| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 26-04-2005 |
| **Materials and Methods** | Applicant's version is acceptable |
| **Results and discussion** | Applicant's version is adopted |
| **Conclusion** | The proportion of boric acid in dilute solutions with a neutral pH is > 99 %. The relative concentration of the tetrahydrate anion, $[B(OH)4]^-$, becomes dominant at pH > 9. Boric acid is an inorganic compound and does not have any chemical bonds prone to hydrolysis. Hydrolysis is thus not a relevant pathway at environmental pH. |
| **Reliability** | 1 |
| **Acceptability** | acceptable |
| **Remarks** | |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *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* |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

**Table A7_1_1_1_1-1: Type and composition of buffer solutions (specify kind of water if necessary)**

| Test Substance* | Natural pH | Buffered pH's | | | |
|---|---|---|---|---|---|
| [redacted] | 8.62 | 6.03 | 6.99 | 8.03 | 9.00 |
| Borax [redacted] | 9.18 | 5.99 | 6.99 | 8.03 | 9.02 |
| Boric Acid [redacted] | 5.10 | 6.02 | 6.99 | 7.99 | 9.00 |

* Solutions of [redacted] Borax [redacted] and Boric Acid [redacted], with a final solution concentration of 0.02mol.l$^{-1}$ were prepared by dissolving 0.5181g, 0.9578g and 0.6206g of the test substances in 500ml ultrapure water respectively. From these test solutions, five portions of 100ml of each substance solution were made. One portion of each test substance was not buffered, whereas the other portions were acidified or made alkaline to pH 6.0, 7.0, 8.0 and 9.0 with the aid of 2M HCl and 2M NaOH respectively.

Results of the comparison of the bands found **for** [redacted]. In non-buffered solution and at pH 6.0, pH 7.0 and pH 8.0 and the bands found for the polyborate solutions in the literature (1)

| Raman shift (Rel. cm$^{-1}$) | Non- buffered pH 8.62 | pH 6.03 | pH 6.99 | pH 8.03 | pH 9.00 |
|---|---|---|---|---|---|
| 385 | - | - | - | - | - |
| 430 | - | - | - | - | - |
| 447 | - | - | - | - | - |
| 458 | - | - | - | - | - |
| 490 | + | + | +/- | +/- | +/- |
| 524/525 | + | - | - | +/- | +/- |
| 565 | + | + | + | + | +/- |
| 609 | - | - | - | +/- | - |
| 745 | +/- | - | - | +/- | - |
| 872 | + | + | + | + | + |
| 917 | - | - | - | - | - |
| 940 | - | - | - | - | - |
| 995 | - | - | - | - | - |

*(1) Maeda, M. Raman spectra of polyborate ions in aqueous solution. J.Inorg. Nucl. Chem., Vol 41, pp 1217-1220 (1979)*

+ = band in accordance with (1)

+/- = intensity of band on detection level

- = band not found in spectrum

Results of the comparison of the bands found **Borax** [redacted]. In non-buffered solution and at pH 6.0, pH 7.0 and pH 8.0 and the bands found for the polyborate solutions in the literature (1)

| Raman shift (Rel. $cm^{-1}$) | Non- buffered pH 8.62 | pH 6.03 | pH 6.99 | pH 8.03 | pH 9.00 |
|---|---|---|---|---|---|
| 385 | - | - | - | - | - |
| 430 | - | - | - | - | - |
| 447 | - | - | - | - | - |
| 458 | - | - | - | - | - |
| 490 | - | - | - | - | - |
| 524/525 | + | - | - | - | - |
| 565 | +/- | + | - | - | +/- |
| 609 | +/- | - | +/- | - | - |
| 745 | + | - | - | +/- | + |
| 872 | + | + | + | + | + |
| 917 | - | - | - | - | - |
| 940 | - | - | - | - | - |
| 995 | - | - | - | - | - |

(1) *Maeda, M. Raman spectra of polyborate ions in aqueous solution. J.Inorg. Nucl. Chem., Vol 41, pp 1217-1220 (1979)*

