

|                               |   |
|-------------------------------|---|
|                               | <p>h. In the alternate study (Barres, 1967) the log Pow value was found to be dependant upon the salt concentration in the aqueous solution and on temperature:<br/> log Pow = -0.757 in water at 25 °C<br/> log Pow = -0.742 in 2 M KCl at 25 °C<br/> log Pow = -0.561 in 3 M NaClO<sub>4</sub> at 25 °C<br/> log Pow = -0.554 in 3 M NaClO<sub>4</sub> at 35 °C</p> <p>It was found that in a B(OH)<sub>3</sub>-NaB(OH)<sub>4</sub> or B(OH)<sub>3</sub>-KB(OH)<sub>4</sub> system, undissociated boric acid was the only compound extracted into octanol.</p> <p>i. The value found in the key study (-1.09 ± 0.16 at 22 °C) differs from the value found in the alternate study (-0.757 ± 0.004 at 25 °C). The notifier indicates that the temperature can give an error of maximum 0.01 log-unit, but this effect may actually be somewhat larger. At least no proof is given for this statement.</p> <p>The difference between the two values is probably caused by differences in boron concentration (&gt; 0.025 M in alternate study, &lt;0.025 M in key study) and differences in the solvent (decarbonated unbuffered water in alternate study, sodium or potassium phosphate buffer in key study).</p> <p>j. The difference between log Pow values obtained at different temperatures, different salinity, different concentration and different analysis, is only 0.5 log Pow unit. No further tests are required.</p> <p>k. The reference is stated wrong in the table for boric acid. The full reference for the key study should be stated as: [REDACTED]</p> |
| <b>Conclusion</b>             | <p>The partition coefficient for disodium octaborate tetrahydrate as such cannot be determined because disodium octaborate tetrahydrate is converted into boric acid/borate upon dissolution in water: Na<sub>2</sub>B<sub>8</sub>O<sub>13</sub>·4H<sub>2</sub>O + 9H<sub>2</sub>O ↔ 2 NaB(OH)<sub>4</sub> + 6 B(OH)<sub>3</sub>. The partition coefficient found will be the partition coefficient for boric acid in the presence of sodium ions.</p> <p>log Pow = -0.561 to -1.09 at 22-25 °C, depending on the presence of metal ions (e.g sodium or potassium from buffered systems) and boron concentration..</p>  |
| <b>Reliability</b>            | key study set at 1, alternate study set at 2, all others set at 4   |
| <b>Acceptability</b>          | acceptable.   |
| <b>Remarks</b>                | -   |
| <b>COMMENTS FROM ...</b>      |   |
| <b>Date</b>                   | <i>Give date of comments submitted</i>  |
| <b>Results and discussion</b> | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Conclusion</b>             | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Reliability</b>            | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Acceptability</b>          | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Remarks</b>                |   |

| Evaluation by Competent Authorities  |  |
|--|--|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |  |
| <b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>   |  |
| <b>Date</b>  | 15-Sept-05   |
| <b>Materials and methods</b>   | Section 3.10 Thermal stability.<br><br>The notifier did not submit any studies, but just repeated the phenomena that were seen in the melting point experiment (see IIIA3.1.1). Therefore, disodium octaborate tetrahydrate is considered stable under the conditions normally required for a storage stability test (14 days at 54-55 °C, OECD guideline 113). No further studies are required. |
| <b>Conclusion</b>  | Disodium octaborate tetrahydrate is stable up to 567 °C. At this temperature a phase transition occurs. A melting point is found at 813/803 °C.  |
| <b>Reliability</b>   | -  |
| <b>Acceptability</b>   | acceptable   |
| <b>Remarks</b>   | -  |
| <b>COMMENTS FROM ...</b>   |  |
| <b>Date</b>  | <i>Give date of comments submitted</i>   |
| <b>Results and discussion</b>  | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Conclusion</b>  | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Reliability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Acceptability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Remarks</b>   |  |

| Evaluation by Competent Authorities  |  |
|--|--|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |  |
| <b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>   |  |
| <b>Date</b>  | 27-Jan-05  |
| <b>Materials and methods</b>   | Section 3.11 Flammability.<br><br>The notifier did not submit data or a statement but just a conclusion that disodium octaborate tetrahydrate is non-flammable. As the a.s. is known for its flame retardant properties, it is not expected that the a.s. is to be classified as (highly) flammable nor will it self-ignite. |
| <b>Conclusion</b>  | no reliable data available; not required   |
| <b>Reliability</b>   | -  |
| <b>Acceptability</b>   | Acceptable.  |
| <b>Remarks</b>   | -  |
| <b>COMMENTS FROM ...</b>   |  |
| <b>Date</b>  | <i>Give date of comments submitted</i>   |
| <b>Results and discussion</b>  | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Conclusion</b>  | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Reliability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Acceptability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Remarks</b>   |  |

| Evaluation by Competent Authorities  |  |
|--|--|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |  |
| <b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>   |  |
| <b>Date</b>  | 15-Feb-05  |
| <b>Materials and methods</b>   | <p>Section 3.13 Surface tension.</p> <p>a. The notifier refers to disodium tetraborate pentahydrate. The notifier submitted one study (Wurster, 1963) where disodium tetraborate pentahydrate was dissolved in water. The study is considered not reliable enough to be a key study by the RMS. The study was not carried out according to GLP nor according to EC guidelines. Purity data are not indicated. The study can be used as indication study (reliability 4).</p> <p>b. For a 3% (w/v) solution of disodium tetraborate pentahydrate, a surface tension of 69.5-71.0 dynes/cm or mN/m was found at 23-24 °C, slightly lower than the surface tension for water (72.8 at 20 °C). Although the surface tension for a solution of disodium tetraborate pentahydrate will be slightly different from the surface tension for a solution of disodium octaborate tetrahydrate, surface tension is considered not applicable for inorganic substances. No further data are required.</p> |
| <b>Conclusion</b>  | <p>The surface tension for disodium octaborate tetrahydrate as such cannot be determined because disodium octaborate tetrahydrate is converted into boric acid/borate upon dissolution in water: <math>\text{Na}_2\text{B}_8\text{O}_{13} \cdot 4\text{H}_2\text{O} + 9\text{H}_2\text{O} \leftrightarrow 2 \text{NaB}(\text{OH})_4 + 6 \text{B}(\text{OH})_3</math>. The surface tension found will be the surface tension for boric acid in the presence of sodium ions.</p> <p>Surface tension is considered not applicable for inorganic substances. Disodium octaborate tetrahydrate is an inorganic substance and the surface tension of a solution in water will be slightly lower than the surface tension for water (72.8 mN/m at 20 °C).</p>   |
| <b>Reliability</b>   | reliability is set at 4.   |
| <b>Acceptability</b>   | acceptable.  |
| <b>Remarks</b>   | -  |
| <b>COMMENTS FROM ...</b>   |  |
| <b>Date</b>  | <i>Give date of comments submitted</i>   |
| <b>Results and discussion</b>  | <p><i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p>   |
| <b>Conclusion</b>  | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Reliability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Acceptability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Remarks</b>   |  |



| <b>Evaluation by Competent Authorities</b>   |   |
|--|---|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |   |
| <b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>   |   |
| <b>Date</b>  | 20-Jan-05   |
| <b>Materials and methods</b>   | Section 3.15 Explosive properties.<br>a. The notifier submitted a statement (Mak, 2004) and is given reliability of 4 because no methods are described. The statement that boric acid contains no reactive groups is acceptable to show that boric acid has no explosive properties and testing according to EC method A14 is not required. |
| <b>Conclusion</b>  | as indicated by the notifier  |
| <b>Reliability</b>   | reliability is 4  |
| <b>Acceptability</b>   | acceptable.   |
| <b>Remarks</b>   | -   |
| <b>COMMENTS FROM ...</b>   |   |
| <b>Date</b>  | <i>Give date of comments submitted</i>  |
| <b>Results and discussion</b>  | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Conclusion</b>  | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Reliability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Acceptability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Remarks</b>   |   |

| Evaluation by Competent Authorities  |  |
|--|--|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |  |
| <b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>   |  |
| <b>Date</b>  | 20-Jan-05  |
| <b>Materials and methods</b>   | Section 3.16 Oxidizing properties.<br><br>The notifier submitted a statement (Mak, 2004) and is given reliability of 4 because no methods are described. The statement that boric acid contains no reactive groups is acceptable to show that boric acid has no oxidizing properties and testing according to EC method A17 is not required. |
| <b>Conclusion</b>  | as indicated by the notifier.  |
| <b>Reliability</b>   | reliability is set at 4.   |
| <b>Acceptability</b>   | acceptable.  |
| <b>Remarks</b>   | -  |
| <b>COMMENTS FROM ...</b>   |  |
| <b>Date</b>  | <i>Give date of comments submitted</i>   |
| <b>Results and discussion</b>  | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Conclusion</b>  | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Reliability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Acceptability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Remarks</b>   |  |

| Evaluation by Competent Authorities  |   |
|--|---|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |   |
| <b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>   |   |
| <b>Date</b>  | 20-Jan-05   |
| <b>Materials and methods</b>   | Section 3.17 Reactivity towards container material.<br><br>Possible plastics: PP (polypropylene) and HDPE (high density polyethylene).<br><br>However, the use of PP at lower temperatures may best be avoided as the material becomes brittle at lower temperatures. |
| <b>Conclusion</b>  | -   |
| <b>Reliability</b>   | 0   |
| <b>Acceptability</b>   | acceptable.   |
| <b>Remarks</b>   | -   |
| <b>COMMENTS FROM ...</b>   |   |

|                               |   |
|-------------------------------|---|
| <b>Date</b>                   | <i>Give date of comments submitted</i>  |
| <b>Results and discussion</b> | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i> |
| <b>Conclusion</b>             | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Reliability</b>            | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Acceptability</b>          | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Remarks</b>                |   |

## Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

### Annex Point IIA4.1/4.2 & IIIA-IV.1

#### Section A4 4.1.1

Official  
use only

### 1 REFERENCE

#### 1.1 Reference

BS 5688 : Part 8 :1979 ISO 1914-1972 [ISO title: Crude sodium borates for industrial use- Determination of sodium oxide and boric oxide contents- Volumetric method] (published)

Copyright

#### 1.2 Data protection

No

##### 1.2.1 Data owner

BSI / ISO

##### 1.2.2

##### 1.2.3 Criteria for data protection

No data protection claimed

### 2

#### 2.1

#### 2.2

#### 2.3

### 3 MATERIALS AND METHODS

#### 3.1 Preliminary treatment

##### 3.1.1 Enrichment

None required

##### 3.1.2 Cleanup

None required

#### 3.2 Detection

##### 3.2.1 Separation method

Not required

##### 3.2.2 Detector

Chemical indicator used

##### 3.2.3 Standard(s)

Standard solutions of sodium hydroxide and hydrochloric acid.

