# Document III-A: Study Summaries - Active Substance

## Section A1 Applicant

**Annex Point IIA1**

| | | | |
|---|---|---|---|
| **1.1** | **Applicant** | **Lead Notifier: Rio Tinto minerals**<br>Contact: [redacted]<br>2 Eastbourne Terrace<br>London, W2 6LG<br>United Kingdom<br>[redacted]<br>**Website: www.riotinto.com**<br>**Joint Notifier Etimine s.a.**<br>Contact: [redacted]<br>Z.I. Scheleck-II,<br>Route de Dudelange<br>L-3225 Bettembourg<br>Luxembourg<br>[redacted]<br><br>**Administrative Consortium Lead**<br>Dr Roger Doome<br>[redacted]<br>Please correct the email address to r.doome@ima-europe.eu<br>*Email: r.doome@ima-eu.org* | **Official use only** |
| **1.2** | **Manufacturer of Active Substance** (if different) | Borates for Biocidal use are manufactured in the USA<br>US Borax Inc<br>14486 Borax Road<br>Boron, CA 93516-2000<br>USA<br>Tel: + 1 760 762 7000<br><br>**Etimine s.a.**<br>Borates for Biocidal use are manufactured in Turkey<br>Eti Mine Works<br>Cihan Sk No: 2<br>06100 Sihhiye<br>Ankara<br>Turkey | X1 |
| **1.3** | **Manufacturer of Product(s) (if different)** | *As above* | |

## Section A1 Applicant

**Annex Point IIA1**

| | Evaluation by Competent Authorities |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 19-Sept-05 |
| **Materials and methods** | Section 1.2 Manufacturer<br>For US Borax Inc the whole address is changed into:<br><br>Borates for Biocidal use are manufactured in the USA<br>US Borax Inc<br>14486 Borax Road<br>Boron, CA 93516-2000<br>USA<br>Tel: + 1 760 762 7000<br><br>The notifier noted that there are two locations for production of the active substance by Etimine S.A.:<br><br>Eti maden isletmeleri g.m.<br>Bandirma bor ve asit fab. Islt. Müdürlügü<br>10200 Bandirma/Balikesir<br>Turkey<br>Tel: +90 (266) 7213100<br>Fax: +90 (266) 7213126<br><br>Eti maden isletmeleri g.m.<br>Emet kolemanit Islt. Müdürlügü<br>43700 Emet/Kütahya<br>Turkey<br>Tel: +90 (274) 4613400<br>Fax: +90 (274) 4613403 |
| **Conclusion** | - |
| **Reliability** | - |
| **Acceptability** | Acceptable |
| **Remarks** | |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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* |

## Section A1 Applicant

**Annex Point IIA1**

| Remarks |
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# Document III-A: Study Summaries - Active Substance

## Section A2 Identity of Active Substance

| Subsection (Annex Point) | | | Official use only |
|---|---|---|---|
| 2.1 | **Common name (IIA2.1)** | Disodium tetraborates; Disodium tetraborate anhydrous; Disodium tetraborate pentahydrate; Disodium tetraborate decahydrate<br><br>Note that the sodium tetraborates are all listed as one entry under EINECS and therefore considered to be one active substance – See EINECS Entry below | X1 |
| 2.2 | **Chemical name (IIA2.2)** | **Disodium tetraborate anhydrous:**<br>Anhydrous borax; Sodium tetraborate; Boron sodium oxide (B4Na2O7); Boron sodium oxide (H2B4O7);Boric acid (H2B4O7), disodium salt; Borax glass; Dehybor; Pyrobor; Etibor 68<br>**Disodium tetraborate pentahydrate:**<br>Borax 5 mol; Sodium borate (Na2B4O5(OH)4) trihydrate; Sodium tetraborate pentahydrate; Boron sodium oxide (B4Na2O7), pentahydrate; Boric acid (H2B4O7), disodium salt, pentahydrate; Neobor; V-bor; Etibor 48<br>**Disodium tetraborate decahydrate:**<br>Borax; Sodium tetraborate dechydrate; Borax decahydrate; sodium biborate decahydrate; sodium pyroborate decahydrate; Boron sodium oxide (B4Na2O7), decahydrate; Boric acid (H2B4O7), disodium salt decahydrate; Boricin; Borascu;Inkabor; Deca | X2 |
| 2.3 | **Manufacturer's development code number(s) (IIA2.3)** | Not applicable | |
| 2.4 | **CAS No and EC numbers (IIA2.4)** | Non-entry field | X3 |
| 2.4.1 | **CAS-No** | **Disodium tetraborate anhydrous:**<br>CAS No. 1330-43-4<br>**Disodium tetraborate pentahydrate:**<br>CAS No. 12179-04-3. This identification code used by Borax worldwide and agreed by EU industry groups<br>Also listed under CAS no 12267-73-1 and CAS no 12045-88-4<br>**Disodium tetraborate decahydrate:**<br>CAS No. 1303-96-4. This identification code used by Borax worldwide and agreed by EU industry groups.<br>Also listed under CAS no 13840-56-7 | |
| 2.4.2 | **EC-No** | Note that the sodium tetraborates are all listed as one entry under EINECS and therefore considered to be one active substance since the rules at the time allowed hydrated salts to be listed with the anhydrous version. However, some hydrated salts were listed. There is an industry agreement to use the anhydrous EINECS entry.<br><br>***Extract from:*** *Manual of Decisions for Implementation of The Sixth and Seventh Amendments to Directive 67/548/EEC on Dangerous Substances (Directives 79/831/EEC And 92/32/EEC). Last modified: 23 January 2002* | |