+ = band in accordance with (1)

+/- = intensity of band on detection level

- = band not found in spectrum

Results of the comparison of the bands found **Boric Acid,** [redacted]. In non-buffered solution and at pH 6.0, pH 7.0 and pH 8.0 and the bands found for the polyborate solutions in the literature (1)

| Raman shift (Rel. $cm^{-1}$) | Non- buffered pH 8.62 | pH 6.03 | pH 6.99 | pH 8.03 | pH 9.00 |
|---|---|---|---|---|---|
| 385 | - | - | - | - | - |
| 430 | - | - | - | - | - |
| 447 | - | - | - | - | - |
| 458 | - | - | - | - | - |
| 490 | +/- | +/- | + | + | + |
| 524/525 | +/- | - | - | - | - |
| 565 | +/- | +/- | - | - | - |
| 609 | - | - | - | - | +/- |
| 745 | - | - | - | - | +/- |
| 872 | + | + | + | + | + |
| 917 | - | - | - | - | - |
| 940 | - | - | - | - | - |
| 995 | - | - | - | - | - |

[1] *Maeda, M. Raman spectra of polyborate ions in aqueous solution. J.Inorg. Nucl. Chem., Vol 41, pp 1217-1220 (1979)*

+ = band in accordance with [1]

+/- = intensity of band on detection level

- = band not found in spectrum

In all spectra a band is observed at 872cm$^{-1}$. the spectra of Borax, [redacted], contain a band at 745cm$^{-1}$ in the natural pH and at pH 9.0. Boric acid, [redacted], has a vibration at 490cm$^{-1}$ at pH 7.0, pH 8.0 and pH 9.0 apart from the band at 872 cm$^{-1}$ in all samples. The Raman spectra of [redacted]. show a band at 565cm$^{-1}$ (non-buffered, pH 6.0, pH7.0 and pH 8.0), a band at 524/525 cm$^{-1}$ (pH = natural) and at 490cm$^{-1}$ (pH= natural and pH=6.0).

**Table A7_1_1_1_1-2: Description of test solution**

| Criteria | Details |
|---|---|
| Purity of water | Ultrapure water, per description by [redacted], where the study was conducted. |
| Preparation of test medium | Solutions of [redacted]., Borax [redacted] and Boric Acid [redacted], with a final solution concentration of 0.02mol.l$^{-1}$ were prepared by dissolving 0.5181g, 0.9578g and 0.6206g of the test substances in 500ml ultrapure water respectively. From these test solutions, five portions of 100ml of each substance solution were made. One portion of each test substance was not buffered, whereas the other portions were acidified or made alkaline to pH 6.0, 7.0, 8.0 and 9.0 with the aid of 2M HCl and 2M NaOH respectively.<br>*Describe preparation in detail* |
| Test concentrations (mg a.i./L) | 0.02M |
| Temperature (°C) | Ambient |
| Controls | Boric Acid |
| Identity and concentration of co-solvent | No co-solvent |
| Replicates | None |

**Table A7_1_1_1_1-3: Description of test system**

| | |
|---|---|
| Glassware | Standard chemical laboratory-ware |
| Other equipment | Raman spectrometer |
| Method of sterilization | Not necessary – inorganic speciation under investigation. |

**Section A7.2-A7.5** **Doc III A Read Across to Boric Acid**

**Annex Point** Section A7.2-A10

## 16 APPLICANT'S SUMMARY AND CONCLUSION

Since all the borates will exist as undissociated boric acid under physiological and environmental conditions, the toxicology and the ecotoxicology of all these simple borates is similar on an equivalent boric acid basis or boron basis. Therefore the data for boric acid and disodium tetraborate decahydrate can be read across to the other borates for both toxicological and ecotoxicological effects

Conversion factors are given below. These conversion factors are important as some studies express dose in terms of B, whereas other studies express the dose in units of boric acid or disodium tetraborate decahydrate. The B equivalents used are a generic designation rather than a designation of the element boron. For comparative purposes, dose levels of borates are expressed in terms B in most toxicology studies