##### 3.2.4 Interfering substance(s)

None identified

#### 3.3 Linearity

##### 3.3.1 Calibration range

Not applicable for volumetric method

##### 3.3.2 Number of measurements

ISO standard method

##### 3.3.3 Linearity

ISO standard method

#### 3.4 Specificity: interfering substances

None identified

#### 3.5 Recovery rates at different levels

Not applicable for this method

## Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

### Annex Point IIA4.1/4.2 & IIIA-IV.1

#### Section A4 4.1.1

|       |                                   |   |
|-------|-----------------------------------|---|
| 3.5.1 | Relative standard deviation       | Not applicable for this method  |
| 3.6   | <b>Limit of determination</b>     | Not applicable for this method; value will depend on standard volumetric solutions being used |
| 3.7   | <b>Precision</b>                  |   |
| 3.7.1 | Repeatability                     | ISO standard method   |
| 3.7.2 | Independent laboratory validation | ISO standard method   |

## 4 APPLICANT'S SUMMARY AND CONCLUSION

### 4.1 Materials and methods

The sodium oxide and boric oxide content are determined on the sme solution. An aqueous solution is treated with excess standard hydrochloric acid solution followed by back titration with standard sodium hydroxide solution in the presence of methyl red as indicator. From this the sodium oxide can be calculated. The subsequent titration with standard sodium hydroxide in the presence of mannitol and phenolphthalein as indicator enables the boric oxide content to be calculated.

### 4.2 Conclusion

ISO standard method that is appropriate for industrial grades of boric acid, boric oxide and sodium borates

Of the boron-based compounds considered in the biocides dossiers, e.g., boric acid ( $B(OH)_3$ ), boric oxide ( $B_2O_3$ ), disodium tetraborates or anhydrous borax ( $Na_2B_4O_7$  or  $Na_2O \cdot 2B_2O_3$ ), disodium octaborate tetrahydrate ( $Na_2B_8O_{13} \cdot 4H_2O$  or  $Na_2O \cdot 4B_2O_3 \cdot 4H_2O$ ), the boron stoichiometry is uniquely described in quantifiable terms of  $B_2O_3$  content. For example, the determination of the specific compounds above would yield  $B_2O_3$  contents of 56.3, 100.0, 69.2, and 67.5 wt. % respectively. The boron chemistry ensures that the  $B_2O_3$  content identifies and quantifies each pure borate compound. Similarly, the unique identification of sodium borates is revealed and confirmed when the  $Na_2O$  value is determined, and the unique ratio of the two oxides is determined. For two sodium borates listed above, this yield the distinctive ratio of 0.5 and 0.22 respectively, thereby in combination with the borate assay, uniquely identifies the compounds.

This approach is practiced worldwide and solidly based on fundamental chemistry principles. An internationally accepted procedure for boron assay from properly prepared samples is described in detail by BS 5688: Part 8 1979 ISO 2216-1972 British Standard Method for Boric acid, boric oxide, disodium tetraborates, sodium perborates and crude sodium borates for industrial use - Part 8 Determination of sodium oxide and boric oxide content of crude sodium borates. Equivalent standard borate assay methods are practiced and issued by national governments that address a host of sample types.

**Section A4 (4.1-4.3)      Analytical Methods for Detection and Identification****Annex Point IIA4.1/4.2 &  
IIIA-IV.1**

Section A4 4.1.1

*Properly conducted by competent analysts, the above technique will satisfy the need for an accurate determination of boron and borate compounds*

4.2.1 Reliability

1

4.2.2 Deficiencies

No

| Evaluation by Competent Authorities  |   |
|--|---|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |   |
| <b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>   |   |
| <b>Date</b>  | 16-Sept-05  |
| <b>Materials and methods</b>   | <p>a. There are no methods to determine the active substance as manufactured. The above mentioned procedure only works for pure borate compounds with known composition. A partly purified borate compound or a borate compound with other alkalimetals as counter ion (e.g. Li, K, Mg, Ca) will not be properly identified.</p> <p>b. The ISO method submitted was developed for the determination of sodium oxide and boric oxide in crude sodium borates. A validation report was not submitted. Because ISO methods are validated among several laboratories before publication, a validation report is not considered necessary by the RMS.</p> <p>c. The ISO method submitted has been withdrawn on 27 May 2002 and is not supported by ISO anymore. The method has been withdrawn because the method was not verified once every 5 years. According to the notifier the Australian BS 5688 method is identical to the ISO 1914 method. According to the notifier this Australian method is still valid, but the RMS cannot verify this statement..</p> |
| <b>Conclusion</b>  | as indicated by the notifier  |
| <b>Reliability</b>   | -   |
| <b>Acceptability</b>   | acceptable  |
| <b>Remarks</b>   | -   |
| <b>COMMENTS FROM ...</b>   |   |
| <b>Date</b>  | <i>Give date of comments submitted</i>  |
| <b>Results and discussion</b>  | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Conclusion</b>  | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Reliability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Acceptability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Remarks</b>   |   |

|  |   |  |                   |
|--|---|--|-------------------|
| <b>4.2 (b) (d)</b><br><b>Annex Point IIA 4.2</b>   |   | <b>Analytical Methods for (b) Air (d) Animal and Human body Fluids and Tissues</b> |                   |
| <b>JUSTIFICATION FOR NON-SUBMISSION OF DATA</b>  |   |  | Official use only |
| <b>Other existing data</b> [ ]   | <b>Technically not feasible</b> [ ]   | <b>Scientifically unjustified</b> [ x ]  |                   |
| <b>Limited exposure</b> [ ]  | <b>Other justification</b> [ x ]  |  |                   |
| <b>Detailed justification:</b>   | <ul style="list-style-type: none"> <li>■ (b) Air - Due to the lack of volatility of borates this is not a relevant compartment to measure – if necessary the analytical technique presented in A4.1 is appropriate</li> <li>■ (d) Animal and Human body Fluids and Tissues – Residues in animals and humans are not relevant for Biocidal Uses. However, work has been carried out for other purposes and due to the background levels present; the contribution from diet and the possibility of contamination of boron from sources such as glassware such measurements are technically difficult and require a specially set up laboratory.</li> </ul> |  |                   |
| <b>Undertaking of intended data submission</b> [ ]   | <i>Not relevant</i>   |  |                   |
| <b>Evaluation by Competent Authorities</b>   |   |  |                   |
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |   |  |                   |
| <b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>   |   |  |                   |
| <b>Date</b>  | 8 Feb 05  |  |                   |
| <b>Evaluation of applicant's justification</b>   | Air: evaluated by environmental assessor<br>Animal and human body fluids and tissues: not relevant  |  |                   |
| <b>Conclusion</b>  | Air: evaluated by environmental assessor<br>Animal and human body fluids and tissues: not relevant  |  |                   |
| <b>Remarks</b>   | -   |  |                   |
| <b>COMMENTS FROM OTHER MEMBER STATE (specify)</b>  |   |  |                   |
| <b>Date</b>  | <i>Give date of comments submitted</i>  |  |                   |
| <b>Evaluation of applicant's justification</b>   | <i>Discuss if deviating from view of rapporteur member state</i>  |  |                   |
| <b>Conclusion</b>  | <i>Discuss if deviating from view of rapporteur member state</i>  |  |                   |
| <b>Remarks</b>   |   |  |                   |



**Section A5****Doc III A Read Across to Boric Acid****Annex Point**

## Section A5

**IIA 5 – 5.8****5 APPLICANT'S SUMMARY AND CONCLUSION****5.1****5.2 Results and discussion**

The simple inorganic borates such as boric acid; boric oxide; disodium tetraborate and disodium octaborate are used for wood preservation formulations depending upon requirements such as pH, total solubility, solubility rate, compatibility with other substances in the formulation, etc. To exemplify this, boric oxide and to some extent sodium tetraborate anhydrous are normally only used as a solid products, such as fused solid rods. These materials dissolves very slowly. Consequently they are used as a slow release product in situ

In solution, borates form a variety of polymeric species derived from undissociated boric acid,  $B(OH)_3$ . The presence of these species is dependent upon solution pH and concentration. It has been shown for solutions of boric acid and sodium borates (Ingr' 1963; Kirk-Othmer, 1992) below pH 8 and at a solution concentration of below 0.1M, the borate is present as undissociated boric acid. This has been borne out in an independent study (de Vette et al., 2001; Maeda, 1979)<sup>1</sup> aimed at identifying the species present in systems under typical biologically active conditions, i.e. pH 6.5-pH7.5 and <0.02M. Raman spectroscopy confirmed the presence of  $B(OH)_3$  as the species present. Please see Doc IIIA 7.1.1.1 Hydrolysis Boric Acid.doc. Therefore when formulated in aqueous solution all the borates will exist as boric acid.

In solution, borates form a variety of polymeric species derived from undissociated boric acid,  $B(OH)_3$ . The presence of these species is dependent upon solution pH and concentration. It has been shown for solutions of boric acid and sodium borates) below pH 8 and at a solution concentration of below 0.1M, the borate is present as undissociated boric acid. (Ingr' 1963; Kirk-Othmer, 1992) It has been verified in an independent studies aimed at identifying the species present in systems under typical biologically active conditions, i.e. pH 6.5-pH7.5 and <0.02M that boric acid,  $B(OH)_3$ , is the dominant species present. (de Vette et al., 2001; Maeda, 1979)<sup>1</sup> See Doc IIIA 7.1.1.1 Hydrolysis Boric Acid.doc).

All formulations will be designed to give an efficacious level of boric acid in the wood to comply with various Standards of Wood preservation (so need to supply a specific boric acid level). The highest loading will come from vacuum impregnation and as such should represent the highest level of borate in any treated wood. There is a specific minimum loading of boric acid in wood needed to comply with European Standards (such as Hazard Classes and the various EN 335 requirements) for efficacy against various organisms. Wood is treated to comply with the various standards depending on the type and use of the wood. Standards are quoted in boric acid equivalents and loading rates are quoted in terms of boric acid.