## Section A2 Identity of Active Substance

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| | | *2.3. Criteria for reporting Substances for EINECS*<br><br>14. Hydrates of a substance or hydrated ions, formed by association of a substance with water should not be reported. The anhydrous form can be reported and will, by implication, represent all hydrated forms. The products of discrete chemical reactions in which water is a reactant, i.e. a metal hydroxide formed by the reaction of a metal oxide and water can be reported.<br><br>**Disodium tetraborate anhydrous:**<br><br>EINECS No. 215-540-4<br><br>Also listed as Orthoboric acid, sodium salt 237-560-2<br><br>**Disodium tetraborate pentahydrate:**<br><br>EINECS No. 215-540-4. This identification code used by Borax worldwide and agreed by EU industry groups<br>Also listed under another EINECS entry<br>Disodium tetraborate x hydrate EINECS no 235-541-3<br><br>**Disodium tetraborate decahydrate:**<br><br>EINECS No. 215-540-4. This identification code used by Borax worldwide and agreed by EU industry groups<br>Also listed under another EINECS entry:<br>Disodium tetraborate x hydrate EINECS no 235-541-3; | |
| **2.4.3** | **Other** | Not relevant | |
| **2.5** | **Molecular and structural formula, molecular mass (IIA2.5)** | Non-entry field | |
| **2.5.1** | **Molecular formula** | **Disodium tetraborate**<br>$Na_2B_4O_7$.<br>**Disodium tetraborate pentahydrate**<br>$Na_2B_4O_7$. $5H_2O$<br>**Disodium tetraborate decahydrate**<br><br>$Na_2B_4O_7$. $10H_2O$ | X4 |
| **2.5.2** | **Structural formula** | Disodium tetraborate decahydrate is a white, free-flowing crystalline material, in the monoclinic system. In the crystal, the polyborate ion has the structure depicted in the structural formula above. The sodium ions exist in two crystallographically unique positions, each being octahedrally coordinated by water molecules. These octahedra share edges to form chains that cross-link the polyborate ions to form parallel sheets. These sheets are integrated by a network of hydrogen bonds. There are eight moles of the water of crystallisation, and two moles of water exist as hydroxyl groups. Aqueous solutions of borax decahydrate contain mixtures of the monomeric species, $B(OH)_3$ and $B(OH)_4^-$, and polyborate ions, such as the ion depicted in the structural formula above. The exact distribution of species will depend on the solution's concentration. Commercial borax decahydrate products exist as crystalline granular or powder materials; particle sizes typically no greater than 2000µm, with a $d_{50}$ = 250µm-50µm.<br><br>See Structures in IUCLID | X5 |

## Section A2 Identity of Active Substance

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| 2.5.3 | **Molecular mass** | **Disodium tetraborate**<br>209.7<br>**Disodium tetraborate pentahydrate**<br>291.35<br>**Disodium tetraborate decahydrate**<br>381.37 | X6 |
| 2.6 | **Method of manufacture of the active substance (IIA2.1)** | See also Section 2.10.1<br>The sodium tetraborates of commerce are borax decahydrate ($Na_2B_4O_7.10H_2O$), borax pentahydrate ($Na_2B_4O_7.5H_2O$) and anhydrous borax ($Na_2B_4O_7$).<br>[redacted] | [redacted] |

## Section A2 Identity of Active Substance

**2.7 Specification of the purity of the active substance, as appropriate (IIA2.7)**

g/l % w/w % v/v

X10

**Borax Europe Ltd:**

| *Disodium tetraborate anhydrous* | % w/w | |
|---|---|---|
| | **B2O3** | **Purity** |
| Typical | 68.9 | 99.6 |
| Maximum | 69.4 | 100.3 |
| Minimum | 68.5 | 99.0 |

| *Disodium tetraborate pentahydrate* | % w/w | |
|---|---|---|
| | **B2O3** | **Purity** |
| Typical | 48.9 | 102.3 |
| Maximum | 49.3 | 103.1 |
| Minimum | 48.6 | 101.7 |

| *Disodium tetraborate decahydrate* | % w/w | |
|---|---|---|
| | **B2O3** | **Purity** |
| Typical | 37.6 | 102.9 |
| Maximum | 38.2 | 104.6 |
| Minimum | 36.9 | 101.0 |

## Section A2 Identity of Active Substance

**Etimine s.a.**

| **Borax Decahydrate** | % | |
|---|---|---|
| | **B2O3** | **Purity** |
| Typical | 37.12 | 101.67 |
| Maximum | 37.71 | 103.29 |
| Minimum | 36.70 | 100.51 |
| **Borax Pentahydrate (Etibor-48)** | % | |
| | **B2O3** | **Purity** |
| Typical | 48.84 | 102.07 |
| Maximum | 49.00 | 102.41 |
| Minimum | 48.59 | 101.55 |
| **Borax Anhydrous (Etibor-68)** | % | |
| | **B2O3** | **Purity** |
| Typical | 68.90 | 101.52 |
| Maximum | 69.13 | 101.86 |
| Minimum | 67.80 | 99.90 |

The possibility in the purity being ≥ 100% is due to the variation of crystal water in boric acid. Since boric acid consists of diboron-trioxide and water ($H_3BO_3 \leftrightarrow 1/2B_2O_3 + 3/2H_2O$), even a slight decrease in the structural water content will yield to a higher diboron-trioxide content which will increase the purity.

| | | | |
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| **2.9** | **The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)** | Natural inorganic mineral ore<br>Borax Europe Limited: Ores<br>Tincal (Na2O.2B2O3.10H2O)<br>*Kernite (Na2O.2B2O3.4H2O)*<br>Etimine data to be submitted via EBA | X11 |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 2-Feb-05 |
| **Materials and methods** | Section 2.1. Common name<br><br>a. names in section 2.2. should be placed in section 2.1 and common name should be discerned from synonyms and trade names.<br><br>b. Other synonyms for disodium tetraborate anhydrous are: sodium borate, sodium biborate; sodium pyroborate; fused sodium borate; fused borax; sodium boron oxide (see IUCLID database for existing substances, and Merck Index on CD-ROM, version 12.1 and http://www.inchem.org/documents/icsc/icsc/eics1229.htm).<br><br>c. Other synonyms for disodium tetraborate pentahydrate are: borax pentahydrate (27th ATP, 27 May 2003).<br><br>d. Other synonyms for disodium tetraborate decahydrate are: borax 10 mol (see http://www.chemistrystore.com/ChemicalMSDS/Borax.pdf and www.rosemill.com/html/msds/ chem_borax10mol_10molph_msds.pdf) |
| **Conclusion** | Common name: **Disodium tetraborate anhydrous**<br>Synonyms: anhydrous borax; sodium tetraborate; boron sodium oxide; boric acid disodium salt; borax glass; sodium borate, sodium biborate; sodium pyroborate; fused sodium borate; fused borax, sodium boron oxide<br>Trade names: Dehybor; Pyrobor; Etibor 68<br><br>Common name: **Disodium tetraborate pentahydrate**<br>Synonyms: borax pentahydrate, borax 5 mol; sodium borate trihydrate; sodium tetraborate pentahydrate; boron sodium oxide pentahydrate; boric acid disodium salt pentahydrate;<br>Trade names: Neobor; V-bor; Etibor 48<br><br>Common name: **Disodium tetraborate decahydrate**<br>Synonyms: borax; borax decahydrate; borax 10 mol; sodium tetraborate decahydrate; sodium biborate decahydrate; sodium pyroborate decahydrate; boron sodium oxide decahydrate; boric acid disodium salt decahydrate;<br>Trade names: Boricin; Borascu; Inkabor; Deca |
| **Reliability** | - |
| **Acceptability** | acceptable |
| **Remarks** | The synonym borax is usually used for disodium tetraborate decahydrate, but may also be used for disodium tetraborate pentahydrate and disodium tetraborate anhydrous (see RAR for boric acid and disodium tetraborate, d.d. 17 December 2003, document TR 417+423_1203_env_hh) |
| | **COMMENTS FROM ...** |