Conversion factors to Boron Equivalents

| | | **Conversion Factor for Equivalent dose of B** |
|---|---|---|
| Boric acid | $H_3BO_3$ | 0.175 |
| Boric oxide | $B_2O_3$ | 0.311 |
| Disodium tetraborate decahydrate (Borax) | $Na_2B_4O_7 \bullet 10H_2O$ | 0.113 |
| Disodium tetraborate pentahydrate | $Na_2B_4O_7 \bullet 5H_2O$ | 0.148 |
| Disodium tetraborate anhydrous | $Na_2B_4O_7$ | 0.215 |
| Disodium octaborate tetrahydrate | $Na_2B_8O_{13} \bullet 4H_2O$ | 0.210 |

The simple inorganic borates (for example, boric acid, boric oxide, sodium tetraborates and octaborates) are highly water-soluble. The mode of dissolution of metal borates as well as of boric acid is complex

and depends on the conditions (pH, temperature, and concentration). Boric acid is a weak acid and is considered a Lewis acid. As such it is an electron acceptor, rather than a proton donor, so will accept hydroxide. Depending on the boron concentration monomeric and, with increasing concentration of boron, polymeric species will be found (Farmer, 1982).

[B(OH)3] < 0,02M

B(OH)3 + H2O --> [B(OH)4]+ + H+ pKa = 9,15

0,025M <= [B(OH)3] <= 0,4/0,6M

[B3O3(OH)4]-; [B3O3(OH)5]2- predominant

[B(OH)3] > 0,6M

[B4O5(OH)4]-; [B5O6(OH)4]2- predominant

The nucleation process can be described as the interaction of boric acid with the borate anion shown in the following equation for the example of [B3O3(OH)5]2-

B(OH)3 + 2 [B(OH)4]- <---> [B3O3(OH)5]2- + 3 H2O

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, whereas above pH 10 the metaborate ion becomes the main species(Ingr, 1963; Kirk-Othmer, 1992). The metaborate ion will also be present in aqueous solutions at

environmental temperature and pH mainly as weakly dissociated boric

acid (pKa value at room temperature 9.25, Holleman, 1995).

Therefore, regardless of whether the boron source is boric acid or one of the other borates (such as boric oxide or a sodium borate), monomeric species are predominant in most biological fluids as well as under environmental conditions (Maeda, 1979). This was verified in an independent study 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 undissociated boric $B(OH)_3$ as the species present (Doc IIIA 7.1.1.1 Hydrolysis Boric Acid.doc) (de Vette et al., 2001)

Boric Oxide

$B_2O_3 + 3H_2O = 2(H_3BO_3)$

Disodium Octaborate Tetrahydrate

$Na_2B_8O_{13}.4H_2O + H_2O = Na_2O + 4(B_2O_3).4H_2O = 2NaOH + 8(H_3BO_3)$

Disodium Tetraborates

$Na_2B_4O_7\ xH_2O$ (x = 0, 5 or 10) $= 2Na_2O + B_2O_3 \times H_2O = 4NaOH + 2(H_3BO_3)$

At environmental pHs undissociated boric acid will be present in

aqueous environment.

**References**

8. Farmer, 1982 Structural Chemistry in the Borate Industry., Chem and Ind.,
9. Ingri, N Sven. Kem. Tidskr. 75(4), 199 (1963)
10. Kirk – Othmer Encyclopedia of Chemical Technology, V4, 1992, pp 378-380
11. Holleman, 1995. Lehrbuch der anorganischen Chemie. 101st ed de Gruyter, Berlin, copyright
12. De Vette, [redacted] 2001 [redacted]
13. Maeda M, Raman Spectra of polyborate ions in aqueous solution. J Inorg. Nucl. Chem., Vol 41, pp 1217-1220 (1979)
14. [redacted] 2004 [redacted]