The efficacy data that is available is primarily is obtained from boric acid studies, but some early work with indicates there is good correlation between the efficacies obtained with boric acid; disodium tetraborate decahydrate and disodium octaborate tetrahydrate when compared on an equivalent boron basis (reviewed in Lloyd, 1993)

**Section A5****Doc III A Read Across to Boric Acid****Annex Point**

## Section A5

**IIA 5 – 5.8**

Therefore for efficacy data is read across to Boric Acid (Doc IIIA)

**References**

1. Ingri, N Sven. Kem. Tidskr. 75(4), 199 (1963)
2. Kirk – Othmer Encyclopedia of Chemical Technology, V4, 1992, pp 378-380.
3. De Vette, [REDACTED] 2001 Hydrolysis as a function of pH and identification of breakdown products, [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]
4. Maeda M, Raman Spectra of polyborate ions in aqueous solution. J Inorg. Nucl. Chem., Vol 41, pp 1217-1220 (1979)
5. Lloyd JD, 1993 The mechanisms of action of boron containing preservatives. Thesis submitted for degree of Doctor of Philosophy of the University of London and the Diploma of Membership of Imperial College (page 45 and 47 Tables 4 and 5)

| Evaluation by Competent Authorities  |   |             |           |              |                             |                                 |   |                                    |   |                                   |   |                                   |  |
|--|---|-------------|-----------|--------------|-----------------------------|---------------------------------|---|------------------------------------|---|-----------------------------------|---|-----------------------------------|--|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |   |             |           |              |                             |                                 |   |                                    |   |                                   |   |                                   |  |
| <b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>   |   |             |           |              |                             |                                 |   |                                    |   |                                   |   |                                   |  |
| <b>Date</b>  | 3-Oct-05  |             |           |              |                             |                                 |   |                                    |   |                                   |   |                                   |  |
| <b>Materials and Methods</b>   | <p>a. The data on boric acid are copied into the present document by the CA (at the end of this evaluation table).</p> <p>b. The notifier submitted 5 studies to support that disodium octaborate tetrahydrate will behave as boric acid. Four of these studies were already evaluated in IIIA3.6. The fifth study (Lloyd, 1993) is an overview table with efficacy results for boric acid, disodium octaborate tetrahydrate and disodium tetraborate decahydrate. The study is given reliability of 4 because no methods are described. The conclusions concerning the boron species are slightly changed (see also IIIA3.6).</p>  |             |           |              |                             |                                 |   |                                    |   |                                   |   |                                   |  |
| <b>Conclusion</b>  | <p>Upon dissolution in water (or when boric oxide rods come into contact with water) all boron species are converted into boric acid/borate according to the following formulae:</p> <table> <tr> <td>boric acid:</td><td><math>B(OH)_3</math></td></tr> <tr> <td>boric oxide:</td><td><math>B_2O_3 + 3H_2O = 2B(OH)_3</math></td></tr> <tr> <td>disodium tetraborate anhydrous:</td><td><math>Na_2B_4O_7 + 7 H_2O = 2 NaB(OH)_4 + 2 B(OH)_3</math></td></tr> <tr> <td>disodium tetraborate pentahydrate:</td><td><math>Na_2B_4O_7 \cdot 5H_2O + 2 H_2O = 2 NaB(OH)_4 + 2 B(OH)_3</math></td></tr> <tr> <td>disodium tetraborate decahydrate:</td><td><math>Na_2B_4O_7 \cdot 10H_2O = 2NaB(OH)_4 + 2B(OH)_3 + 3H_2O</math></td></tr> <tr> <td>disodium octaborate tetrahydrate:</td><td><math>Na_2B_8O_{13} \cdot 4H_2O + 9H_2O \leftrightarrow 2NaB(OH)_4 + 6 B(OH)_3</math></td></tr> </table> <p>At low boron concentrations (<math>B \leq 0.025</math> M) the following equilibrium is found:</p> $B(OH)_3 + 2H_2O \leftrightarrow B(OH)_4^- + H_3O^+$ <p>In dilute aqueous solutions (<math>B \leq 0.025</math> M) boron species exists as undissociated boric acid <math>B(OH)_3</math> at <math>pH &lt; 7</math>, at <math>pH &gt; 11</math> the metaborate ion <math>B(OH)_4^-</math> becomes the main species in solution. At inbetween values (<math>pH</math> 7-11) both species are present.</p> <p>At higher boron concentrations (<math>B &gt; 0.025</math> M) an equilibrium is formed between <math>B(OH)_3</math>, polynuclear complexes of <math>B_3O_3(OH)_4^-</math>, <math>B_4O_5(OH)_4^{2-}</math>, <math>B_5O_6(OH)_4^{2-}</math>, <math>B_3O_3(OH)_5^{2-}</math> and <math>B(OH)_4^-</math>. In short:</p> $B(OH)_3 \leftrightarrow \text{polynuclear anions} \leftrightarrow B(OH)_4^-$ <p>In acid solution at <math>pH &lt; 5</math>, boron is mainly present as <math>B(OH)_3</math> and in alkaline solution at <math>pH &gt; 12.5</math>, boron is mainly present as <math>B(OH)_4^-</math>. At inbetween values (<math>pH</math> 5-12) polynuclear anions are found as well as <math>B(OH)_3</math> and <math>B(OH)_4^-</math>.</p> <p>In the presence of metal ions (e.g. Na, Mg, Ca) ion-pair complexes are formed, which further reduce the undissociated boric acid concentration:</p> $M^{n+} + B(OH)_4^- \leftrightarrow MB(OH)_4^{(n-1)+}$ <p>These ion pair complexes are expected to be present in solutions of disodium tetraborate, disodium octaborate and buffered solutions of boric acid and boric oxide.</p> <p>For all boron species, solutions will contain undissociated boric acid <math>B(OH)_3</math>, borate ions <math>B(OH)_4^-</math>, alkali metal ion-pair complexes and possibly polynuclear boron complexes. Amounts of each of these compounds depend on <math>pH</math>, boron concentration and concentrations of alkali metals (Na, K).</p> | boric acid: | $B(OH)_3$ | boric oxide: | $B_2O_3 + 3H_2O = 2B(OH)_3$ | disodium tetraborate anhydrous: | $Na_2B_4O_7 + 7 H_2O = 2 NaB(OH)_4 + 2 B(OH)_3$ | disodium tetraborate pentahydrate: | $Na_2B_4O_7 \cdot 5H_2O + 2 H_2O = 2 NaB(OH)_4 + 2 B(OH)_3$ | disodium tetraborate decahydrate: | $Na_2B_4O_7 \cdot 10H_2O = 2NaB(OH)_4 + 2B(OH)_3 + 3H_2O$ | disodium octaborate tetrahydrate: | $Na_2B_8O_{13} \cdot 4H_2O + 9H_2O \leftrightarrow 2NaB(OH)_4 + 6 B(OH)_3$ |
| boric acid:  | $B(OH)_3$   |             |           |              |                             |                                 |   |                                    |   |                                   |   |                                   |  |
| boric oxide:   | $B_2O_3 + 3H_2O = 2B(OH)_3$   |             |           |              |                             |                                 |   |                                    |   |                                   |   |                                   |  |
| disodium tetraborate anhydrous:  | $Na_2B_4O_7 + 7 H_2O = 2 NaB(OH)_4 + 2 B(OH)_3$   |             |           |              |                             |                                 |   |                                    |   |                                   |   |                                   |  |
| disodium tetraborate pentahydrate:   | $Na_2B_4O_7 \cdot 5H_2O + 2 H_2O = 2 NaB(OH)_4 + 2 B(OH)_3$   |             |           |              |                             |                                 |   |                                    |   |                                   |   |                                   |  |
| disodium tetraborate decahydrate:  | $Na_2B_4O_7 \cdot 10H_2O = 2NaB(OH)_4 + 2B(OH)_3 + 3H_2O$   |             |           |              |                             |                                 |   |                                    |   |                                   |   |                                   |  |
| disodium octaborate tetrahydrate:  | $Na_2B_8O_{13} \cdot 4H_2O + 9H_2O \leftrightarrow 2NaB(OH)_4 + 6 B(OH)_3$  |             |           |              |                             |                                 |   |                                    |   |                                   |   |                                   |  |

|                               |  |
|-------------------------------|--|
|                               | <p>Primary mode of action of boron solutions is the complexation of the borate anion <math>B(OH)_4^-</math> with polyols of biological significance such as oxidised co-enzymes (<math>NAD^+</math>, <math>NMN^+</math>, <math>NADP^+</math>) and vitamins.</p> <p>Efficacy studies with boric acid, disodium octaborate tetrahydrate (DOT), disodium tetraborate decahydrate (Borax) or sodium metaborate showed similar toxic threshold levels based on boric acid equivalents (BAE), when similar target species (fungi, wood-boring insects) were compared in tests with the same wood type (pine, spruce, oak, yellow carrabeen, eucalyptus) as can be seen in the studies summarized in RMS table IIIA.5.3. Compounds used and target organisms tested are indicated in the table (RMS table IIIA5.3).</p> <p>From this studies it can be concluded that boric acid/borate is indeed the toxic component for all boron species. Therefore efficacy studies with all types of boron species can be used to establish toxic threshold levels for disodium octaborate tetrahydrate containing products. For this purpose, toxic threshold levels for each boron species can either be expressed as equivalent boric acid concentration or as equivalent boron concentration. Because the intended uses were expressed as boric acid equivalents (BAE) all efficacy studies were recalculated as equivalent boric acid concentrations.</p> |
| <b>Reliability</b>            | Reliability is set at 4 for all studies, except Ingri, 1963, is set at 2.  |
| <b>Acceptability</b>          | acceptable   |
| <b>Remarks</b>                |  |
|                               | <b>COMMENTS FROM ... (specify)</b>   |
| <b>Date</b>                   | <i>Give date of comments submitted</i>   |
| <b>Materials and Methods</b>  | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Results and discussion</b> | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Conclusion</b>             | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Reliability</b>            | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Acceptability</b>          | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Remarks</b>                |  |

## Section A5 Effectiveness against target organisms and intended uses

| Subsection<br>(Annex Point)  | Official<br>use only   |
|--|--|
| <b>5.1 Function<br/>(IIA5.1)</b>   | PT 08 - Fungicide, insecticide   |
| <b>5.2 Organism(s) to be controlled and products, organisms or objects to be protected<br/>(IIA5.2)</b>              | <i>Non-entry field</i>   |
| <b>5.2.1 Organism(s) to be controlled<br/>(IIA5.2)</b>   | <p>Dry rot (<i>Serpula lacrymans</i>) - preventive</p> <p>Wet rot (<i>Coniophora puteana</i>, <i>Gloeophyllum trabeum</i>, <i>Poria placenta</i>, <i>Coriolus versicolor</i>) – preventive</p> <p>Common furniture beetle (<i>Anobium punctatum</i>) - preventive</p> <p>House longhorn beetle (<i>Hylotrupes bajulus</i>) - preventive</p> <p>Lyctus powderpost beetle (<i>Lyctus brunneus</i>) – preventive</p> <p>Subterranean termites (<i>Reticulitermes santonensis</i>, <i>Reticulitermes flavipes</i>, <i>Reticulitermes lucifugis</i>) – preventive</p>   |
| <b>5.2.2 Products, organisms or objects to be protected<br/>(IIA5.2)</b>   | <p><u>Products to be protected:</u></p> <p>Timbers exposed to risk of attack by wood destroying organisms. For example:</p> <p>Use Class 1 timbers under cover including indoor joinery (preventive)</p> <p>Use Class 2 timbers under cover including indoor roofing timbers – risk of wetting (preventive)</p> <p>Use Class 3 exterior timbers out of ground contact including joinery protected with a surface coating (preventive)</p> <p>Use Class 4a remedial application to timbers in service in ground contact e.g. boron rods inserted into utility poles which are already in service and may have been treated in the past with creosote (curative and preventive).</p> |
| <b>5.3 Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)</b> | <i>Non-entry field</i>   |

## Section A5

## Effectiveness against target organisms and intended uses

|  |  |    |
|--|--|----|
| <b>5.3.1 Effects on target organisms (IIA5.3)</b>                          | See summary table section 5.3 and supplied Master Tables of references. In the majority of cases the studies determine toxic thresholds as lying between two of the concentrations of the active substance (boric acid equivalent) used in the study. The highest toxic threshold for the test organisms is 0.4% (for <i>G. trabeum</i> ). At a BAE retention of 0.4% all organisms listed are prevented from attacking the timber.  | X2 |
| <b>5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)</b> | PT-08: for preventive pre-treatment of timber commodities in Use Classes 1, 2 and 3 the likely concentration is 2 kg/m <sup>3</sup> BAE (equivalent to 0.4% BAE assuming wood density is 500 kg/m <sup>3</sup> ) See BS 8417 (2003). Remedial treatment of timber using boron rods often results in effective killing of any decay present and further protection from attack at retentions of 4 kg/m <sup>3</sup> BAE (0.8% BAE).   | X3 |
| <b>5.4 Mode of action (including time delay) (IIA5.4)</b>                  |  |    |
| <b>5.4.1 Mode of action</b>  | <p>Fungicide, borate ions form chelate complexes with polyols of biological significance (oxidised co-enzymes) leading to a disruption of the organisms metabolic pathways</p> <p>Insecticide, borate ions form chelate complexes with polyols of biological significance (oxidised co-enzymes) leading to a disruption of the organisms metabolic pathways</p> <p>The biochemical effects of boron are largely attributed to the fact that boron (in the form of boric acid or ionized as tetrahydroxy borate anion) forms oxygen compounds that will chelate organic compounds containing adjacent alcohol groups. Vitamins and co-enzymes can react to form complexes with the borate ion within the cell and can produce dramatic changes in metabolism. Borates can also act as an inhibitor in a purely ionic manner, inhibiting the production of enzymes.</p> <p>The toxicity of boron containing compounds to most organisms would appear to be due to the ability to complex with organic compounds. This effect in mirco-organisms has been shown to be more biostatic than biocidal, with organisms appearing to “starve”.</p> <p>The fungicidal mechanism of action of borates has been investigated . It was hypothesised that its primary mode of action was in general metabolism by interaction of the borate anion with polyols of biological significance. The oxidised co-enzymes NAD<sup>+</sup>, NMN<sup>+</sup> and NADP<sup>+</sup> were suggested as the most likely target of the borate ion. This theory was upheld in tests in vivo and it was concluded that the same mechanism was likely in all organisms, not just decay fungi</p> <p><u>References – Also listed at the end</u></p> <p>Lloyd JD (1998) Borates and their biological applications. The International Research Group on Wood Preservation. 21<sup>st</sup> annual meeting , Maastricht, The Netherlands. IRG Doc no. IRG/WP98-301 78. Published by the IRG Secretariat , Stockholm.</p> | X4 |

## Section A5

## Effectiveness against target organisms and intended uses

Lloyd J D & Dickinson D J (1991) Comparison of the inhibitory effects of borate, germanate, tellurate, arsenite and arsenate on 6-phosphogluconate dehydrogenase. The International Research Group on Wood Preservation. 21<sup>st</sup> annual meeting, Kyoto, Japan. IRG Doc no. IRG/WP1508. Published by the IRG Secretariat, Stockholm.

Lloyd J D, Dickinson D J & Murphy RJ (1990) The probable mechanisms of action of boric acid and borates as wood preservatives. The International Research Group on Wood Preservation. 21<sup>st</sup> annual meeting, Rotorua, NZ. IRG Doc no. IRG/WP1450. Published by the IRG Secretariat, Stockholm.

Lloyd J D, Dickinson D J & Murphy RJ (1991) The effect of sorbitol on the decay of boric acid treated Scots pine. The International Research Group on Wood Preservation. 21<sup>st</sup> annual meeting, Kyoto, Japan. IRG Doc no. IRG/WP1509. Published by the IRG Secretariat, Stockholm

**5.4.2 Time delay** None

**5.5 Field of use envisaged (IIA5.5)**

MG02: Preservatives Product types PT06-13 PT-08

**5.6 User (IIA5.6)** Industrial Professional and Amateur (General Public)

**Industrial** See Section 2.10

**Professional**

**General public**

**5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)** No resistance

**5.7.1 Development of resistance** Not relevant

**5.7.2 Management strategies** Not relevant

**5.8 Likely tonnage to be placed on the market per year (IIA5.8)** To be submitted by EBA – Confidential information

Section 5.3: Summary table of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged, where applicable

| Function  | Field of use envisaged   | Test substance  | Test organism(s)  | Test method  | Test conditions   | Test results: effects, mode of action, resistance   | Reference*)  |
|---|--|---|---|--|---|---|--|
| <i>Include respective code(s) for function type(s) given in section 5.1</i> | <i>Include respective code(s) for product type(s) given in section 5.5</i> | <i>Describe specification if deviating from that given in section 2</i> | <i>Specify species, strain, sex, weight, growth stage etc. as appropriate</i> | <i>Shortly describe test system and application method used in the tests</i>   | <i>Shortly describe test conditions including concentrations applied and exposure time</i>  | <i>Describe relevant results; quantify the effects on target organisms; indicate the dependence on the concentrations of the A.S. and the possible existence of a threshold concentration. Also describe if results indicate the mode of action and/or the development of resistance.</i> | <i>Only author(s) and year of publication/ report; full bibliographic data in footnote</i> |
| fungicide   | PT-08  | Boric acid  | <i>Coniophora puteana</i> BAM440  | DIN wood block over agar   | Cultures grown for four weeks at 22°C, test samples and controls introduced and exposed for 12 weeks at 22°C  | Toxic threshold concentrations determined as 0.1 – 0.16% BAE (0.5 – 0.8 kg/m <sup>3</sup> BAE) assuming wood density is 500 kg/m <sup>3</sup> .   | Becker 1966  |
| fungicide   | PT-08  | Boric acid  | <i>Coriolus (Trametes) versicolor</i> (L.:Fr.) Pil. 2666                      | Agar block test pine feeder strips on malt agar nutrient. Vacuum impregnation and diffusion.   | Cultures grown for four weeks at 25°C, test samples and controls introduced and exposed for 12 weeks at 25°C. Mean retentions in blocks of 0, 0.1, 1.0 and 10 kg/m <sup>3</sup> BAE | Toxic threshold concentration determined as 0.2% BAE (1.0 kg/m <sup>3</sup> BAE).   | Cookson & Pham 1995  |
| fungicide   | PT-08  | Boric acid  | <i>Gloeophyllum (Lenzites) trabeum</i> Madison 617                            | Soil block test following method of Leutritz (1946). Blocks placed on inoculated pine feeder strips in volcanic soil. Vacuum impregnation and diffusion. | Cultures grown for four weeks at 23°C, test samples and controls introduced and exposed for 14 weeks at 23°C. test concentrations of boric acid 0, 0.1, 0.24, 0.48 and 0.9% BAE.    | Toxic threshold concentrations determined as 0.2 – 0.4% BAE (1.0 – 2.0 kg/m <sup>3</sup> BAE) assuming wood density is 500 kg/m <sup>3</sup> .  | Harrow 1950  |



|                          |       |                   |                                  |  |  |  |                       |
|--------------------------|-------|-------------------|----------------------------------|--|--|--|-----------------------|
| fungicide                | PT-08 | Boric acid        | <i>Poria placenta</i>            | Soil block test  | 12 weeks at 22°C   | Toxic threshold concentrations determined as 0.12 – 0.24% BAE (0.6 – 1.2 kg/m <sup>3</sup> BAE) assuming wood density is 500 kg/m <sup>3</sup> .   | Carr 1957             |
| fungicide                | PT-08 | Boric acid        | <i>Serpula lacrymans</i> BAM133  | Agar block test  | 12 weeks at 20°C   | Toxic threshold concentrations determined as 0.11 – 0.18% BAE (0.55 – 0.88 kg/m <sup>3</sup> BAE) assuming wood density is 500 kg/m <sup>3</sup> .   | Bravery & Carey 1983  |
| insecticide              | PT-08 | Boric acid        | <i>Anobium punctatum</i> de Geer | Egg laying and larval survival   | 9 month test. Loadings of boric acid ranged from 0.004 to 3.25 % BAE | Toxic threshold concentrations determined as 0.022 – 0.043% BAE (0.11 – 0.21 kg/m <sup>3</sup> BAE) assuming wood density is 500 kg/m <sup>3</sup> .   | Spiller 1948          |
| insecticide              | PT-08 | Sodium metaborate | <i>Lyctus brunneus</i>           | Egg laying and larval survival   | 16 weeks   | Toxic threshold concentrations determined as 0.06 – 0.14% BAE (0.29 – 0.72 kg/m <sup>3</sup> BAE) assuming wood density is 500 kg/m <sup>3</sup> .   | Cummins & Wilson 1936 |
| insecticide              | PT-08 | Borax<br>DOT      | <i>Hylotrupes bajulus</i>        | Borax applied by vacuum impregnation to Corsican pine sapwood. BS 3651 newly hatched larvae introduced into holes. | 6 months<br><br>0.012% to 1.2% solutions of DOT                      | For borax the toxic threshold concentrations determined as 0.008 – 0.045% BAE (0.068 – 0.34 kg/m <sup>3</sup> borax). For DOT the toxic threshold concentrations determined as 0.019 – 0.09% BAE (0.077 – 0.39 kg/m <sup>3</sup> DOT). | Taylor 1967           |
| Insecticide/ termiticide | PT-08 | Boric acid        | <i>Reticulitermes flavipes</i>   | Subterranean termite attack in a field test in Hawaii  | 6 months   | Toxic threshold concentrations determined as 0.3% BAE (1.5 kg/m <sup>3</sup> BAE) assuming wood density is 500 kg/m <sup>3</sup> .   | Mauldin 1996          |

\*) References:

List the references cited in alphabetical order with full bibliographic data (Author(s) (year) Title. Source)

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Spiller D. (1949) Toxicity of boric acid to the common house borer, *Anobium punctatum*. NZ Journal Sci. & Tech. Vol B 30, 20, 22-30.

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### Section 5.4.1 References

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Lloyd J D & Dickinson D J (1991) Comparison of the inhibitory effects of borate, germanate, tellurate, arsenite and arsenate on 6-phosphogluconate dehydrogenase. The International Research Group on Wood Preservation. 21<sup>st</sup> annual meeting , Kyoto, Japan. IRG Doc no. IRG/WP1508. Published by the IRG Secretariat , Stockholm.

Lloyd J D (1993) The mechanisms of action of boron containing preservatives. Thesis submitted for degree of Doctor of Philosophy of the University of London and the Diploma of Membership of Imperial College.

Lloyd J D, Dickinson D J & Murphy RJ (1990) The probable mechanisms of action of boric acid and borates as wood preservatives. The International Research Group on Wood Preservation. 21<sup>st</sup> annual meeting , Rotorua, NZ. IRG Doc no. IRG/WP1450. Published by the IRG Secretariat , Stockholm.