| | |
|---|---|
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

| **Evaluation by Competent Authorities** | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 2-Feb-05 |
| **Materials and methods** | Section 2.2: Chemical name<br>a. names in section 2.2. should be placed in section 2.1 and common name should be discerned from synonyms and trade names.<br>b. RMS prefers disodium tetraborate anhydrous; disodium tetraborate pentahydrate; disodium tetraborate decahydrate as chemical names |
| **Conclusion** | Chemical name: Disodium tetraborate anhydrous<br>Disodium tetraborate pentahydrate<br>Disodium tetraborate decahydrate |
| **Reliability** | - |
| **Acceptability** | acceptable |
| **Remarks** | - |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

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| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 19-Sept-05 |
| **Materials and methods** | Section 2.4 CAS number and EC number<br><br>a. Several CAS and EC numbers exist for the same hydration form of a compound.<br><br>b. For **disodium tetraborate anhydrous** the CAS number used in this CA-report is 1330-43-4 together with EC no 215-540-4.<br>These entries were also given in the RAR for boric acid and disodium tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh).<br><br>In the 29th ATP, 27th May 2003 three entries were given:<br>* Disodium tetraborate anhydrous or boric acid disodium salt CAS 1330-43-4; EC 215-540-4<br>* Orthoboric acid sodium salt CAS 13840-56-7; EC 237-560-2 is an unspecified sodium salt and is listed under disodium tetraborate anhydrous.<br>* Tetraboron disodium heptaoxide hydrate CAS 12267-73-1, EC 235-541-3 is an unspecified hydrate salt and is listed under disodium tetraborate anhydrous.<br><br>Other CAS numbers for disodium tetraborate anhydrous are 12447-40-4 (see http://www.chemicalland21.com/arokorhi/industrialchem/inorganic/BORAX%20DECAHYDRATE.htm.<br><br>c. For **disodium tetraborate pentahydrate** the CAS numbr used in this CA-report is 12179-04-3 together with EC no is 215-540-4.<br>These entries were also given in the RAR for boric acid and disodium tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh).<br><br>In the 29th ATP, 27th May 2003 the following entries were given:<br>disodium tetraborate pentahydrate or borax pentahydrate CAS 12179-04-3, EC 215-540-04.<br><br>Other CAS numbers for disodium tetraborate pentahydrate are: 12267-73-1 (listed by notifier), 12045-88-4 (listed by notifier), 11130-12-4 (see http://www.rosemill.com/html/**msds**/chem_borax5_mol_**msds**.pdf) and http://www.chemicalland21.com/arokorhi/industrialchem/inorganic/BORAX%20DECAHYDRATE.htm.<br><br>Other EC numbers for disodium tetraborate pentahydrate are: 235-541-3 (listed by notifier).<br><br>e. For **disodium tetraborate decahydrate** the CAS number used in this CA-report is 1303-96-4 together with EC no is 215-540-4.<br>These entries were also given in the RAR for boric acid and disodium tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh).<br><br>In the 29th ATP, 27th May 2003 the following entries were given:<br>disodium tetraborate decahydrate or borax decahydrate CAS 1303-96-4, EC 215-540-04.<br><br>Other CAS numbers for disodium tetraborate decahydrate are 13840-56-7 (listed by notifier). |

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| | Other EC numbers for disodium tetraborate decahydrate are: 235-541-3 (listed by notifier) and 271-536-2 (see: http://www.chemicalland21.com/arokorhi/industrialchem/inorganic/BORAX%20DECAHYDRATE.htm). |
| **Conclusion** | Several CAS numbers and several EC numbers exist for the disodium tetraborates.<br>In the present CA-report only the following numbers are assessed:<br>Disodium tetraborate anhydrous, CAS no 1330-43-4; EC no 215-540-4.<br>Disodium tetraborate pentahydrate, CAS no 12179-04-3; EC no 215-540-4.<br>Disodium tetraborate decahydrate, CAS no 1303-96-4, EC no 215-540-4. |
| **Reliability** | - |
| **Acceptability** | acceptable |
| **Remarks** | - |

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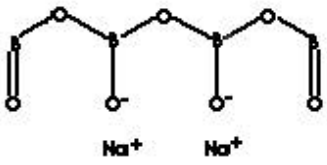
|---|---|
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*Discuss if deviating from view of rapporteur member state*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

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 2-Feb-05 |
| **Materials and methods** | Section 2.5.1. Molecular formula.<br>Although the general formula is $Na_2B_4O_7.xH_2O$ another frequently used formula is $Na_2O.2B_2O_3.xH_2O$. |
| **Conclusion** | Disodium tetraborate anhydrous, general formula $Na_2B_4O_7$; another frequently used formula is $Na_2O.2B_2O_3$ (water free).<br>Disodium tetraborate pentahydrate, general formula $Na_2B_4O_7.5H_2O$; another frequently used formula is $Na_2O.2B_2O_3.5H_2O$.<br>Disodium tetraborate decahydrate, general formula $Na_2B_4O_7.10H_2O$ another frequently used formula is $Na_2O.2B_2O_3.10H_2O$. |
| **Reliability** | - |
| **Acceptability** | acceptable |
| **Remarks** | - |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 2-Feb-05 |
| **Materials and methods** | Section 2.5.2: Structural formula.<br>The notifier refers to the IUCLID database for the structural formula. The structural formula should also be given here. The structure provided is however a structure for $B4O9H4^{2-}$. A more approprate structure for $Na_2B_4O_7$ was found at:<br>http://www.chemicalland21.com/arokorhi/industrialchem/inorganic/BORAX%20DECAHYDRATE.htm or<br>http://ull.chemistry.uakron.edu/erd/chemicals1/9/8558.html |
| **Conclusion** | Structural formula:<br>  <br> |
| **Reliability** | - |
| **Acceptability** | acceptable |
| **Remarks** | - |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 2-Feb-05 |
| **Materials and methods** | Section 2.5.2: Molecular mass<br>It is not clear where the molecular mass as submitted by the notifier came from. The molecular mass is given as 201.22 for disodium tetraborate anhydrous, 291.296 for disodium tetraborate pentahydrate and 381.373 for disodium tetraborate decahydrate in the CRC Handbook of Chemistry and Physics, 1999. These molecular masses are used throughout the CA-report. |
| **Conclusion** | Disodium tetraborate anhydrous, molecular mass 201.22<br>Disodium tetraborate pentahydrate, molecular mass 291.296<br>Disodium tetraborate decahydrate, molecular mass 381.373 |
| **Reliability** | - |
| **Acceptability** | acceptable |
| **Remarks** | - |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 2-Feb-05 |
| **Materials and methods** | Section 2.6: Manufacturing process<br>a. The manufacturing process is considered as an industrial scale process, although this is not indicated by the notifier.<br>b. There are two manufacturers and only one manufacturing process is described.<br>The manufacturing process described is the manufacturing process for Borax Europe Ltd. The manufacturing process for Etimine s.a. is classified as confidential. The description of the process is given in a separate appendix, indicated as Doc IIIA (2.6 and 2.9) Etimine. |
| **Conclusion** | as indicated by the notifier |
| **Reliability** | - |
| **Acceptability** | acceptable |
| **Remarks** | - |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 19-Sept-05 |
| **Materials and methods** | Section 2.7: Purity of the active substance<br><br>a. The specification data cannot be verified by the RMS, because batch analyses are not submitted. These are, however, not required.<br><br>b. An active substance purity higher than 100% is not possible.<br><br>c. Another frequently used formula for sodium tetraborates is $Na_2O.2B_2O_3.xH_2O$ (x = 0, 5, or 10). Based on this formula the purity can also be expressed as $B_2O_3$-content. In this case 68%-70% $B_2O_3$ for anhydrous form, 48%-50% $B_2O_3$ for pentahydrate and 37%-39% $B_2O_3$ for decahydrate form. It is not useful to express the content as boric oxide, because this compound as such is not present in sodium tetraborates. The formula suggests that sodium tetraborates are boric oxide with added sodium oxide and crystallisation water, which is not correct. Both boric oxide, sodium oxide and water are not present in sodium tetraborates.<br><br>d. The table is reordered by the RMS to maintain the same sequence throughout the document and to prevent reading errors. Further the common names are used to indicate the compounds. % values are assumed to be % w/w although this is not specified by the notifier for the Etimine s.a. products. The $B_2O_3$ column is deleted.<br><br>e. Minimum purity data at 100% or higher are considered not realistic. Based on purity data (IIIA2.7) and impurity data (IIIA2.8) a minimum purity of 99.0%, 99.9%, 99.9% (w/w) is possible for disodium tetraborate anhydrous (Borax Europe Ltd and Etimine s.a.), disodium tetraborate pentahydrate (Borax Europe Ltd and Etimine s.a.), and disodium tetraborate decahydrate (Borax Europe Ltd and Etimine s.a.) respectively.<br><br>f. In tests for physical chemical properties (see IIIA3.1.3, IIIA3.4) with disodium tetraborate anhydrous the minimum purity was 99.0%, which complies with purity data. In tests for physical chemical properties with disodium tetraborate pentahydrate (see IIIA3.1.1; IIIA3.1.3, IIIA3.4, IIIA3.5) the minimum purity was 101.7%, which is not realistic.<br><br>g. The minimum purity data for disodium tetraborate decahydrate for both manufacturers (101.0% or 100.51%) does not comply with the purity of the active substance used in tests for physical chemical properties (see IIIA3.1.1; IIIA3.1.3, IIIA3.4, IIIA3.5, IIIA3.9). In these tests the minimum purity was 99.0%.<br><br>h. The only indication from realistic minimum purity comes from tests with disodium tetraborate anhydrous and disodium tetraborate decahydrate: minimum 99.0%. Because the pentahydrate form is very likely produced from either the decahydrate form or the anhydrous form, a minimum purity of 99.0% is proposed by the RMS for both manufacturers and all hydration forms. |
| **Conclusion** | Based on impurity data and tests with the active substance, the minimum purity specification proposed by the RMS is 99.0% (w/w) for both manufacturers and for all hydration forms (expressed as $Na_2B_4O_7.xH_2O$, where x = 0, 5 or 10). |
| **Reliability** | - |
| **Acceptability** | acceptable |
| **Remarks** | - |

| | COMMENTS FROM ... |
|---|---|
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

## RMS Section A2 Identity of Active Substance

**RMS Subsection (Annex Point)**

**RMS 2.7**

**Specification of the purity of the active substance, as appropriate (IIA2.7)**

**Borax Europe Ltd:**

| | | % w/w Purity |
|---|---|---|
| Disodium tetraborate anhydrous | Typical | 99.6 |
| | Maximum | 100.3 |
| | Minimum | 99.0 |
| Disodium tetraborate pentahydrate | Typical | 102.3 |
| | Maximum | 103.1 |
| | Minimum | 101.7 |
| Disodium tetraborate decahydrate | Typical | 102.9 |
| | Maximum | 104.6 |
| | Minimum | 101.0 |

**Etimine s.a.**

| | | % w/w Purity |
|---|---|---|
| Disodium tetraborate anhydrous | Typical | 101.52 |
| | Maximum | 101.86 |
| | Minimum | 99.90 |
| Disodium tetraborate pentahydrate | Typical | 102.07 |
| | Maximum | 102.41 |
| | Minimum | 101.55 |
| Disodium tetraborate decahydrate | Typical | 101.67 |
| | Maximum | 103.29 |
| | Minimum | 100.51 |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 2-Feb-05 |
| **Materials and methods** | Section 2.9: Origin of natural active substance<br>The origin of the natural active substance of Etimine s.a. is classified as confidential. The origin is given in a separate appendix, indicated as Doc IIIA (2.6 and 2.9) Etimine. |
| **Conclusion** | as indicated by the notifier |
| **Reliability** | - |
| **Acceptability** | acceptable |
| **Remarks** | - |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

## Document III-A: Study Summaries - Active Substance

## Section A2.8 Identity of impurities and additives (active substance)

**Annex Point IIA2.8** *fill in one form for each impurity/additive*

**Subsection (Annex Point)**

**Official use only**

**2.8 Identity of impurities and additives, as appropriate (IIA2.8)**

X1

**Borax Europe Ltd :**

| *Disodium tetraborate (anhydrous)* | % | |
|---|---|---|
| | **Fe** | **$SO_4$** |
| Typical | 0.0021 | 0.0098 |
| Maximum | 0.0040 | 0.0150 |
| Minimum | 0.0000 | 0.0000 |

| *Disodium tetraborate pentahydrate* | % | | |
|---|---|---|---|
| | **Fe** | **Cl** | **$SO_4$** |
| Typical | 0.0005 | 0.0073 | 0.0071 |
| Maximum | 0.0010 | 0.0120 | 0.0100 |
| Minimum | 0.0000 | 0.0000 | 0.0000 |

| *Disodium tetraborate decahydrate* | % | | |
|---|---|---|---|
| | **Fe** | **Cl** | **$SO_4$** |
| Typical | 0.0006 | 0.0149 | 0.0140 |
| Maximum | 0.0020 | 0.0500 | 0.0400 |
| Minimum | 0.0000 | 0.0000 | 0.0000 |

Variation in the purity and impurities is also due to the degree of hydration of the sodium tetraborates. This variable is dependant on the manufacturing process. Therefore water will be the difference up to 100%.

**Etimine s.a.:**

| **Borax Decahydrate** | % | | | |
|---|---|---|---|---|
| | **Fe** | **Cl** | **SO4** | **Insolubles in water*** |
| Typical | 0.0003 | 0.0017 | 0.0024 | 0.0104 |
| Maximum | 0.0010 | 0.0030 | 0.0025 | 0.0130 |
| Minimum | 0.0001 | 0.0010 | 0.0020 | 0.0060 |
| **Borax Pentahydrate (Etibor-48)** | % | | | |
| | **Fe** | **Cl** | **SO4** | **Insolubles in water*** |
| Typical | 0.0002 | 0.0035 | 0.0025 | 0.0101 |
| Maximum | 0.0005 | 0.0038 | 0.0030 | 0.0140 |
| Minimum | 0.0001 | 0.0027 | 0.0020 | 0.0070 |

## Section A2.8 Identity of impurities and additives (active substance)

**Annex Point IIA2.8** *fill in one form for each impurity/additive*

| Borax Anhydrous | % | | | |
|---|---|---|---|---|
| Typical | 0.0[illegible]1 | 0.0[illegible]41 | 0.[illegible]043 | Insoluble[illegible]water* |
| Maximum | 0.0460 | 0.0070 | 0.0112 | 0.0900 |
| Minimum | 0.0092 | 0.0030 | 0.0075 | 0.0450 |

* Insolubles in water consists of Ca, Mg, Si, Al etc.

**2.8.1 Isomeric composition** Not relevant

**2.8.1.1 Common name**

**2.8.1.2 Function** Not relevant

**2.8.2 IUPAC name**

**2.8.3 CAS-No**

**2.8.4 EC-No**

**2.8.5 Other**

**2.8.6 Molecular formula**

**2.8.7 Structural formula**

**2.8.8 Molecular mass** *Give molecular mass in g/mol*

**2.8.9** g/kg g/l % w/w % v/v

## RMS, Section A2.8 — Identity of impurities and additives (active substance)

**Annex Point IIA2.8** — *fill in one form for each impurity/additive*

**RMS 2.8.1 Common name and function** — non-entry field

**RMS 2.8.1.1. Common name** — traces of iron, chlorine, sulphate

**RMS 2.8.1.1. Function** — impurity of starting material

**RMS 2.8.2 IUPAC name** — not applicable

**RMS 2.8.3 CAS no** — not applicable

**RMS 2.8.4 EC no** — not applicable

**RMS 2.8.5 Other** — not applicable

**RMS 2.8.6 Molecular formula** — Fe, Cl, $SO_4$

**RMS 2.8.7 Structural formula** — unknown

**RMS 2.8.8 Molecular mass**

Fe = 55.845

Cl = 35.4527

$SO_4$ = 32.066(6) + 4x 15.9994(3) = 96.043

Reference:

CRC Handbook of Chemistry and Physics, 1999

**RMS 2.8.9 Concentration of impurity or additive** *typical and range of concentrations* — Borax Europe Ltd.

| disodium tetraborate | | Fe (% w/w) | Cl (% w/w) | SO4 (% w/w) | insolubles (% w/w) |
|---|---|---|---|---|---|
| anhydrous | typical | 0.0021 | | 0.0098 | |
| | maximum | 0.0040 | | 0.0150 | |
| | minimum | 0.0000 | | 0.0000 | |
| pentahydrate | typical | 0.0005 | 0.0073 | 0.0071 | |
| | maximum | 0.0010 | 0.0120 | 0.0100 | |
| | minimum | 0.0000 | 0.0000 | 0.0000 | |
| decahydrate | typical | 0.0006 | 0.0149 | 0.0140 | |
| | maximum | 0.0020 | 0.0500 | 0.0400 | |
| | minimum | 0.0000 | 0.0000 | 0.0000 | |

Etimine s.a.

| disodium tetraborate | | Fe (% w/w) | Cl (% w/w) | SO4 (% w/w) | insolubles (% w/w) |
|---|---|---|---|---|---|
| anhydrous | typical | 0.0111 | 0.0041 | 0.0093 | 0.0650 |
| | maximum | 0.0460 | 0.0070 | 0.0112 | 0.0900 |
| | minimum | 0.0092 | 0.0030 | 0.0075 | 0.0450 |
| pentahydrate | typical | 0.0002 | 0.0035 | 0.0025 | 0.0101 |
| | maximum | 0.0005 | 0.0038 | 0.0030 | 0.0140 |
| | minimum | 0.0001 | 0.0027 | 0.0020 | 0.0070 |
| decahydrate | typical | 0.0003 | 0.0017 | 0.0024 | 0.0104 |
| | maximum | 0.0010 | 0.0030 | 0.0025 | 0.0130 |
| | minimum | 0.0001 | 0.0010 | 0.0020 | 0.0060 |

* Insolubles in water consist of Ca, Mg, Si, Al etc.

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 20-Sept-05 |
| **Materials and methods** | Section 2.8. Identity of impurities<br><br>a. The summary written by the notifier is not according to template. Therefore the whole section was rewritten by the RMS. The table is reordered by the RMS to maintain the same sequence throughout the document and to prevent reading errors. Further the common names are used to indicate the compounds. % values are assumed to be % w/w although this is not specified by the notifier for the Etimine s.a. products.<br><br>b. The specification data for impurities cannot be verified by the RMS, because batch analyses are not submitted for both manufacturers. These are, however, required.<br><br>c. The impurities for the Borax Europe Ltd disodium tetraborate anhydrous, pentahydrate and decahydrate add up to a maxium of 0.019% (w/w), 0.023% (w/w) and 0.092% (w/w), respectively, assuming that the concentrations are stated as % w/w. For the pentahydrate and decahydrate form this is higher than can be expected from the minimum purity requirement for the active substance of 101.7% w/w and 101.0% w/w, respectively (see section IIIA2.7). But impurities for all hydrate forms are compliable with the proposed minimum purity of 99.0% as proposed by the RMS (see section IIIA2.7).<br><br>d. The impurities for the Etimine s.a.Borax anhydrous, pentahydrate and decahydrate add up to a maximum of 0.1542% (w/w), 0.0213% (w/w) and 0.0195% (w/w) respectively, assuming that the concentrations are stated as % w/w. For the pentahydrate and decahydrate form, this is higher than can be expected from the minimum purity requirement for the active substance of 101.55%, and 100,51% w/w, respectively. (see section IIIA2.7). But impurities for all hydrate forms are compliable with the proposed minimum purity of 99.0% as proposed by the RMS (see section IIIA2.7). |
| **Conclusion** | Maximum specified impurities are compliable with the minimum purity of 99.0% (w/w) as proposed by the RMS for both manufacturers and for all hydration forms (expressed as $Na_2B_4O_7.xH2O$, where x = 0, 5 or 10). |
| **Reliability** | - |
| **Acceptability** | acceptable |
| **Remarks** | - |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

## Document III-A: Study Summaries - Active Substance

### Section A2.10 — Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Annex Point IIA2.10

| Subsection | | Official use only |
|---|---|---|
| **2.10.1 Human exposure towards active substance** | In the occupational exposure measurements of borates it is preferential to determine the boron value of the sample and to equate this to individual borates where appropriate. The basis for this is due to a number of factors.<br>1. Borates are susceptible to weight change due to uptake or loss of water and this hydration instability can lead to gravimetric and interpretation errors in field samples.<br>2. There may be a mix of borates in the sample and borate species cannot be easily characterised by chemical analysis.<br>3. Boron can be measured to a high level of accuracy.<br>Therefore assessment of all borates is covered in Doc IIIA Boric Acid<br>REF: *Smith, R.A.; Ascherl, F.M Issues concerning the measurement of borate in occupational environments. Am. Ind. Hyg. Assoc. J.,* 60, *No. 5, p.651-658. (September - October 1999)* | |
| **2.10.1.1 Production** | See Doc III A Boric Acid | |
| **2.10.1.2 Intended use(s)** | Wood Preservation Professional (Industrial and Professional) and Non Professional (Amateur Use ) use<br>The simple inorganic borates such as boric acid; boric oxide; disodium tetraborate and disodium octaborate tetrahydrate are used for wood preservation formulations depending upon requirements such as pH, total solubility, solubility rate, compatibility with other substances in the formulation, etc. They are primarily used in solution where they are completely dissolved. 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).<br>Once the borate is in solution and the wood is treated, the risk assessment of the wood will be the same regardless of the starting material at Mixing and Loading Stage. Therefore the Exposure data is the same regardless of the borate staring material and is all presented in the Boric Acid Dossier Doc IIIA & B | |
| **2.10.2 Environmental exposure towards active substance** | Releases to the environment are measured in terms of boron and are covered in Doc IIIA Boric Acid | |
| **2.10.2.1 Production** | See Doc IIIA Boric Acid | |
| **2.10.1.2 Intended use(s)** | Emissions to the environment will be the same species of borate (boric acid). In solution, borates form a variety of polymeric species derived from monomeric 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 boric acid. | |

| Section A2.10<br>Annex Point IIA2.10 | Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC |
|---|---|

This has been borne out 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 $B(OH)_3$ as the species present. The pH or soils and rain is typically in the range 6-8 and therefore the borate leached from timber which is present at low concentration will be $B(OH)_3$.

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 4-Oct |
| **Materials and methods** | Section IIIA2.10<br><br>Human exposure assessment<br><br>a. In Doc. II B Exposure Assessment for the Biocidal Product' the exposure assessment is described in section 8. Background information about the processes and values are described in Doc. III A2.10. The exposure calculation was not given, it was received from the notifier via the Board for the Authorization of Pesticides (Mail EBA, 11-05-05).<br><br>b. To calculate the dermal exposure during mixing and loading and during application the notifier used the 'dermal absorption flux'. The dermal exposure was calculated by multiplying this flux (in mg/($cm^2$ x hour)) with the total body surface area and with the exposure duration. The flux is derived from a dermal absorption study in volunteers (see Doc IIIA6.2). The flux (µg / ($cm^2$ x hour)) which is calculated here for the different active substances (a.s.), is a measure for the quantities of the different a.s. absorbed by the skin in the test concerned. This flux is a measure for the amount absorbed by the skin. However, in the exposure calculation during mixing and loading and application, it is used as measure for the amount of active substance deposited on the skin. This is not correct.<br><br>Environmental exposure assessment<br><br>c. Upon evaluation, the main input (use classes under consideration, dosages and leaching rates) as used in the applicant's assessment appeared to be either not relevant, incorrect or inconsistent. Therefore, RMS conducted a new environmental exposure assessment according to the OECD Emission Scenario Document for Wood preservatives. The reader is therefore referred to the environmental exposure assessment as performed by RMS, which is included in Doc IIB, Sections 8.3 and following subsections. |

| | |
|---|---|
| **Conclusion** | Human exposure assessment<br><br>In our view, the approach in which the notifier has calculated the exposure is not correct. The calculations are therefore not provided with annotations. The exposure can be calculated by means of the models mentioned in the TNsG (2002). In the User Guidance TNsG (2002), the human exposure to wood preservatives is extensively described; to calculate the exposure to wood preservatives the most appropriate models and its parameter values are stated.<br><br>The exposure to borates is calculated by using the selected models and default values for wood preservatives from the User Guidance TNsG (2002) as a guideline. Via the Board for Authorization of Pesticides (CTB) the proposal to the notifier was to calculate the exposure with this approach in addition to their own method. The notifier has done these calculations likewise (mail EBA, 09-05-05).<br><br>In Doc IIB, section 8 'Exposure Assessment' the calculations which we have done are reported. In the calculations the process information given by the notifier is used as base for the calculations. Where the calculations differ from the notifier's calculations, this is mentioned.<br><br>Environmental exposure assessment<br><br>The above presented exposure assessment of the applicant is not considered correct. The reader is therefore referred to the environmental exposure assessment as performed by RMS, which is included in Doc IIB, Sections 8.3 and following subsections. |
| **Reliability** | 3 |
| **Acceptability** | Not acceptable |
| **Remarks** | |

| | |
|---|---|
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

## Document III-A: Study Summaries - Active Substance

### Section A3 Physical and Chemical Properties of Active Substance - *Disodium tetraborate (anhydrous borax)*

| Subsection (Annex Point) | Method | Purity/ Specification | Results<br>Give also data on test pressure, temperature, pH and concentration range if necessary | Remarks/ Justification | GLP (Y/N) | Reliability | Reference | Official use only |
|---|---|---|---|---|---|---|---|---|
| **3.1 Melting point, boiling point, relative density (IIA3.1)** | | | | | | | | |
| **3.1.1 Melting point** | | | | | | | | X1 |
| Melting pt. 1 | - | Disodium tetraborate-unspecified | **result:** 742.5°C | The two hydrated forms of disodium tetraborate do not melt as such. When disodium tetraborate decahydrate is heated (in an open space) above about 62°C, it gradually loses water of crystallisation, first forming the pentahydrate,<br>Na2B4O.5H2O, and on further heating forms anhydrous disodium tetraborate, Na2B4O7, the crystal form of which melts at 742°C. | No data | 2 | Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley<br>& Sons Inc., 1992, 4th Edition, Volume 4, page 382. | |
| **3.1.2 Boiling point** | | | | | | | | X2 |
| Boiling pt. 1 | No data | No data | **result:** 1575°C | Not applicable for<br>disodium tetraborate decahydrate or disodium tetraborate pentahydrate as these lose water of crystallisation on heating. The anhydrous form starts to decompose at 1575°C (giving Na2O and B2O3). | No data | 2 | CRC Handbook of Chemistry and Physics, CRC Press, 1990-1991, 71st Edition, page 4-102. ISBN - 0-8493-0471-7. | |
| **3.1.3 Bulk density/ relative density** | | | | | | | | X3 |

## Section A3 Physical and Chemical Properties of Active Substance - *Disodium tetraborate (anhydrous borax)*

| Subsection (Annex Point) | Method | Purity/ Specification | Results<br>Give also data on test pressure, temperature, pH and concentration range if necessary | Remarks/ Justification | GLP (Y/N) | Reliability | Reference | Official use only |
|---|---|---|---|---|---|---|---|---|
| Bulk/rel. density 1 | - | Disodium tetraborate – unspecified | Relative density = 2.37 at 20°C. | - | No data | 2 | Borax internal product spec. | |
| Bulk/rel. density 2 | Test Guideline A.3 of EC Directive 92/69/EEC and TNO-PML Standard Operation Procedure Q-211-W-030.<br>A multi-volume pyncnometer was used. | >99.0% | Relative Density = 2.354 ± 0.007 @ 26°C ±1°C | - | Y | 1 | Spruit WET [redacted] 2005, | |
| **3.2 Vapour pressure (IIA3.2)** | - | - | Not applicable. | The vapour pressure value for both disodium tetraborate<br>pentahydrate and disodium tetraborate is negligible at ambient temperatures. A vapour pressure study on Boric acid (Tremain et al., 1998) indicated a negligible vapour pressure of 0.000000099 hPa at 25°C and on disodium octaborate tetrahydrate 0.000000000099 hPa at 25°C (Howard et al., 1995). Therefore no further testing is required. | Y | 1 | Tremain SP, [redacted] 1998<br>Howard R, [redacted] 1995, | X4 |

## Section A3 Physical and Chemical Properties of Active Substance - *Disodium tetraborate (anhydrous borax)*

| Subsection (Annex Point) | Method | Purity/ Specification | Results<br>Give also data on test pressure, temperature, pH and concentration range if necessary | Remarks/ Justification | GLP (Y/N) | Reliability | Reference | Official use only |
|---|---|---|---|---|---|---|---|---|
| **3.2.1 Henry´s Law Constant (Pt. I-A3.2)** | - | - | - | Not required due to low vapour pressure. | - | - | - | X5 |
| **3.3 Appearance (IIA3.3)** | | | | | | | | X6 |
| **3.3.1 Physical state** | | | Solid | | | | | |
| **3.3.2 Colour** | | | White | | | | | |
| **3.3.3 Odour** | | | Odourless | | | | | |
| **3.4 Absorption spectra (IIA3.4)** | | | | | | | | X7 |
| **UV/VIS** | OECD Test Guideline 101 and TNO-PML Standard Operating Procedure Q213-W-058 | >99.0% | The molar extinction coefficient of the test substance could not be determined because there were no absorption maxima or minima in twice distilled water, basic of acidic medium observed. | No unusual effects were observed in running the spectra. | Y | 1 | Spruit WET [redacted] 2005 | |
| **IR** | TNO-PML Standard Operating Procedure Q214-W-125; version 2 | >99.0% | Major peaks observed at 702, 945, 1002 and 1347 $cm^{-1}$. | The sample was ground in KBr powder and pressed. The test substance was recorded on an FTIR-spectrometer. | Y | 1 | Spruit WET [redacted] | |

## Section A3 Physical and Chemical Properties of Active Substance - *Disodium tetraborate (anhydrous borax)*

| Subsection (Annex Point) | Method | Purity/ Specification | Results<br>Give also data on test pressure, temperature, pH and concentration range if necessary | Remarks/ Justification | GLP (Y/N) | Reliability | Reference | Official use only |
|---|---|---|---|---|---|---|---|---|
| | (No EC Test Guideline specified). | | | The recorded FTIR-spectrum of the test substance is depicted in spectrum number ITA0004 of the report. | | | [redacted] 2005, | |
| **NMR** | - | - | - | The recording of the $^{13}C$ NMR Spectrum of the test substance as reflected in TNO protocol no. 014.16565 dated August 23, 2004 is irrelevant due to the fact that the test substance does not contain carbon atoms. | Y | 1 | Spruit WET, [redacted] 2005, | |
| **MS** | - | - | - | At TNO mass spectrometery of inorganic boron compounds, like sodium tetraborate anhydrous, can be done with liquid chromatography and electrospray mass spectrometry (LC-ES MS). However, earlier experience with these compounds has shown that the electrospray mass spectra do not provide any direct information on the particular boron compounds, see reports TNO-PML 2002-C041rr, -C042rr, -C043rr, -C044rr. Elecgtrospray does not ionise inorganic boron compounds in a way that allows recording of mass spectral characteristics relevant to the compounds identity and | Y | 1 | Spruit WET, [redacted] 2005, | |