## Section A7.2-A7.5 Doc III A Read Across to Boric Acid

**Annex Point** Section A7.2-A10

[redacted]

| | Evaluation by Competent Authorities |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 25 March 2005 |
| **Materials and Methods** | Not applicable. |
| **Results and discussion** | In aqueous solutions at physiological and acidic pH, simple borates such as disodium tetraborate decahydrate ($Na_2B_4O_7 \bullet 10H_2O$; borax), disodium tetraborate pentahydrate ($Na_2B_4O_7 \bullet 5H_2O$; borax pentahydrate), boric oxide ($B_2O_3$) and disodium octaborate tetrahydrate ($Na_2B_8O_{13} \bullet 4H_2O$) will exist as undissociated boric acid. Therefore, the toxicokinetics and toxicological effects of boric acid, disodium tetraborate decahydrate, boric oxide (B2O3) and disodium octaborate tetrahydrate are likely to be similar on a boron equivalents basis.<br><br>Therefore, it is justified to draw conclusions on boric oxide on the basis of data on studies on toxicokinetics and toxicity of other simple borates such as boric acid and the disodium tetraborates. |
| **Conclusion** | It is justified to draw conclusions on boric oxide on the basis of data on studies on toxicokinetics and toxicity of other simple borates such as boric acid and the disodium tetraborates.<br><br>The effects assessment of borates, as described above by the applicant, is not adopted. |
| **Reliability** | |
| **Acceptability** | |
| **Remarks** | |
| | **COMMENTS FROM ...** *(specify)* |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *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* |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

**Section A8**
**Annex Point IIA8**

**26 MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT**

Section B8

| Subsection | | Official use only |
|---|---|---|
| **8.1 Handling and Storage** | No special handling precautions are required, but dry indoor storage is recommended. Good housekeeping procedures should be followed to minimise dust generation and accumulation. No specific firefighting measures are required since boric acid in not flammable, combustible or explosive. The product is itself a flame retardant. | X |
| **8.2 Combustion Products** | Fused borate glass and water | |
| **8.3 Emergency measures in case of accident** | **Inhalation:** If symptoms such as nose or throat irritation are observed, remove to fresh air.<br><br>**In case of contact with Eyes:** Rinse immediately with plenty of clean water or sterile saline solution for at least 15 minutes. If appropriate, remove contact lenses after 5 minutes rinsing. If symptoms persist, seek medical attention.<br><br>**Skin Contact:** No treatment necessary because non-irritating.<br><br>**Ingestion:** Swallowing small quantities (one teaspoon) will cause no harm to healthy adults. If larger amounts are swallowed, give two glasses of water to drink and seek medical attention.<br><br>Avoid creation of dust. Use vacuum cleaners wherever possible. | |
| **8.4 Decontamination** | a) **Air:** Borates are non-volatile. As a dust borates rapidly settle from the atmosphere.<br><br>b) **Water:** Borates are naturally occurring minerals and are present in surface and underground waters. Borates are rapidly dissolved in water and will disperse with dilution. Removal at low concentrations is unnecessary. Where water containing high levels of borates can be captured precipitation with lime can be used to reduce boron levels to the 100ppm range. Treatments with boron specific ion exchange resins and activated carbon are also possible.<br><br>c) **Soil:** Borates are naturally found in rocks and soil and are an essential micronutrient for all plant growth. Contaminated soil can be leached with water or acid to reduce boron levels. | |
| **8.5 Waste Management** | Small quantities can usually be disposed to landfill sites. No special disposal treatment is required, but local authorities should be consulted about any specific local requirements. Tonnage quantities of products are not considered appropriate for landfills. Such products should, if possible, be used for an appropriate application. | |

**8.6 Unintended side effects**

Borates are essential micronutrients for all plant life but at high levels they are phytotoxic.

| | **Evaluation by Competent Authorities** |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the<br>comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 27-May-08 |
| **Materials and methods** | Section 8.1<br>Information on container material is given in Doc IIIA3.17 |
| **Conclusion** | Adapted in doc IIC and Doc I |
| **Reliability** | - |
| **Acceptability** | acceptable |
| **Remarks** | - |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* |
| **Date** | *Give date of comments submitted* |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |