be excluded when it is applied according to the recommended uses and relevant RMMs specified.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Transfer of the active substance in Boracol 15 into foods (or drinking water) can be excluded when it is applied according to the recommended uses and relevant RMMs specified.

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

Boracol 15 is for professional use only. Thus, no transfer of biocidal active substance into food (or drinking water) is expected.

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 (TM-I-06) 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 which is an existing biocidal active substance within the EU.

Aggregated exposure

The active substance boric acid is currently only authorised for use in PT8. An aggregate exposure assessment has not been performed, as exposure to the active substance in Boracol 15 from sources other than the biocidal product is expected to be negligible.

Summary of exposure assessment

Scenarios and values* to be used in risk assessment			
Exposure scenario	**Exposed group**	**Tier/ PPE**	**Estimated total uptake*** (mg B/kg bw/d)
1. Mixing and loading	Professional	1	0.0024
		2	0.0002
2. Application by brushing	Professional	1	0.2989
		2	0.0321
3. Application by non-pressurised injection	Professional	1	0.1203
		2	0.0120
4. Cleaning the brush	Professional	1	0.0184
		2	0.0018
5. Cleaning non-pressurised injection equipment	Professional	1	0.0253
		2	0.0025
6. Sanding treated wood	Professional	1	0.0047
		2	0.0015
7. Laundering work clothes	General public, professional	1	0.0147
8. Toddler touching freshly treated wood	General public	1	1.0595

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

2.2.6.3 Risk characterisation for human health

In the following risk assessments the estimates for systemic exposure to the active substance boric acid – expressed as its equivalent dose of boron (B) – during the exposure scenarios identified for Boracol 15 are compared to the AEL (i.e. total systemic exposure/AEL = %AEL) to determine if the risk is acceptable (i.e. %AEL ≤ 100) for the task(s) in question. An AEL value of 0.1 mg B/kg bw/d is used in all calculations as this is the acute- medium- and long-term AEL for boric acid (see the table of *Reference Values* below).

The reference values and other information presented in the table below are derived from the PT8 CAR (NL CA, 2009) for the active substance boric acid.

Reference values* to be used in Risk Characterisation of boric acid

Reference	**Study**	**NOAEL (LOAEL)*** (mg B/kg bw/d)	**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

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

1 Default value of 100 that accounts for inter-species variation (x10) and intra-species variation (x10).

2 Not required, as the PT8 CAR for boric acid (NL CA, 2009) state 100% oral absorption.

Risk for industrial users

Not applicable.

Risk for professional users

Systemic effects

Exposure scenario	**Tier/ PPE**	**Systemic NOAEL*** mg B/kg bw/d	**AEL*** mg B/kg bw/d	**Estimated uptake*** mg B/kg bw/d	**Estimated uptake/ AEL** (%)	**Accept-able** (Yes/**No**)
1. Mixing and loading	1	9.6	0.1	0.0024	2.4	Yes
	2	9.6	0.1	0.0002	0.2	Yes
2. Application by brushing	1	9.6	0.1	0.2989	299	**No**
	2	9.6	0.1	0.0321	32.1	Yes
3. Application by non-pressurised injection	1	9.6	0.1	0.1396	120	**No**
	2	9.6	0.1	0.0140	12.0	Yes
4. Cleaning the brush	1	9.6	0.1	0.0184	18.4	Yes
	2	9.6	0.1	0.0018	1.8	Yes
	1	9.6	0.1	0.0253	25	Yes

5. Cleaning non-pressurised injection equipment	2	9.6	0.1	0.0025	2.5	Yes
6. Sanding treated wood	1	9.6	0.1	0.0047	4.7	Yes
	2	9.6	0.1	0.0015	1.5	Yes

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

Combined scenarios

Scenarios combined	**Tier /PPE**	**Systemic NOAEL*** (mg B/kg bw/d)	**AEL*** (mg B/kg bw/d)	**Estimated uptake*** (mg B/kg bw/d)	**Estimated uptake/AEL** (%)	**Accept-able** (Yes/**No**)
Brush & injection application & associated activities (1+2+3+4+5)	2	9.6	0.1	0.0487	49	Yes
Worst case Brush & injection application & associated activities, plus laundry (1+2+3+4+5+7)	2, except laundry (Tier 1)	9.6	0.1	0.0634	63	Yes
Brush & injection application & associated activities, plus sanding & laundry (1+2+3+4+5+6+7)	2, except sanding and laundry (Tier 1)	9.6	0.1	0.0649	65	Yes

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

Local effects

Boracol 15 is not classified for local effects, thus risk assessment for local effects is not required.

Conclusion on the risk assessment for professional users

The risk assessment for professionals shows an unacceptable risk when Boracol 15 is applied by brushing or by non-pressurised injection without PPE. When PPE is considered (gloves and coated coveralls for the brushing task, gloves for the non-pressurised injection tasks; 90% mitigation in for both PPE), Tier 2 calculations show acceptable risk for both tasks. An acceptable risk at Tier 1 is indicated for each of the activities associated with application tasks (i.e. loading a painting pot or non-pressurised injection equipment,

cleaning the brush or injection equipment) and for the other professional exposures (i.e. sanding, laundering work clothes).

A combined scenario which assumes that a professional applies Boracol 15 by both application methods (brushing, non-pressurised injection) and perform the associated activities (i.e. product loading and equipment cleaning) during the same working day, indicates acceptable risk when the PPE (coated coveralls and/or gloves) evaluated for the individual tasks is considered (Tier 2). The risk remains acceptable when exposure from laundering work clothes (Tier 1) is added to the combined scenario to give a worst-case combined scenario. The risk remains acceptable when exposure from the sanding task (Tier 1) is also added to the worst-case combined scenario, though the resulting combined scenario is unrealistic as the time required to perform all the activities greatly exceeds the duration (8 h) of a work day.

Risk for non-professional users

Boracol 15 is for professional use only.

Risk for the general public

Systemic effects

Exposure scenario	**Tier**	**Systemic NOAEL*** mg B/kg bw/d	**AEL*** mg B/kg bw/d	**Estimated uptake*** mg B/kg bw/d	**Estimated uptake/ AEL** (%)	**Accept-able** (Yes/**No**)
7. Laundering work clothes	1	9.6	0.1	0.0147	14.7	Yes
8. Toddler touching freshly treated wood	1	9.6	0.1	1.0595	1059	**No**

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

Combined scenarios

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

Local effects

Boracol 15 is not classified for local effects, thus risk assessment for local effects is not required.

Conclusion on risk assessment for the general public

The risk assessment for the general public shows an unacceptable risk for the incidental exposure of a toddler touching wood freshly treated with Boracol 15 and subsequently mouthing fingers. This triggers the requirement for the RMM '*Keep children* [*and pets*] *away from the product and treated wood during application and drying*'. The only other exposure of the general public envisaged – laundering professional work clothes[25] – did not result in unacceptable exposure. No combined exposures are identified the general public.

Risk for consumers via residues in food

No risk for consumers being exposed via residues in food (or drinking water) is expected when the product is applied according to the recommended uses.

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

Not relevant as Boracol 15 contains only one active substance and no SoCs.

2.2.7 Risk assessment for animal health

Exposure of domestic animals and livestock directly, or via their food or drinking water, to the active substance in Boracol 15 (boric acid) can be excluded when the product is applied according to the recommended uses.

Risk of exposure of domestic animals during /shortly after application (i.e. to freshly treated wood) can be evaluated with reference to the scenario 'toddler touching freshly treated wood with subsequent mouthing of fingers'. While different aspects of cat and dog anatomy and behaviour may, individually, act to increase or decrease exposure relative to the toddler, the size of unacceptable exposure estimated in the aforementioned toddler scenario is considered to warrant the RMM '*Keep* [*children and*] *pets away from the product and treated wood during application and drying*'.

2.2.8 Risk assessment for the environment

Boracol 15 contains 16.5% (w/w) boric acid. The biocidal product is a wood preservative (PT8) for *in situ* treatment of indoor/covered wood constructions such as roof trusses, braces, and floor separations (Use class 1 and 2) to which people, domestic animals and

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

livestock do not come into direct contact. Boracol 15 can be used for preventive treatment of wood against brown rot fungi. 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. Boracol 15 can be used for preventive treatment of softwood and hardwood against wood-boring beetles (*Hylotrupes bajulus*, *Anobium punctatum*, and *Lyctus brunneus*). The product is applied to wood and masonry by superficial application (brushing) supplemented, where required, by non-pressurised injection into wood. Boracol 15 is intended for professional use.

2.2.2.1 Effects assessment on the environment

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

No substance in the product has an environmental hazard classification.

Further Ecotoxicological studies

No studies relevant.

2.2.2.2 Exposure assessment

General information

Assessed PT	PT 8
Assessed scenarios	Scenario 1: Use class 1-2
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 *in-situ* treatment is performed indoor thus there are no emissions to any environmental compartment. Therefore, no risk assessment has 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 UC1-2. 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.

Emission estimation

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	
Air	No emission	
Soil Groundwater	No emission No emission	

2.2.2.3 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 applied indoors and the service life is indoors. Therefore, no environmental exposure or risk will occur based on the applied use.

As Boracol 15 can be harmful to protected species such as bats, hornets or birds that may reside in treated buildings, the presence of protected species in the area to be treated must be assessed prior to use of the product. Appropriate protective measures must be taken if necessary.

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.
- Ensure good ventilation. Avoid breathing vapour or mist.
- Avoid contact with skin and eyes.
- 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 when handling dry treated wood (glove material to be specified by the authorisation holder within the product information).
- Use automatic dosage equipment instead of manual mixing and loading.
- Wash hands after use of the product and before eating, drinking, smoking or using the lavatory, and at the end of a working period.

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 species such as bats, hornets or birds. The presence of protected species 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.
- 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 157 mL/m^2 (equivalent to 182 g/m^2) as a single application.

Non- pressurized injection: Application rate of 157 mL/m^2 (equivalent to 182 g/m^2).

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.
- Store below 40 °C.
- Protect from light.
- Opened containers must be carefully resealed and kept upright to prevent leakage.
- Do not store where leakage to the ground or surface water can occur.
- 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 of in drains or sewers, including rainwater canals.

Packaging:

- Dispose in compliance with local / regional / national / international 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.

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 / regional / national / international 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 EXPOSED OR CONCERNED: Get medical advice/attention.
- IF INHALED: Get medical advice / attention.
- IF SWALLOWED: Get medical advice / attention.
- IF ON SKIN: Wash skin with water. Get medical advice / attention.
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

Most important symptoms, acute and delayed

- No specific symptoms.

Emergency measures to protect the environment

- Contain and absorb spill with sand or other absorbent material and transfer to suitable waste containers. Disposed of safely as hazardous waste in accordance with local / regional / national / international regulations.
- 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 / regional / national / international 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

Not relevant. Boracol 15 is not intended to be used together with other biocidal products.

2.2.11 Comparative assessment

DK CA COMPARATIVE ASSESSMENT REPORT FOR Boracol 15

Background

The Danish Competent Authority has been processing an application for a biocidal product, Boracol 15, a wood preservative containing one active substance, boric acid. Boric acid active substance meets the exclusion criteria of Article 5(1)c of the Biocidal Products Regulation (BPR) (528/2012), however according to paragraph 10 of Annex VI of the BPR, Article 5(2) of the BPR, and Article 10(1)a of the BPR the DK CA considers boric acid to be a candidate for substitution. Thus in line with Article 23(1) of the BPR, the DK CA has conducted a comparative assessment for the product and has produced the following comparative assessment report.

Active substance in Boracol 15 and criteria for substitution and exclusion

The biocidal product Boracol 15 contains the active substance boric acid. Boric acid active substance meets the exclusion criteria under Article 5(1)c of the Biocidal Products Regulation (BPR) (528/2012) as it has been classified according to Regulation (EC) No 1272/2008 as toxic for reproduction, category 1B (H360DF). Paragraph 10 of Annex VI (*Common principles for the evaluation of dossiers for biocidal products*) of the BPR states that in the case of biocidal products containing active substances covered by the exclusion criteria in Article 5(1)c, the competent authorities [or the Commission] shall also evaluate whether the conditions of Article 5(2) can be satisfied. Fungal- and wood-boring beetle infestation of wooden building constructions can be problematic in Denmark. The DK CA considers it necessary to have biocidal products against wood-destroying fungi (including dry rot) and wood-boring beetles on the Danish market, particularly for use in the preservation of culturally important building such as churches and other buildings considered worthy of preservation. The Applicant has presented information regarding the suitability of the active substance (boric acid) in Boracol 15 for use in treating wooden building constructions, including when affected by elevated moisture content, and documented the efficacy of Boracol 15 for treatment of wood against wood-destroying fungi and wood-boring beetles. Evaluation of the claimed uses of Boracol 15 shows acceptable exposure for professionals (the only user category) at worst-case; exposure of the general public is limited to possible handling of contaminated work clothing prior to mechanical laundering, while exposure of pets and domestic animals, and emissions to the environment, are not expected. Thus Boracol 15 is considered to meet the conditions of 5(2)c of the BPR. According to Article 10(1)a of the BPR, an active substance that meets

at least one of the exclusion criteria listed in Article 5(1) but which may be approved in accordance with Article 5(2) is considered a candidate for substitution.

Under Article 23(1) of the BPR, Member States evaluating a 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[26] 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 substance – mode of action combination in authorised biocidal products is adequate.

2.1.11.1 Screening phase

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[27] 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 1 and 2.
Target organism (including, where relevant development stage)	Brown rot fungi, including dry rot, and wood-boring beetles.
Field(s) of use	Indoor. For use as a surface application *in-situ* building material to preserve against attack from brown rot fungi and wood-boring beetles.
Application method(s)	Brushing Non-pressurised injection
Category(ies) of users	Professionals

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

26 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.

27 The uses are also acceptable according to the specific provisions for boric acid as set out in the Annex to COMMISSION DIRECTIVE 2009/94/EC.

According to the information available to the DK CA, there are approximately 32 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 nine active substances: tebuconazole, propiconazole, permethrin, DDAC, cypermethrin, IPBC, two boron compounds (disodium-octaborate-tetrahydrate and boric acid) and basic copper carbonate, which are used either alone or in combination.

DK CA conclusions on the screening phase of the comparative assessment

During the screening phase only one product on the Danish market with efficacy claim against wood destroying fungi, and insects for Use class 1 and 2 was identified, and this product contains propiconazole, cypermethrin, tebuconazole and IPBC. This means that this product have a similar use to Boracol 15, and can be considered an alternative biocidal product. Therefore, the conclusion to the screening phase is that adequate chemical diversity to minimise resistance development was not found.

As boric acid meets the exclusion criteria, the assessment also needs to include Tier I-B and Tier II.

2.2.11.2 Tier IB

The relevant use for this Comparative Assessment is: PT8, against brown rot fungi (including dry rot fungus *Serpula lacrymans*), wood-boring beetles, professional use, indoor use, and application by brushing or non-pressurised injection.

Boric acid meets the exclusion criteria due to classification as toxic for reproduction, category 1B, therefore this criteria is to be compared. One of the active substances in the alternative biocidal product, propiconazole, has a harmonised classification for reproductive toxicity, category 1B. 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 15.

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 and the wood in question has a high moisture content, for example a window frame outdoor or a beam in a cellar indoor. In both cases, it can be impossible to dry the wood enough before treatment and boron-containing products may be the best chemical treatment 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 containing propiconazole show significant economical and practical disadvantages.

2.2.11.3 Tier II

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.

2.2.11.4 Overall conclusion

Boric acid meets the exclusion criteria due to classification as toxic for reproduction category 1B, however in accordance with paragraph 10 of Annex VI of the BPR, the DK CA considers that the biocidal product, Boracol 15, meets the conditions of Article 5(2), thus a Comparative Assessment was conducted in accordance with Article 23(1) of the BPR.

Boracol 15 has been shown to be effective against brown rot fungi and wood-boring beetles, and these target organisms were considered in the comparative assessment. During the screening phase the DK CA found only 1 biocidal products on the Danish market approved for wood destroying fungi, including dry rot; this product had propiconazole, cypermethrin, IPBC and tebuconazole as active substances. 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 are 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 contains an active substance which has the same classification as toxic for reproduction category 1B, and so the alternative biocidal product(s) would have the same impact on human and environmental health.

Fungal- and wood-boring beetle infestation of wooden building constructions can be problematic in Denmark. The DK CA considers it necessary to have biocidal products against wood-destroying fungi (including dry rot) and wood-boring beetles on the Danish market, particularly for use in the preservation of culturally important building such as churches and other buildings considered worthy of preservation. Evaluation of the claimed uses of Boracol 15 shows acceptable exposure for professionals (the only user category) at worst case; exposure of the general public is limited to possible handling of contaminated work clothing prior to mechanical laundering, while exposure of pets and domestic

animals, and emissions to environmental compartments, are not expected. The DK CA finds it justifiable to approve Boracol 15, a biocidal product containing an active substance (boric acid) that meets the exclusion criteria, on the basis of condition c) of Article 5(2) of the BPR, and as the Comparative Assessment shows that there is not an adequate number of safer alternative biocidal products on the Danish market.

It is the opinion of the DK CA that Boracol 15 can be approved to the following use:

Product type	PT8, wood preservative
Where relevant, an exact description of the authorised use	Wood preservative for wood in Use class 1 and 2.
Target organism (including, where relevant development stage)	Brown rot fungi, including dry rot, and wood-boring beetles.
Field(s) of use	Indoor. For use as a surface application *in-situ* building material to preserve against attack from brown rot fungi and wood-boring beetles.
Application method(s)	Brushing Non-pressurised injection
Category(ies) of users	Professionals

3 ANNEXES

3.1 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
3.1	852037 ACC (rev. 5)	Danish Tech-nological Institute; Jonannesen, S. A.	2019	Test report. Phys/chem data and Storage stability of Boracol 15. Report no.: 852037 ACC (rev. 5)	KRS ApS			X	
3.4.1	845540 20M	Danish Technological Institute; Johannesen, S. A.	2020	Test report. Long term storage stability study of Boracol 15 for 20 months	KRS ApS			X	
4.16	938346 (rev. 1)	Danish Technological Institute; Bjørke, B.	2020	Test report. Test for determining the corrosive properties of Boracol 15	KRS ApS			X	
4.17.1	PS20190438-1	Siemens AG, Prozess-Sicherheit; Krack, M.	2020	Auto-ignition temperature (liquids and gasses) A.15	KRS ApS			X	
5.	740675	Danish Tech-nological Institute; Jacobsen, E.	2017	DTI report 740675, Determination of BA equivalents in Boracol 10-3BD, validation of analytical method	KRS ApS			X	
5.	845540-1	Danish Technological Institute; Johannesen, S. A.	2020	Test report. Recovery test of boron in the test material Boracol 15	KRS ApS			X	
6.	825979-T1	Danish Technological Institute	2019	EN 839 + EN 73 wood rotting fungi, surface treatment, UC 2	KRS ApS			X	
6.	825979-T2	Danish Technological Institute	2019	EN 839 + EN 73 wood rotting fungi, surface treatment, UC 2 *Serpula lacrymans*	KRS ApS			X	
6.	825984	Danish Technological Institute	2019	ENV 12404 *Serpula lacrymans* – mortar	KRS ApS			X	
6.	826016-1 (rev 1)	Danish Technological Institute /FCBA	2020	EN 20-1 + EN 73 wood-boring beetles, surface treatment, *Lyctus brunneus*	KRS ApS			X	
6.	826020	Danish Technological Institute /FCBA	2019	EN 46-1 + EN 73, wood-boring beetles, surface treatment, *Hylotrupes bajulus*	KRS ApS			X	
6.	826029-1	Danish Technological Institute /FCBA	2020	EN 49-1 + EN 73, wood-boring beetles, surface treatment, *Anobium punctatum*	KRS ApS			X	
6.		ECHA		Assessment report Boric acid	ECHA	X			X

IUCLID Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
6.	IRG/WP 1450	IRG/WP	1990	The Probable Mechanisms of Action of Boric Acid and Borates As Wood Preservatives	IRG/WP			X	
13.		KRS ApS	2019	NA-APP statement	KRS ApS				X
13.		Brenntag	2016	MSDS NaOH	Brenntag				X
13.		Brenntag	2015	MSDS PROPYLENGLYCOL _IBC 1000	Brenntag				X
13.		EtiMaden	2016	MSDS Boric Acid DK	KRS ApS				X
13.		EBA	2019	LoA Boron DK	EBA	X			
13.		EBA	2019	LoA Boron DE	EBA	X			
13.		EBA	2019	LoA Boron EE	EBA	X			
13.		EBA	2019	LoA Boron FI	EBA	X			
13.		EBA	2019	LoA Boron NO	EBA	X			
13.		EBA	2019	LoA Boron SE	EBA	X			
13.		KRS ApS	2019	MSDS B15 EE	KRS ApS				X
13.		KRS ApS	2019	MSDS B15 FI	KRS ApS				X
13.		KRS ApS	2019	MSDS B15 NO	KRS ApS				X
13.		KRS ApS	2019	MSDS B15 SE	KRS ApS				X
13.		KRS ApS	2019	MSDS B15 DE	KRS ApS				X
13.		KRS ApS	2019	MSDS B15 DK	KRS ApS				X
13.		DTI	2019	ED properties of co-formulant	KRS ApS			X	
13.		Kassotis et al.	2015	Endocrine-Disrupting Activity of Hydraulic Fracturing Chemicals and Adverse Health Outomes After Prenatal Exposure in Male Mice	KRS ApS				X
13.		Massarsky et al.	2016	Exposure to 1,2-Propane-diol Impacts Early Development of Zebrafish (Danio rerio) and Induces Hyperactivity	KRS ApS				X
13.		Gamarra et al.	2018	Oral propylene glycol modifies follicular fluid and gene expression profiles in cumulus–oocyte complexes and embryos in feed-restricted heifers	KRS ApS				X
13.		KRS ApS	2020	Letter concerning the used concentrations for testing	KRS ApS			X	
13.		KRS ApS	2020	Guidance to non-pressurised injection	KRS ApS			X	

3.2 Output tables from exposure assessment tools

Scenario 1. Mixing & loading (professionals)

Activity / Parameter	Units	Tier 1 (no PPE)	Tier 2 (gloves)
Concentration of a.s. in Boracol 15	% w/w	16,5%	16,5%
Duration of activity	min	1,5	1,5
Hand Exposure			
Hands, rate (90% percentile)[1]	mg/min	13	13
Hands, b.p. loading (90% percentile)[1]	mg	20	20
Peneration of a.s. through gloves	%	100%	10%
Hand dermal deposit as b.p.	mg	20	2,0
Hand dermal deposit as a.s.	mg	3,3000	0,3300
Hand dermal deposit as boron[2]	mg	0,5775	0,0578
Total dermal exposure			
A Total (= hand) dermal deposit as boron	mg	0,5775	0,0578
B Dermal absorption	%	25%	25%
Total systemic exposure via dermal route as boron[3]	mg/kg bw/day	0,1444	0,0144
Systemic exposure			
Total systemic exposure as boron from the a.s.[4]	mg/kg bw/day	0,0024	0,0002
AEL (boron)	mg/kg bw/day	0,1	0,1
% AEL	**%**	**2,4%**	**0,2%**

[1] Determined using RISKOFDERM dermal exposure model *Loading liquid, automated or semi-automated.*

[2] Conversion factor from mg a.s. to mg boron is 0.175.

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

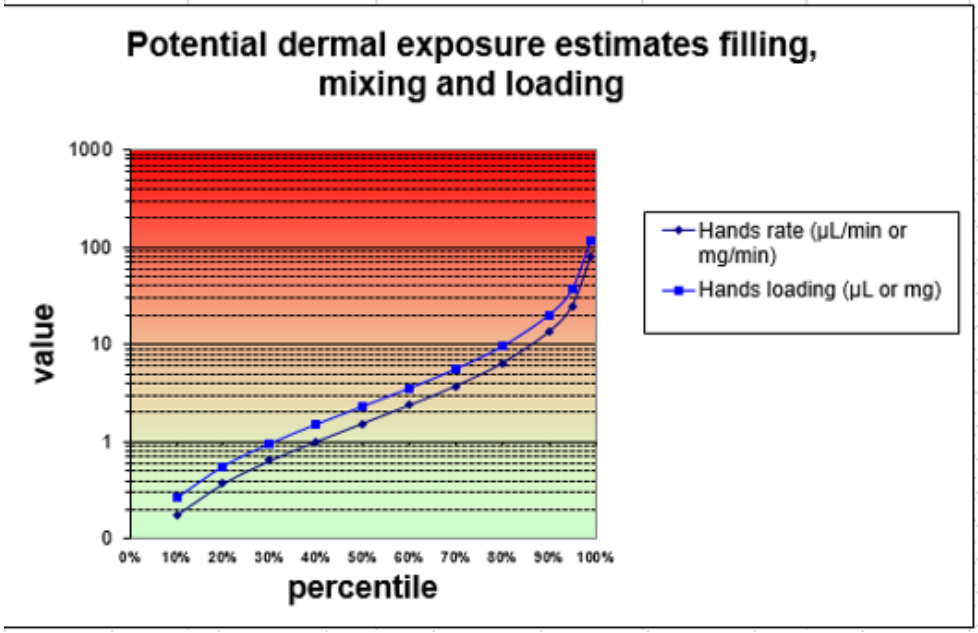
Output from the RISKOFDERM *Potential Dermal Exposure Model* calculator estimating potential dermal exposure to Boracol 15 during *Loading liquid, automated or semi-automated* is presented below. The 90% percentile value for hand loading (marked with orange box) was used in the calculation of dermal exposure to the active substance (above).

Output from the RISKOFDERM *Potential Dermal Exposure Model* calculator estimating potential dermal exposure to Boracol 15 during *Loading liquid, automated or semi-automated*. The 90% percentile value for hand loading (marked with yellow box) was used in the calculation of dermal exposure during mixing and loading.

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)	1,5

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	0	
20,0%	0	1	
30,0%	1	1	
40,0%	1	2	
50,0%	2	**2**	
60,0%	2	4	
70,0%	4	6	
80,0%	6	10	
90,0%	13	20	
95,0%	25	37	
99,0%	78	118	



Scenario 2. Application by brushing (professionals)

Activity / Parameter	Units	Tier 1 (no PPE)	Tier 2 (gloves, coated coveralls)
Concentration of a.s. in Boracol 15	% w/w	16,5%	16,5%
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	3,9303	3,9303
Application area	m^2	31,6	31,6
Penetration of a.s. through coated coveralls	%	100%	10%
D Body dermal deposit as a.s.	mg	124,1975	12,4197
Body dermal deposit as boron[1]	mg	21,7346	2,1735
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	8,9381	8,9381
Application area	m^2	31,6	31,6
Penetration of a.s. through gloves	%	100%	10%
C Hand dermal deposit as a.s	mg	282,4424	28,2442
Hand dermal deposit as boron[1]	mg	49,4274	4,9427
Total dermal exposure			
A Total dermal deposit as boron	mg	71,1620	7,1162
B Dermal absorption	%	25%	25%
Total systemic exposure via dermal route as boron[2]	mg/kg bw/day	0,2965	0,0297
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	0,0264	0,0264
Application area	m^2	31,6	31,6
E Inhaled a.s.	mg	0,8342	0,8342
Systemic exposure via inhalation route as a.s.[3]	mg/kg bw/day	0,0139	0,0139
Systemic exposure via inhalation route as boron[1]	mg/kg bw/day	0,0024	0,0024
Systemic exposure			
Total systemic exposure as boron from the a.s.	mg/kg bw/day	0,2989	0,0321
AEL boron	mg/kg bw/day	0,1	0,1
% AEL	**%**	**299%**	**32,1%**

[1] Conversion factor from mg a.s. to mg boron is 0.175.

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

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

Scenario 3. Application by injection (professionals)

Activity / Parameter	Units	Tier 1 (no PPE)	Tier 2 (gloves)
Concentration of a.s. in Boracol 15	% w/w	16,5%	16,5%
Hand exposure			
A Indicative value	mg/loading	10	10
B Loadings	per day	100	100
Hands, b.p. loading[1]	mg	1000	1000
Penetration of a.s. through gloves	%	100%	10%
Hand dermal deposit as b.p.	mg	1000	100
Hand dermal deposit as a.s.	mg	165,0000	16,5000
C Hand dermal deposit as boron[2]	mg	28,8750	2,8875
D Dermal absorption	%	25%	25%
Systemic exposure			
Total systemic exposure as boron[3]	mg kg^{-1} day^{-1}	0,1203	0,0120
AEL (boron)	mg kg^{-1} day^{-1}	0,1	0,1
% AEL	**%**	**120%**	**12,0%**

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

[2] Conversion factor from mg a.s. to mg boron is 0.175.

[3] Calculation: (**C** x **D**) / body weight (60 kg).

Scenario 4. Cleaning the brush (professionals)

Activity / Parameter	Unit	Tier 1 (no PPE)	Tier 2 (gloves)
Volume of brush	mL	200	200
Volume of paint remaining on brush after painting ($^1/_8$ of 200 ml = 25 ml)	mL	25	25
Density of paint	g/mL	1,16	1,16
Weight of paint on brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	g	29,00	29,00
Concentration of a.s. in paint	% w/w	16,5	16,5
A. Weight of a.s. on brush after painting	mg	4785,0	4785,0
B. Residues of a.s. on brush after 1st washing (10% of A)	mg	478,50	478,50
Amount of a.s. removed from the brush into the cleaning fluid (A minus B)	mg	4306,50	4306,50
C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	mg	239,25	239,25
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of C)	mg	23,93	23,93
Penetration of a.s. through gloves	%	100	10
J Weight of a.s. on hand	mg	23,925	2,393
Dermal absorption of a.s.	%	25	25
Weight of a.s. entering the body	mg	5,9813	0,5981
D. Weight of a.s. left on the brush after 1st wash and squeezing (B minus C)	mg	239,25	239,25
E. Residues of a.s. on brush after 2nd washing (10% of D)	mg	23,93	23,93
Amount of a.s. removed from the brush into the cleaning fluid (D minus E)	mg	215,33	215,33
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	mg	11,96	11,96
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of F)	mg	1,20	1,20
Penetration of a.s. through gloves	%	100	10
K Weight of a.s. on hand	mg	1,196	0,120
Dermal absorption of a.s.	%	25	25
Weight of a.s. entering the body	mg	0,2991	0,0299
G. Weight of a.s. left on the brush after 2nd wash and squeezing (E minus F)	mg	11,96	11,96
H. Residues of a.s. on brush after 3rd washing (10% of G)	mg	1,20	1,20

Amount of a.s. removed from the brush into the cleaning fluid (G minus H)	mg	10,77	10,77
I. Weight of a.s. squeezed out from a brush onto a cloth (50% of H)	mg	0,60	0,60
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of I)	mg	0,06	0,06
Penetration of **a.s.** through gloves	%	100	10
L Weight of a.s. on hand	mg	0,060	0,006
Dermal absorption of a.s.	%	25	25
Weight of a.s. entering the body	mg	0,0150	0,0015
A Total weight of a.s. entering the body	mg	6,2953	0,6295
B Body weight	kg	60	60
Systemic exposure			
Total systemic exposure[2] as boron[1] from the a.s.	mg/kg bw/day	0,0184	0,0018
AEL boron	mg/kg bw/day	0,1	0,1
%AEL	**%**	**18,4%**	**1,8%**

[1] Conversion factor from mg a.s. to mg boron is 0.175.

[2] Calculation: (**A** / **B**) x conversion factor for mg a.s. to mg boron.

Scenario 5. Cleaning of non-pressurised injection equipment (professionals)

Activity / Parameter	Units	Tier 1 (no PPE)	Tier 2 (gloves)
Concentration of a.s. in Boracol 15	% w/w	16,5%	16,5%
Hand exposure			
Hands, b.p. loading (90% percentile)[1]	mg	210	210
Penetration of a.s. through gloves	%	100%	10%
Hand dermal deposit as b.p.	mg	210	21,0
Hand dermal deposit as a.s.	mg	34,6500	3,4650
A Hand dermal deposit as boron[2]	mg	6,0638	0,6064
B Dermal absorption	%	25%	25%
Systemic exposure			
Total systemic exposure as boron[3]	mg kg^{-1} day^{-1}	0,0253	0,0025
AEL (boron)	mg kg^{-1} day^{-1}	0,1	0,1
% AEL	**%**	**25,3%**	**2,5%**

[1] From HEadhoc Recommendation no. 4 *Cleaning of spray equipment in antifouling use (PT21)*.

[2] Conversion factor from mg a.s. to mg boron is 0.175.

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

Scenario 6. Sanding treated wood (professionals)

Activity / Parameter	Tier 1 (no PPE)	Tier 2 (gloves)
Concentration of a.s. in Boracol 15 (% w/w)	16,5%	16,5%
Density (g/cm³)	1,16	1,16
Concentration in wood		
Application rate* (mL/m²) (* highest rate)	157	157
Application rate* of b.p. (g/m²) (* highest rate)	182	182
Application rate of a.s. (mg/cm²)	3,0031	3,0031
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)	12108	12108
Exposure by inhalation		
Concentration of a.s. in wood dust (mg/cm³)	4,0254	4,0254
Wood dust concentration in air (mg/m³)	5	5
Exposure duration (h)	6	6
Inhalation rate (m³/h)	1,25	1,25
Retention of a.s. in wood	100%	100%
Density of wood (g/cm³)	0,40	0,40
Amount dust inhaled in 6 hour (cm³)	0,094	0,094
Inhaled a.s (mg)	0,3774	0,3774
Body weight (kg)	60	60
Systemic exposure by inhalation route as a.s. (mg/kg bw/day)	0,0063	0,0063
Systemic exposure by inhalation route as boron[1] (mg/kg bw/day)	0,0011	0,0011
Dermal exposure		
A Concentration on the wood surface (mg/cm²)	3,0031	3,0031
B Transfer coefficient (%): **Tier 2** = with gloves (10% penetration)	2%	0,2%
C Surface of palms of hands (cm²)	410	410
D Contaminated area of palms (%)	20%	20%
E Dermal absorption (%)	25%	25%
F Body weight (kg)	60	60
Systemic exposure by dermal route as a.s. (mg/kg bw/day)[2]	0,0205	0,0021
Systemic exposure by dermal route as boron[1] (mg/kg bw/day)	0,0036	0,0004
Systemic exposure		
Total systemic exposure as boron from the a.s. (mg/kg bw/day)	0,0047	0,0015
AEL boron (mg/kg bw/day)	0,1	0,1
%AEL	**4,7%**	**1,5%**

[1] Conversion factor from mg a.s. to mg boron is 0.175.

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

Scenario 7. Laundering work clothes (general public)

Activity / Parameter	Tier 1
Concentration of a.s. in Boracol 15 (% w/w)	16,5%
Clothing contamination	
Clothes deposit of a.s.[3] (mg/day)	124,1975
Clothing contamination (%)[4]	90%
Actual clothes deposit of a.s. (mg/day)	111,7777
Overall surface (cm²)	22700
Surface concentration of a.s. (mg/cm²/day)	0,0049
No of working days before washing	5
Percentage dislodgeable (%)	50%
Dislodgeable residues of a.s. (mg/cm²)	0,0123
Hand exposure	
Area: both palms 3-times + backs of hands once (cm²)	1640
Hand deposit of a.s. (mg/day)	20,1889
Dermal absorption (%)	25%
A Systemic exposure via dermal route as a.s. (mg)	5,0472
B Body weight (kg)	60
Systemic exposure	
Systemic exposure[2] as boron[1] from a.s. (mg/kg bw/day)	0,0147
AEL boron (mg/kg bw/d)	0,1
%AEL	**14,7%**

[1] Conversion factor from mg a.s. to mg boron is 0.175.

[2] Calculation: (**A** / **B**) x conversion factor for mg a.s. to mg boron.

[3] **D** from Scenario 2.

[4] Assuming 10% penetration through clothing; see Scenario 2.

Scenario 8. Toddler touching freshly treated wood (general public)

Activity / Parameter	Tier 1
Concentration of a.s. in Boracol 15 (% w/w)	16,5%
Wood contamination	
Application rate* of b.p. (g/m²) (* highest rate)	182
Application rate of a.s. (mg/cm²)	3,0030
Percentage dislodgeable (%)	50%
Dislodgeable a.s. residues (mg/cm²)	1,5015
Hand exposure	
Area: both palms (cm²)	115,2
Fraction of palms in contact with b.p. (%)	100%
Hand deposit of a.s. (mg/day)	172,9728
Dermal absorption (%)	25%
Body weight (kg)	10
Systemic exposure via dermal route to a.s. (mg)	43,2432
Systemic exposure via dermal route as boron[1] (mg/kg bw/d)	0,7568
Oral exposure	
Hand deposit of a.s. (mg/day)	172,9728
Transfer efficiency for hand to mouth (%)	10%
Oral absorption (%)	100%
Body weight (kg)	10
Systemic exposure via oral route to a.s. (mg)	17,2973
Systemic exposure via oral route as boron[1] (mg/kg bw/d)	0,3027
Systemic exposure	
Total systemic exposure to a.s. (mg)	60,5405
Total systemic exposure as boron[1] from a.s. (mg/kg bw/day)	1,0595
AEL boron (mg/kg bw/day)	0,1
%AEL	**1059%**

[1] Conversion factor from mg a.s. to mg boron is 0.175.

Combined exposure scenarios

Professionals	**Tier**	**Inhalation uptake*** (mg B/kg bw/d)	**Dermal uptake*** (mg B/kg bw/d)	**Oral uptake*** (mg B/kg bw/d)	**Total systemic uptake*** (mg B/kg bw/d)	**%AEL**
Brush application & associated activities (1+2+4)	Tier 2	0,0024	0,0317	0	0,0342	34
Brush application & associated activities, plus laundery (1+2+4+7)	Tier 2[2]	0,0024	0,0464	0	0,0489	49
Injection application & associated activities (1+3+5)	Tier 2	0	0,0148	0	0,0148	15
Injection application & associated activities, plus laundry (1+3+5+7)	Tier 2[2]	0	0,0295	0	0,0295	30
Brush & injection application & associated activities (1[1]+2+3+4+5)	Tier 2	0,0024	0,0463	0	0,0487	49
Brush & injection application & associated activities, plus laundry (1[1]+2+3+4+5+7)	Tier 2[2]	0,0024	0,0610	0	0,0634	63
Sanding plus laundry (6+7)	Tier 1	0,0011	0,0183	0	0,0194	19
Sanding plus laundry (6+7)	Tier 2[2]	0,0011	0,0151	0	0,0162	16
Brush & injection application & associated activities, plus sanding & laundry (1[1]+2+3+4+5+6+7)[3]	Tier 2[2]	0,0035	0,0614	0	0,0649	65

* Values are for boric acid expressed as the equivalent dose of boron (B), i.e. mg B/kg bw/d.

[1] The value for Scenario 1 (Mixing and loading) is included once as it covers the combined exposure associated with the loading task for both application scenarios (brushing, non-pressurised injection).

[2] Tier 1 for 'Laundering work clothes' (Scenario 7).

[3] Not a realistic scenario, as the time required to perform all the activities greatly exceeds the duration (8 h) of a work day.

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

Find study summaries of the efficacy studies in IUCLID and the evaluation of these in section 2.2.5.5.

3.6 Environmental Risk Assessment

Not required.

3.7 Confidential annex

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