Lloyd J D, Dickinson D J & Murphy RJ (1991) The effect of sorbitol on the decay of boric acid treated Scots pine. The International Research Group on Wood Preservation. 21<sup>st</sup> annual meeting , Kyoto, Japan. IRG Doc no. IRG/WP1509. Published by the IRG Secretariat , Stockholm

| Evaluation by Competent Authorities  |   |
|--|---|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |   |
| <b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>   |   |
| <b>Date</b>  | 28-Feb-05   |
| <b>Materials and methods</b>   | Section IIIA5.2 Organisms to be controlled<br><br>No indication is given in which parts of the Community the organisms to be controlled exist.  |
| <b>Conclusion</b>  | Incomplete data.  |
| <b>Reliability</b>   | not applicable  |
| <b>Acceptability</b>   | not acceptable<br><br>The notifier is requested to indicate for which part of the Community the organisms to be controlled exist.   |
| <b>Remarks</b>   | -   |
| <b>COMMENTS FROM ...</b>   |   |
| <b>Date</b>  | <i>Give date of comments submitted</i>  |
| <b>Results and discussion</b>  | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i> |
| <b>Conclusion</b>  | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Reliability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Acceptability</b>   | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Remarks</b>   |   |

| Evaluation by Competent Authorities  |   |
|--|---|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |   |
| <b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>   |   |
| <b>Date</b>  | 9-Nov-05  |
| <b>Materials and methods</b>   | <p>Section IIIA5.3.1 Effects on target organisms</p> <p>a. In section IIIB5.7 some extra information concerning the effect on target organisms is available which is copied here:</p> <p>Preventive efficacy – prevents the use of the treated wood as a food source by the fungus or insect. Criterion in laboratory tests is less than a 3% mass loss in treated blocks when validated by the required mass losses in controls. Products often applied by dip-diffusion or vacuum impregnation.</p> <p>Curative efficacy – kills any decay fungi or insects that are present in the wood. For example fused boron rods slowly diffusing into the heartwood of a utility pole to remedially treat incipient decay.</p> <p>b. Efficacy studies were available on all target organisms mentioned above except for <i>Reticulitermes santonensis</i> and <i>Reticulitermis lucifugis</i>. The RMS expects that toxic threshold levels for <i>Reticulitermes santonensis</i> and <i>Reticulitermis lucifugis</i> are similar to toxic threshold levels for <i>Reticulitermis flavipes</i> (for which an efficacy study has been carried out), because they belong to the same genus.</p> <p>c. The summary table was incomplete. The RMS added 3 studies submitted for IIIB5.10, one study submitted for IIA and 4 studies submitted for IIB and made a new summary table. This table is appended at the end of the RMS section (see RMS table IIIA5.3). Values from this table are used to assess the efficacy.</p> <p>In addition, study summaries made by the notifier are considered incomplete, because relevant data were not reported. Therefore a new summary table was made by the RMS (see RMS table IIIA5.3).</p> <p>Carr, 1957, is considered as key study for treatment of decay fungi. The study of Cummins and Wilson, 1936, is considered as key study for treatment against larvae of wood-boring insects. The study of Mauldin and Kard, 1996, is considered as key study for treatment against termites. The notifier is requested to summarize these studies.</p> <p>d. Toxic threshold levels depend on the way the test is carried out. Toxic threshold levels are higher when leaching or evaporation occurs during the test period. Toxic threshold levels presented in the current CA-report are derived from experiments where blocks were placed on (damp) feeder strips, nylon nets, glass rests or plastic mesh squares. Experiments where blocks were placed directly on soil or agar were not taken into account, because experimental outcome is influenced by possible leaching during the test period. These experiments are indicated in the table (RMS table IIIA5.3).</p> <p>e. For some studies ranges in toxic threshold levels are given. For these studies several experiments were reported with different results. In most of the cases different toxic threshold levels are the result of different concentration steps used in the experiments. For evaluation of efficacy the highest level is taken as toxic threshold level.</p> |

f. Distribution of the product through the wood depends on wood type (impregnability, volumic mass) and on the wood loading procedure.

#### Wood type

Density of wood types varies between 360-1000 kg/m<sup>3</sup>. Density for pine wood is 500 kg/m<sup>3</sup>. Pine wood (pine, fir) is the wood type that is mainly used in the European Union. Therefore, toxic threshold levels for fungi, wood-boring insects and termites are based on a default wood density of 500 kg/m<sup>3</sup>.

#### Wood loading procedure

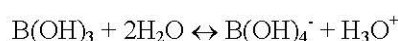
In the table for intended use (table IIB 7.5-2), several wood loading procedures are stated (e.g. vacuum pressure, dipping, spraying, injection), while most efficacy studies have been carried out with vacuum impregnation of solutions of boric acid or borates. In the present CA-report, the way the particular wood load is reached (application method), the time needed to reach this wood load and the homogeneity of the product distribution through the wood are not taken into account, because wood load is considered to be the crucial criterion for assessment of efficacy.

Efficacy studies with different application method or with different product distribution through the wood are therefore not required.

g. Upon dissolution in water (or when boric oxide rods come into contact with water) all boron species are converted into boric acid/borate according to the following formulae:

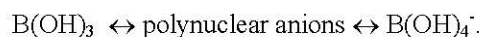
|                                    |   |
|------------------------------------|---|
| boric acid:                        | $B(OH)_3$   |
| boric oxide:                       | $B_2O_3 + 3H_2O = 2B(OH)_3$ .   |
| disodium tetraborate anhydrous:    | $Na_2B_4O_7 + 7H_2O = 2NaB(OH)_4 + 2B(OH)_3$ .                              |
| disodium tetraborate pentahydrate: | $Na_2B_4O_7 \cdot 5H_2O + 2H_2O = 2NaB(OH)_4 + 2B(OH)_3$ .                  |
| disodium tetraborate decahydrate:  | $Na_2B_4O_7 \cdot 10H_2O = 2NaB(OH)_4 + 2B(OH)_3 + 3H_2O$ .                 |
| disodium octaborate tetrahydrate:  | $Na_2B_8O_{13} \cdot 4H_2O + 9H_2O \leftrightarrow 2NaB(OH)_4 + 6B(OH)_3$ . |

At low boron concentrations ( $B \leq 0.025$  M) the following equilibrium is found:



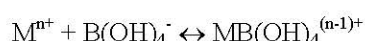
In dilute aqueous solutions ( $B \leq 0.025$  M) boron species exists as undissociated boric acid  $B(OH)_3$  at pH < 7, at pH > 11 the metaborate ion  $B(OH)_4^-$  becomes the main species in solution. At inbetween values (pH 7-11) both species are present.

At higher boron concentrations ( $B > 0.025$  M) an equilibrium is formed between  $B(OH)_3$ , polynuclear complexes of  $B_3O_3(OH)_4^-$ ,  $B_4O_5(OH)_4^{2-}$ ,  $B_3O_3(OH)_5^{2-}$ ,  $B_3O_6(OH)_4^-$  and  $B(OH)_4^-$ . In short:



In acid solution at pH < 5, boron is mainly present as  $B(OH)_3$  and in alkaline solution at pH > 12.5, boron is mainly present as  $B(OH)_4^-$ . At inbetween values (pH 5-12) polynuclear anions are found as well as  $B(OH)_3$  and  $B(OH)_4^-$ .

In the presence of metal ions (e.g. Na, Mg, Ca) ion-pair complexes are formed, which further reduce the undissociated boric acid concentration:



These ion pair complexes are expected to be present in solutions of disodium tetraborate, disodium octaborate and buffered solutions of boric acid and boric oxide.

For all boron species, solutions will contain undissociated boric acid  $B(OH)_3$ , borate ions  $B(OH)_4^-$ , alkali metal ion-pair complexes and possibly polynuclear boron complexes. Amounts of each of these compounds depend on pH, boron

concentration and concentrations of alkali metals (Na, K).

Primary mode of action of boron solutions is the complexation of the borate anion  $B(OH)_4^-$  with polyols of biological significance such as oxidised co-enzymes ( $NAD^+$ ,  $NMN^+$ ,  $NADP^+$ ) and vitamins.

Efficacy studies with boric acid, disodium octaborate tetrahydrate (DOT), disodium tetraborate decahydrate (Borax) or sodium metaborate showed similar toxic threshold levels based on boric acid equivalents (BAE), when similar target species (fungi, wood-boring insects) were compared in tests with the same wood type (pine, spruce, oak, yellow carrabeen, eucalyptus) as can be seen in the studies summarized in RMS table IIIA.5.3. Compounds used and target organisms tested are indicated in the table (RMS table IIIA5.3).

From this studies it can be concluded that boric acid/borate is indeed the toxic component for all boron species. Therefore efficacy studies with all types of boron species can be used to establish toxic threshold levels for disodium octaborate tetrahydrate containing products. For this purpose, toxic threshold levels for each boron species can either be expressed as equivalent boric acid concentration or as equivalent boron concentration. Because the intended uses were expressed as boric acid equivalents (BAE) all efficacy studies were recalculated as equivalent boric acid concentrations.

h. Of the fungi mentioned in IIIA5.2.1 highest tolerancy for boron species was found for *Gloeophyllum trabeum* syn *Lenzites trabea* with toxic threshold levels of 2.2 kg/m<sup>3</sup> BAE in wood or 0.44 % (w/w) BAE in wood (Carr, 1957)

Of the wood-boring insects mentioned in IIIA5.2.1 highest tolerancy for boron species was found for larvae of *Lyctus brunneus*. Toxic threshold levels for egg larvae were 1.5 kg/m<sup>3</sup> BAE in wood or 0.30% (w/w) BAE in wood. Boron was not effective against larger larvae from *Lyctus brunneus* up to the highest concentration tested of 15 kg/m<sup>3</sup> in wood or 3.0% (w/w) BAE in wood. Next highest tolerancy for boron species was found for larger larvae of *Anobium punctatum* at 9.5 kg/m<sup>3</sup> BAE in wood or 1.9% (w/w) BAE in wood. However, larger larvae are not considered to be target organisms.

For the termites mentioned in IIIA5.2.1, toxic threshold levels for *Reticulitermes flavipes* were 1.5 kg/m<sup>3</sup> BAE in wood or 0.30% (w/w) BAE in wood.

i. None of the studies has been carried out according to present day standards.

Evaporative ageing procedures (EN 73) required for class 1-4a have only been carried out in some of the fungi tests (4-6 weeks at air dry conditions or 48 hrs in a ventilated environment). Evaporative ageing (air-drying for 4 weeks) for the most persistent decay fungus *Gloeophyllum trabeum* syn *Lenzites trabea* resulted in the toxic threshold levels of 2.2 kg/m<sup>3</sup> BAE in wood or 0.44 % (w/w) BAE in wood, as mentioned above. No evaporative ageing procedures have been carried out for wood-boring insects or termites. Evaporative ageing procedures according to EN73 are not applicable, because this test is based on evaporation of the active substance. For disodium octaborate tetrahydrate, the evaporation of water may cause problems. Once the water is evaporated from the wood, disodium octaborate tetrahydrate is converted into the solid state active substance (boric acid, sodium borate), while efficacy is based on the presence of the borate anion, which is only formed in a humid environment. Therefore, additional studies are required where treated wood is dried (e.g. 4-6 weeks) and is exposed to wood-boring insects and termites. Therefore no final conclusions can be drawn concerning efficacy against all target organisms to be controlled.

Leaching procedures (EN 84 or EN 330) required for class 3-4a have not been carried out. This is acceptable for the Annex I evaluation phase, but for product authorisation phase additional tests are required.

j. Study report Smith, 1969 is incomplete. Because the study describes efficacy data for the most boron tolerant fungi, the complete study report is required.

## Conclusion

Efficacy studies were available on all target organisms mentioned above except for *Reticulitermes santonensis* and *Reticulitermis lucifugis*. The RMS expects that toxic threshold levels for *Reticulitermes santonensis* and *Reticulitermis lucifugis* are similar to toxic threshold levels for *Reticulitermis flavipes* (for which an efficacy study has been carried out), because they belong to the same genus.

Efficacy studies with boric acid, disodium octaborate tetrahydrate (DOT), disodium tetraborate decahydrate (Borax) or sodium metaborate showed similar toxic threshold levels based on boric acid equivalents. From this studies it can be concluded that boric acid/borate is indeed the toxic component for all boron species. Therefore efficacy studies with all types of boron species can be used to establish toxic threshold levels for disodium octaborate tetrahydrate containing products.

Of the fungi mentioned in IIIA5.2.1 highest tolerancy for boron species was found for *Gloeophyllum trabeum* syn *Lenzites trabea* with toxic threshold levels of 2.2 kg/m<sup>3</sup> BAE in wood or 0.44 % (w/w) BAE in wood. However, larger larvae are not considered to be target organisms. Of the wood-boring insects mentioned in IIIA5.2.1 highest tolerancy for boron species was found for larvae of *Lyctus brunneus*. Toxic threshold levels for egg larvae were 1.5 kg/m<sup>3</sup> BAE in wood or 0.30% (w/w) BAE in wood. Boron was not effective against larger larvae from *Lyctus brunneus* up to the highest concentration tested of 15 kg/m<sup>3</sup> in wood or

3.0% (w/w) BAE in wood. Next highest tolerancy for boron species was found for larger larvae of *Anobium punctatum* at 9.5 kg/m<sup>3</sup> BAE in wood or 1.9% (w/w) BAE in wood.

For the termites mentioned in IIIA5.2.1, toxic threshold levels for *Reticulitermes flavipes* were 1.5 kg/m<sup>3</sup> BAE in wood or 0.30% (w/w) BAE in wood.



|                               |   |
|-------------------------------|---|
| <b>Reliability</b>            | <p>Harrow, 1950, set at 2</p> <p>Baechler and Roth, 1956, set at 4 (no experimental conditions)</p> <p>Carr, 1957, set at 2, key study for decay fungi</p> <p>Becker, 1966, set at 2</p> <p>Gallagher, 1968, set at 2</p> <p>Smith, 1969, set at 4 (incomplete study report)</p> <p>Bechgaard, 1979, set at 2</p> <p>Doi et al, 1994, set at 4 (leaching not prevented)</p> <p>Cooksen and Pham, 1995, set at 2</p> <p>Cummins and Wilson, 1936, set at 2, key study for wood boring insects</p> <p>Cummins, 1939, set at 4 (no experimental conditions)</p> <p>Spiller, 1948, set at 4 (no experimental conditions)</p> <p>Taylor, 1967, set at 2</p> <p>Mauldin and Kard, 1996, set at 2, key study for termites</p> <p>Findley, 1959, set at 4 (no experimental conditions)</p> <p>Becker, 1959, set at 4 (no experimental conditions)</p> <p>Bravery and Carey, 1983, set at 4 (no experimental conditions)</p> |
| <b>Acceptability</b>          | <p>Acceptable for annex I inclusion, however in the product authorisation phase additional information is required: 1. For use class 1-3, efficacy tests on wood boring insects and termites with the biocidal product are required where treated wood is dried (e.g. 4-6 weeks) and is exposed to wood-boring insects and termites.</p> <p>2. For use class 3, efficacy tests on decay fungi, wood boring insects and termites with the biocidal product are required where leaching procedures are included, according to present day standards (EN 84).</p> <p>3. A complete study report from Smith, 1969.</p> <p>4. Detailed summaries for key studies on decay fungi (Carr, 1957), larvae of wood-boring insects (Cummins and Wilson, 1936) and on termites (Mauldin and Kard, 1996) are required.</p>  |
| <b>Remarks</b>                | -   |
| <b>COMMENTS FROM ...</b>      |   |
| <b>Date</b>                   | <i>Give date of comments submitted</i>  |
| <b>Results and discussion</b> | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Conclusion</b>             | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Reliability</b>            | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Acceptability</b>          | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Remarks</b>                |   |

### Evaluation by Competent Authorities

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

**Date**

9-Nov-05

**Materials and methods**

#### EVALUATION BY RAPPORTEUR MEMBER STATE

Section IIIA5.3.2 Likely concentrations at which the a.s. will be used.

a. The notifier submitted additional information on application rates which should overrule all other concentration rates stated earlier. Full reference: Borax, 2005, Explanatory note on efficacy assessment, application rates, environmental exposure assessment, boric acid. [REDACTED].

This information is summarized by the RMS as follows:

Disodium octaborate tetrahydrate is used in PT8 products either

- as a stand alone product, that is to say there are no other co-formulants or co-biocides.
- as a co-biocide, used to enhance the spectrum of activity of the wood preservative formulation.
- as a co-formulant to assist in the properties of the formulation, e.g. stability.
- or to perform both co-formulant and co-biocide functions.

It is common practice to categorise the application of wood preservatives and their application rates according to the Biological Hazard (Use) Classes, for example UC 1, 2, 3, 4 and 5. These increase in the severity of the biological challenge that the timber will be exposed in service.

| FORM OF APPLICATION<br>(preventive treatments) | UC1 | UC2 | UC3 | UC4 | UC5 |
|--|-----|-----|-----|-----|-----|
| Stand alone borate biocide                     | √   | √   | √   | X   | X   |
| Co-biocide                                     | √   | √   | √   | √   | √   |
| Co-formulant                                   | √   | √   | √   | √   | √   |
| Co-formulant & biocide                         | √   | √   | √   | √   | √   |

In UC1, UC 2 and UC3, disodium octaborate tetrahydrate is normally used as a biocide. However when incorporated in formulations for use in UC4 and UC5, it is present principally as a formulation aid (e.g. pH control, solubility aid etc) rather than for efficacy purposes.

## MAXIMUM APPLICATION RATES (Preventive treatment)

| FORM OF APPLICATION<br>(preventive treatments) | UC1 Max application rate* BAE | UC2 Max application rate* BAE | UC3 Max application rate* BAE | UC4 Max application rate* BAE | UC5 Max application rate* BAE |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Stand alone borate biocide                     | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           | N/A                           | N/A                           |
| Co-biocide                                     | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           |
| Co-formulant                                   | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           |
| Co-formulant & co-biocide                      | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           | 2 kg/m <sup>3</sup>           |

\* expressed in terms of overall loading of boric acid equivalent (BAE) in 1 m<sup>3</sup> of timber, that is to assume the heartwood and sapwood ratio of the timber to be treated is 50:50.

## TYPICAL APPLICATION RATES (Preventive treatment)

| FORM OF APPLICATION<br>(preventive treatments) | UC1 Typical application rate* BAE | UC2 Typical application rate* BAE | UC3 Typical application rate* BAE | UC4 Typical application rate* BAE | UC5 Typical application rate* BAE |
|--|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| Stand alone biocide                            | 1 kg/m <sup>3</sup>               | 1 kg/m <sup>3</sup>               | 1 kg/m <sup>3</sup>               | N/A                               | N/A                               |
| Co-biocide                                     | 0.4kg/m <sup>3</sup>              | 0.4 kg/m <sup>3</sup>             | 0.4 kg/m <sup>3</sup>             | 0.4 kg/m <sup>3</sup>             | 0.4 kg/m <sup>3</sup>             |
| Co-formulant                                   | 0.4 kg/m <sup>3</sup>             | 0.4 kg/m <sup>3</sup>             | 0.4 kg/m <sup>3</sup>             | 0.4 kg/m <sup>3</sup>             | 0.4 kg/m <sup>3</sup>             |
| Co-formulant & biocide                         | 0.4 kg/m <sup>3</sup>             | 0.4 kg/m <sup>3</sup>             | 0.4 kg/m <sup>3</sup>             | 0.4 kg/m <sup>3</sup>             | 0.4 kg/m <sup>3</sup>             |

\* expressed in terms of overall loading of boric acid equivalent (BAE) in 1 m<sup>3</sup> of timber, that is to assume the heartwood and sapwood ratio of the timber to be treated is 50:50.

## TERMITE TREATMENT APPLICATION RATES (Preventive treatment)

| FORM OF APPLICATION<br>(preventive treatments)  | UC1 Typical application rate* BAE | UC2 Typical application rate* BAE | UC3 Typical application rate* BAE | UC4 Typical application rate* BAE | UC5 Typical application rate* BAE |
|---|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| Termite treatments (stand alone borate biocide) | 4.0kg/m <sup>3</sup>              | 4.0kg/m <sup>3</sup>              | 4.0kg/m <sup>3</sup>              | N/A                               | N/A                               |

\* expressed in terms of overall loading of boric acid equivalent (BAE) in 1 m<sup>3</sup> of timber, that is to assume the heartwood and sapwood ratio of the timber to be treated is 50:50.

**Conclusion**

The notifier submitted various documents with inconsistent information on dose rates used in the different application methods. The RMS proposes to assess the efficacy against the dose rates as presented in section IIIA5.3.2 and table IIB 7.5-2 and which is also summarized below. The reader is referred to intended uses as proposed by RMS, which is included in Doc IIB, Section 7.5.

Application rates of disodium octaborate tetrahydrate containing products for the different types of application as proposed by the RMS.

| Treatment process | Intended application method            | Normal use<br>(decay fungi and wood-boring insects)            | Termite prevention   |  | Intended type            |
|-------------------|--|--|--|--|--------------------------|
| Industrial        | vacuum pressure<br>double vacuum       | 2.0 kg/m <sup>3</sup> BAE in wood or<br>0.4% (w/w) BAE in wood | 8.5 kg/m <sup>3</sup> BAE in wood or<br>1.7% (w/w) BAE in wood |  | preventive<br>class 1, 2 |
| Industrial        | automated dipping<br>industrial deluge | wood 0.05 kg/m <sup>2</sup> BAE on wood                        | not for termites   |  | preventive<br>class 1, 2 |
| Industrial        | automated spraying                     | 0.05 kg/m <sup>2</sup> BAE on wood                             | not for termites   |  | preventive<br>class 1, 2 |
| In-situ           | injection                              | 2.0 kg/m <sup>3</sup> BAE in wood or<br>0.4% (w/w) BAE in wood | not for termites   |  | remedial<br>(curative)   |
| In-situ           | brushing<br>spraying                   | 0.05 kg/m <sup>2</sup> BAE on wood                             | not for termites   |  | remedial<br>(curative)   |

BAE = boric acid equivalents, i.e. "expressed as boric acid"

The notifier proposed to use disodium octaborate tetrahydrate containing products:

- as a stand alone product, that is to say there are no other co-formulants or co-biocides.
- as a co-biocide, used to enhance the spectrum of activity of the wood preservative formulation.
- as a co-formulant to assist in the properties of the formulation, e.g. stability.
- or to perform both co-formulant and co-biocide functions.

In the present CA-report only the proposed use as stand alone product is assessed. No information is available on the other product uses. Therefore only use class 1, 2, 3 and 4a are assessed as is indicated in IIIA5.2.2.

At the proposed concentrations of 2.0 kg/m<sup>3</sup> or 0.4% (w/w) BAE for preventive treatment in use class 1, 2, and 3, egg larvae of wood-boring insects and termites will be controlled. Although most fungi (wet rot and dry rot) will be controlled, the most persistent fungi (*Gloeophyllum trabeum* syn *Lenzites trabea*) will not be controlled completely: toxic threshold levels are 2.2 kg/m<sup>3</sup> BAE in wood or 0.44 % (w/w) BAE in wood. Therefore, the notifier is requested to reconsider the proposed dose rates.

At the proposed concentrations of 2.0 kg/m<sup>3</sup> or 0.4% (w/w) BAE for remedial treatment in use class 4a, egg larvae of wood-boring insects and termites will be controlled. Although most fungi (wet rot and dry rot) will be controlled, the most persistent fungi (*Gloeophyllum trabeum* syn *Lenzites trabea*) will not be controlled completely: toxic threshold levels are 2.2 kg/m<sup>3</sup> BAE in wood or 0.44 % (w/w) BAE in wood. However, larger larvae of *Anobium punctatum* and *Lyctus brunneus* survive treatment. Therefore disodium octaborate tetrahydrate containing products can only be used for preventive treatment and not for remedial (curative) treatment. Use Class 4a remedial application to timbers in service in ground contact is therefore not feasible.

|                               |  |
|-------------------------------|--|
|                               | At present no final conclusions for use in classes 1, 2, and 3 can be drawn, because evaporative ageing processes (class 1-3) for wood-boring insects and termites and leaching processes (class 3) for all target organisms have not been carried out.  |
| <b>Reliability</b>            | -  |
| <b>Acceptability</b>          | Acceptable for as part of annex I inclusion. For the product authorisation phase additional information is required:<br><br>2. The notifier proposed to use 12% w/v BAE and 35% w/v BAE in treatment solutions. But the solubility for boric acid is about 50 g/L (see Doc IIB 1.3) , which is 5% w/v BAE. Therefore it is impossible to prepare the proposed treatment solutions. The notifier is requested to clarify this issue.<br><br>3. For use class 1-3, efficacy tests on decay fungi, wood boring insects and termites, show that at least a concentration of 2.2 kg/m <sup>3</sup> or 0.44% (w/w) BAE in wood is required for efficacy of the boron containing product against decay fungi. The notifier is requested to reconsider the proposed dose rates.<br><br>4. At present no final conclusions for use in classes 1, 2, and 3 can be drawn, because evaporative ageing processes (class 1-3) for wood-boring insects and termites and leaching processes (class 3) for all target organisms have not been carried out.  |
| <b>Remarks</b>                | Clarification on discrepancies in intended use (see question 1) is required for:<br><br>a. Application concentrations for injection/brushing/spraying in section IIIB2 (max 12% w/v BAE) and section IIIB5.3 (max 12% w/v BAE) are not consistent with the concentration levels stated in section IIIB5.4 for injection/brushing/spraying (11.5%-17.25% w/v)<br><br>b. Wood loading of 1.7% w/w BAE in wood (i.e. 8.5 kg/m <sup>3</sup> BAE in wood) for termites in section IIIB2 is not consistent with the wood loading stated in the additional information supplied by the notifier and summarized by the RMS in section IIIA5.3 (4.0 kg/m <sup>3</sup> BAE in wood)<br><br>c. Wood loading of 2.0 kg/m <sup>3</sup> BAE in wood for fungi and wood boring insects stated in section IIIA5.3.2 is not consistent with the wood loading stated in the additional information supplied by the notifier and summarized by the RMS in section IIIA5.3.2 (0.4-1.0 kg/m <sup>3</sup> BAE in wood for typical application rates).<br><br>d. Injection at 0.05 kg/m <sup>2</sup> BAE on wood calculated from kg/m <sup>3</sup> BAE in wood dose rates and default conversion factors from OECD guidelines is not consistent with the value of 0.0345 kg/m <sup>2</sup> BAE as listed in the notifier's List of Endpoints. |
| <b>COMMENTS FROM ...</b>      |  |
| <b>Date</b>                   | <i>Give date of comments submitted</i>   |
| <b>Results and discussion</b> | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Conclusion</b>             | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Reliability</b>            | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Acceptability</b>          | <i>Discuss if deviating from view of rapporteur member state</i>   |
| <b>Remarks</b>                |  |

| Evaluation by Competent Authorities  |  |
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| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |  |
| <b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>   |  |
| <b>Date</b>  | 22-Mar-05  |
| <b>Materials and methods</b>   | <p>Section IIIA5.4.1 Mode of action</p> <p>a. Four studies were submitted. Study 1 (Lloyd, 1998) is a review article without methods and is given reliability of 4. Study 2 (Lloyd and Dickinson, 1991) compare activity of other compounds with borates and is considered not relevant here. The study is given reliability of 4. Study 3 and 4 (Lloyd et al, 1990 and 1992) are considered as key studies by the RMS, because the hypothesis for the mode of action is experimentally tested. Studies are given reliability of 2 because of non-GLP and no indications of purity of the active substance.</p> <p>b. The hypothesis for the mode of action assumes that boron compounds are converted as much as possible into the tetrahydroxyborate ion <math>B(OH)_4^-</math>. The borate anion acts by complexation with polyols of biological significance such as oxidised co-enzymes (NAD<sup>+</sup>, NMN<sup>+</sup>, NADP<sup>+</sup>), vitamins and others.</p> <p>c. In study 3 (Lloyd et al, 1990) the effect of boric acid (pH=7) was tested in an in-vitro enzyme system (yeast 6-phosphogluconate dehydrogenase) and in-vitro fungal systems (<i>Trichoderma viride</i>, <i>Coriolus versicolor</i>, and <i>Coniophora puteana</i>). The 6-phosphogluconate dehydrogenase was found to be inhibited by the borate anion (41.7 mM borate). Fungal growth was reduced with increasing borate concentrations (0.02-0.12% borate). White rot (<i>Coriolus versicolor</i>) was least affected by the borate. The addition of different polyols reduced the inhibitory effect of the borate anion both in the enzyme system and in the fungal system. Highest reduction was found for sorbitol, followed by ribose and then glucose.</p> <p>d. In study 4 (Lloyd et al, 1991) the effect of boric acid (pH=7) was tested in an in-vivo system. Small blocks of scots pine sapwood (<i>Pinus sylvestris</i>, 30x10x5 mm) were treated with a boric acid -sorbitol solution (0-0.14% boric acid, 0-500 mM sorbitol), equivalent to 0-1.2 kg/m<sup>3</sup> boric acid. The blocks were immersed in the solution and treated under vacuum for one hour, followed by 2 hrs of atmospheric pressure. The blocks were left to dry for 2 weeks, while the blocks were turned every 24 hrs. Blocks were sterilized by gamma-irradiation. Blocks were placed on agar plates covered for 95% with cultures of <i>Coniophora puteana</i> (FPRL 11E) or <i>Coriolus versicolor</i> (FPRL 28A). Plates were incubated for 7 weeks at 22 °C. The addition of high sorbitol concentrations (250-500 mM) reduced the inhibitory effect of the borate anion (at 0.45 kg/m<sup>3</sup> and higher).</p> <p>e. Results substantiate the theory that the polyol complexing ability of the borate anion is responsible for the protection against decay (or insects) of boron treated timber.</p> |
| <b>Conclusion</b>  | Primary mode of action is the interaction of the borate anion with polyols of biological significance e.g. oxidised co-enzymes (NAD <sup>+</sup> , NMN <sup>+</sup> and NADP <sup>+</sup> ).   |
| <b>Reliability</b>   | <p>study 1 (Lloyd, 1998) set at 4</p> <p>study 2 (Lloyd and Dickinson, 1991) set at 4</p> <p>study 3 (Lloyd et al, 1990) set at 2</p> <p>study 4 (Lloyd et al, 1991) set at 2</p>  |
| <b>Acceptability</b>   | acceptable   |
| <b>Remarks</b>   | -  |

| COMMENTS FROM ...             |   |
|-------------------------------|---|
| <b>Date</b>                   | <i>Give date of comments submitted</i>  |
| <b>Results and discussion</b> | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i> |
| <b>Conclusion</b>             | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Reliability</b>            | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Acceptability</b>          | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Remarks</b>                |   |

RMS table IIIA5.3 Summary table of experimental data on the effectiveness of the active substance against target organisms

| Function  | Field of use envisaged | Test substance                      | Test organism(s)   | Test method   | Test conditions   | Test results: effects, mode of action, resistance   | Reference*)             |
|-----------|------------------------|-------------------------------------|--|---|---|---|-------------------------|
| fungicide | PT-08                  | Boric acid                          | Three species<br><i>Lenzites trabea</i> syn <i>Gloeophyllum trabeum</i> highest boron tolerancy<br><br>Other relevant species:<br><i>Coniophora cerebella</i> (2 strains) syn <i>Coniophora puteana</i> , <i>Poria vaporaria</i> syn <i>Poria placenta</i> | Pine ( <i>Pinus radiata</i> ) blocks treated by vacuum impregnation and diffusion. Blocks were left until air dry (period not stated). No ageing or leaching.<br><br>Soil block test according to method of Leutritz (1946), mass loss in weight. Treated autoclaved blocks were placed on feeder strips which were placed on the soil surface. | Test concentrations 0, 0.4-3.7 kg/m <sup>3</sup> BAE or 0, 0.10%-0.90% w/w BAE. Blocks exposed for 14 weeks at 23°C.                                  | Highest boron tolerancy for <i>Lenzites trabea</i> syn <i>Gloeophyllum trabeum</i> on pine ( <i>Pinus radiata</i> ): Toxic threshold concentrations determined as 0.48% w/w BAE (2.0 kg/m <sup>3</sup> BAE).<br><br>No conversion factors used, actual values from the test.  | Harrow 1950             |
| fungicide | PT-08                  | Sodium borate (assumed to be borax) | Four species<br><i>Lenzites trabea</i> syn <i>Gloeophyllum trabeum</i> highest boron tolerancy.<br><br>Other relevant species:<br><i>Poria monticola</i> .   | Pine and oak blocks. Wood treatment conditions not stated. No ageing or leaching.<br><br>Soil block test, mass loss in weight. Test conditions not stated.<br><br>Slightly higher toxic threshold levels are found for oak than for pine for <i>G. trabeum</i> (factor 1.5) but not for <i>P. monticola</i> (factor 0.82)                       | Not stated.   | Highest boron tolerancy for <i>Lenzites trabea</i> syn <i>Gloeophyllum trabeum</i> on oak:<br>Toxic thresholds 0.22-0.37% w/w BAE (1.11-1.84 kg/m <sup>3</sup> BAE, 0.107-0.177 lb/ft <sup>3</sup> as borax).<br><br>Conversion factor lb/ft <sup>3</sup> → kg/m <sup>3</sup> multiply by 15.99.<br>Conversion factor kg/m <sup>3</sup> → % w/w multiply by 0.2.<br>Conversion factor borax → BAE multiply by 0.65.   | Baechler and Roth, 1956 |
| fungicide | PT-08                  | Boric acid or borax                 | Three species<br><i>Lenzites trabea</i> syn <i>Gloeophyllum trabeum</i> highest boron tolerancy<br><br>Other relevant species:<br><i>Coniophora cerebella</i> syn <i>Coniophora puteana</i> , <i>Poria vaporaria</i> syn <i>Poria placenta</i>             | <i>Pinus radiata</i> sapwood treated by vacuum impregnation and diffusion. Blocks were air dried for 4 weeks (ageing). No leaching.<br><br>Soil block test, mass loss in weight. Treated autoclaved blocks were placed on feeder strips which were placed on the soil surface.  | Blocks exposed for 12 weeks at 27°C. Test concentrations 0, 0.08-0.37 lb/ft <sup>3</sup> for boric acid or 0, 0.09-0.36 lb/ft <sup>3</sup> for borax. | Highest boron tolerancy for <i>Lenzites trabea</i> syn <i>Gloeophyllum trabeum</i> on pine sapwood ( <i>Pinus radiata</i> ):<br>Toxic threshold concentrations for <b>boric acid</b> determined as 0.26 – 0.44% BAE (1.3 – 2.2 kg/m <sup>3</sup> BAE, 0.08-0.14 lb/ft <sup>3</sup> as boric acid) assuming wood density is 500 kg/m <sup>3</sup> .<br><br>Toxic threshold concentrations for <b>borax</b> determined as 0.28%-0.38% BAE (1.4-1.9 kg/m <sup>3</sup> BAE, 0.14- | Carr 1957               |



| Function  | Field of use envisaged | Test substance | Test organism(s)  | Test method  | Test conditions  | Test results: effects, mode of action, resistance   | Reference*)     |
|-----------|------------------------|----------------|---|--|--|---|-----------------|
|           |                        |                |   |  |  | <p>0.19 lb/ft<sup>3</sup> as borax).</p> <p>Toxicities of boric acid and borax are in proportion to their boron content.</p> <p>Conversion factor lb/ft<sup>3</sup> → kg/m<sup>3</sup> multiply by 15.99.</p> <p>Conversion factor kg/m<sup>3</sup> → % w/w multiply by 0.2.</p> <p>Conversion factor borax → BAE multiply by 0.65.</p>   |                 |
| fungicide | PT-08                  | Boric acid     | <p>Three species and several strains.</p> <p><i>Coniophora cerebella</i> Pers.<br/>EMPA62 syn <i>Coniophora puteana</i> highest boron tolerancy</p> <p>Other relevant species:<br/><i>Merulius lacrymans</i> (Wulf.) Fr. syn <i>Serpula lacrymans</i> and <i>Polystictus versicolor</i> (Linn.) Fr. syn <i>Coriolus versicolor</i>.</p> | <p>DIN 52176;<br/>NF X 41-512;<br/>Agar block test, mass loss in weight. Wood type, wood treatment and cultivation conditions not indicated.</p> <p>ASTM D1413 resulted in higher toxic threshold levels. Results considered not reliable because of leaching and evaporation during the test. These results are not taken into account for derivation of the toxic threshold concentration.</p>     | Concentration range not indicated. Blocks exposed for 6-18 weeks at 20-25°C.                       | <p>Highest boron tolerancy for <i>Coniophora cerebella</i> Pers.<br/>EMPA62 syn <i>Coniophora puteana</i> on unknown wood type:<br/>Toxic threshold concentrations determined as 0.12 – 0.28% w/w BAE (0.6 – 1.4 kg/m<sup>3</sup> BAE) assuming wood density is 500 kg/m<sup>3</sup>.</p> <p>Conversion factor kg/m<sup>3</sup> → % w/w multiply by 0.2.</p>                            | Becker 1966     |
| fungicide | PT-08                  | Timbor (=DOT)  | <p>Two species.</p> <p><i>Coniophora cerebella</i> syn <i>Coniophora puteana</i> highest boron tolerancy.</p> <p>Other relevant species: <i>Poria xantha</i>.</p>   | <p>Scots pine sapwood and heartwood treated by vacuum pressure or vacuum diffusion process. Treated wood dried at 50 °C for 3 hrs and ventilated in a filtered air-flow for 48 hours.</p> <p>Agar block test, mass loss in weight. Blocks placed on glass rests on the agar surface.</p> <p>Toxic threshold levels for Scots pine heartwood were a factor 1.8 lower than for Scots pine sapwood.</p> | Retention in blocks 0, 0.07-0.89 kg/m <sup>3</sup> as borax. Blocks exposed for 12 weeks at 22 °C. | <p>Highest boron tolerancy for <i>Coniophora cerebella</i> syn <i>Coniophora puteana</i> on pine sapwood:<br/>Toxic threshold concentration determined as 0.13% w/w BAE (0.65 kg/m<sup>3</sup> BAE, 0.54 kg/m<sup>3</sup> as DOT).</p> <p>Conversion factor kg/m<sup>3</sup> → % w/w multiply by 0.2.</p> <p>No conversion factor used for DOT to BAE, actual values from the study</p> | Gallagher, 1968 |

| Function  | Field of use envisaged | Test substance  | Test organism(s)   | Test method   | Test conditions   | Test results: effects, mode of action, resistance  | Reference*)      |
|-----------|------------------------|---|--|---|---|--|------------------|
| fungicide | PT-08                  | Timbor (=DOT)   | <i>Lenzites trabea</i> Pers ex Fr FPL V 47B syn <i>Gloeophyllum trabeum</i>  | Ponderosa pine sapwood treated by vacuum impregnation. No ageing or leaching.<br><br>Soil block test, mass loss in weight and total carbon dioxide evolution measured by GC-FID (after reduction to methane). ASTM D1413 (1961). Blocks were placed on feeder strips, placed on the soil surface.   | Concentration range not stated. Blocks exposed for 12 weeks at 23 °C.   | Due to incomplete study report toxic threshold values could not be evaluated (figure 4 and table 2 are missing). Data are required because <i>G. trabeum</i> is considered the most boron tolerable decay fungus.  | Smith, 1969      |
| fungicide | PT-08                  | boric acid  | Two species<br><br><i>Lentinus lepideus</i> BK C-1 highest boron tolerancy, but not relevant for present evaluation.<br><br>Relevant species for toxic threshold concentration: <i>Gloeophyllum trabeum</i> (A570)   | <i>Pinus sylvestris</i> L. sapwood treated by vacuum/pressure process. Blocks air dried for 24 hrs. No ageing or leaching.<br><br>Agar block test, mass loss in weight. Blocks were placed on a nylon net, which was placed on the agar surface.  | Retentions in blocks 0.1-1.0 kg/m <sup>3</sup> BAE. Blocks exposed for 6 months at 50°C.  | Highest boron tolerancy for <i>Gloeophyllum trabeum</i> (A570) on pine ( <i>Pinus sylvestris</i> ) sapwood: Toxic threshold concentration determined as 0.08%-0.18% w/w BAE (0.40-0.92 kg/m <sup>3</sup> BAE).<br><br>Conversion factor kg/m <sup>3</sup> → % w/w multiply by 0.2.   | Bechgaard, 1979  |
| fungicide | PT-08                  | boric-acid triethanolamine (BTEA); boric acid or Timbor (= DOT) | Four species.<br><br><i>Chaetomium globosum</i> Kunze IAM 8059 highest boron tolerancy, but not relevant for present evaluation.<br><br>Relevant species for toxic threshold concentration in sequence of highest boron tolerancy: <i>Coriolus versicolor</i> L ex. Fr. Quel FFPR 1030 and <i>Serpula lacrymans</i> FFPR 0739. | Yezo spruce ( <i>Picea jezoensis</i> ) and Japanese beech ( <i>Fagus crenata</i> ) sapwood treated by vacuum impregnation. JIS A9201 (1991) test without weathering.<br><br>Soil block test or agar block test ( <i>C. globosum</i> only), mass loss in weight. Blocks were placed directly on the soil or agar surface.<br><br>Toxic threshold levels on Japanese beech ( <i>Fagus crenata</i> ) were higher than on Yezo spruce (only tested for <i>C. versicolor</i> ), but dose rates were not high enough to deduce a toxic threshold level for Japanese beech (> 1.45 or >1.53 kg/m <sup>3</sup> BAE for Timbor and boric acid, | Retention in blocks 0, 0.39-4.29 kg/m <sup>3</sup> BAE for Tim-bor and 0, 0.40-1.65 kg/m <sup>3</sup> BAE for boric acid. Blocks exposed for 120 days at 26 °C or 20 °C ( <i>S. lacrymans</i> only).<br><br>BTEA is considered not relevant for the present evaluation, because the tri-ethanol amine has synergic effects on boron efficacy.<br><br>Toxic threshold levels for Timbor and boric acid are similar: 0.85 and 0.83 kg/m <sup>3</sup> BAE, respectively. for <i>S. lacrymans</i> on Yezo spruce, | Highest boron tolerancy for <i>Coriolus versicolor</i> L ex. Fr. Quel FFPR 1030 on Yezo spruce ( <i>Picea jezoensis</i> ) sapwood: For <b>Tim-bor</b> toxic threshold concentration determined as 0.77%-0.86% w/w BAE (3.84-4.29 kg/m <sup>3</sup> BAE).<br><br><b>Boric acid</b> was not tested on the combination <i>C. versicolor</i> and Yezo spruce.<br><br>Conversion factor kg/m <sup>3</sup> → % w/w multiply by 0.2.<br><br>Toxic threshold levels in this study were higher compared to other studies, because leaching was not prevented during test. This study is | Doi et al., 1994 |