**Section A3** **Physical and Chemical Properties of Active Substance - *Disodium tetraborate (anhydrous borax)***

| Subsection (Annex Point) | Method | Purity/ Specification | Results<br>Give also data on test pressure, temperature, pH and concentration range if necessary | Remarks/ Justification | GLP (Y/N) | Reliability | Reference | Official use only |
|---|---|---|---|---|---|---|---|---|
| | | | | composition. | | | | |
| **3.5 Solubility in water (IIA3.5)** | *including effects of pH (5-9)* | | | | | | | X8 |
| Water solubility 1 | - | Test substance: disodium tetraborate – unspecified. | **result:** 24.8 g/l<br>**temperature:** 20°C<br>**pH:** 9.2<br><br>**Concentration**: 24.8 g/l at 20°C. | pH remains unchanged over a wide range of concentrations.<br><br>**Description: soluble (1000-10000 mg/l).** | No data. | 2 | Mellor's Comprehensive Treatise on Inorganic &<br>Theoretical Chemistry, Volume V Boron, Part A: Boron-Oxygen<br>Compounds, Longman London and New York, (1980), ISBN<br>0-582-46277-0, page 254. (Solubility)<br><br>Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons, Inc., New York, 1992, 4th Edition, Volume 4, pages 381-386. (pH) | |
| **3.6 Dissociation constant (-)** | - | - | Not required. | *Only if additional data are required (see BPD, TNsG)* | - | - | - | X9 |
| **3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)** | - | - | Methanol: 167 g/l<br>Ethylene glycol: 300 g/l<br>Formamide: 40.6 g/l<br>(temperature: 25°C). | - | No data | 2 | Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons, Inc., New York, 1992, 4th Edition, Volume 4, pages 381 | X10 |
| **3.8 Stability in organic** | - | - | Not required. | *Only if additional data are required* | - | - | - | X11 |

## Section A3 Physical and Chemical Properties of Active Substance - *Disodium tetraborate (anhydrous borax)*

| Subsection (Annex Point) | Method | Purity/ Specification | Results<br>Give also data on test pressure, temperature, pH and concentration range if necessary | Remarks/ Justification | GLP (Y/N) | Reliability | Reference | Official use only |
|---|---|---|---|---|---|---|---|---|
| **solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)** | | | | *(see BPD, TNsG)* | | | | |
| **3.9 Partition coefficient n-octanol/water (IIA3.6)** | - | - | Not applicable. | The partition coefficient of disodium tetraborate<br>(anhydrous, pentahydrate and decahydrate) in<br>n-octanol/water cannot be measured accurately, because in aqueous solution sodium tetraborates are converted substantially into undissociated boric acid, H3BO3. | - | 2 | Barres M, Rev. Chim. Miner., 1967, 4, 803-838; Chem.<br>Abstr.,1968,69, 30628 | X12 |
| **3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)** | - | - | - | Heat of formation: -3.2767 MJ/mol. Anhydrous borax is obtained y dehydrating borax hydrates and is the stable form above 600-700°C. | - | 2 | Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons, Inc., New York, 1992, 4th Edition, Volume 4, pages 386. | X13 |
| **3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)** | - | - | Non flammable. | Disodium tetraborates (anhydrous, pentahydrate and<br>decahydrate) are non-flammable solids (flammability<br>classification U.S.A. 29CFR 1920.1200) | - | - | - | X14 |
| **3.12 Flash-point (IIA3.9)** | - | - | Test not applicable. | Sodium tetraborates (anhydrous,<br>pentahydrate and decahydrate) are non-flammable inorganic | - | - | - | |

## Section A3 Physical and Chemical Properties of Active Substance - *Disodium tetraborate (anhydrous borax)*

| Subsection (Annex Point) | Method | Purity/ Specification | Results<br>Give also data on test pressure, temperature, pH and concentration range if necessary | Remarks/ Justification | GLP (Y/N) | Reliability | Reference | Official use only |
|---|---|---|---|---|---|---|---|---|
| | | | | solids. | | | | |
| **3.13 Surface tension (IIA3.10)** | | | | | | | | X15 |
| Surface tension 1 | - | - | Refer to disodium tetraborate pentahydrate. | - | - | - | - | |
| **3.14 Viscosity (-)** | - | - | Not applicable. | Disodium tetraborate (anhydrous) is a solid substance. | - | - | - | |
| **3.15 Explosive properties (IIA3.11)** | - | - | - | Potential explosive properties are indicated by the presence of certain reactive groups in the molecule. The molecular structure of none of the substances indicates that such groups are present. No reactive or instable groups are present. The molecular structure does not indicate that these substances will explode under the conditions of the test as described in Test Guideline A.14 of EC Directive 92/69/EEC.<br>Conclusion: Considering the molecular structure and the information that is available in the literature, disodium tetraborate anhydrous is not expected to have explosive properties in the sense of EC Directive 92/69/EEC. | - | 1 | Mak [redacted] 2004. [redacted] | X16 |
| **3.16 Oxidizing properties (IIA3.12)** | - | - | - | In principle, inorganic substances that contain oxygen may show | - | 1 | Mak [redacted] 2004. [redacted] | X17 |

## Section A3 Physical and Chemical Properties of Active Substance - *Disodium tetraborate (anhydrous borax)*

| Subsection (Annex Point) | Method | Purity/ Specification | Results<br>Give also data on test pressure, temperature, pH and concentration range if necessary | Remarks/ Justification | GLP (Y/N) | Reliability | Reference | Official use only |
|---|---|---|---|---|---|---|---|---|
| | | | | oxidizing properties and these should therefore be tested according to Test Guideline A.17 of EC Directive 92/69/EEC. However, a search of available literature has not resulted in any indication of oxidizing properties, neither has it shown any accident data that may be attributed to oxidizing properties.<br>Conclusion: Considering the molecular structure and the information that is available in the literature, disodium tetraborate anhydrous is not expected to have oxidizing properties in the sense of EC Directive 92/69/EEC. | | | [redacted] | |
| **3.17 Reactivity towards container material (IIA3.13)** | Suitable container materials: Paper, Cardboard, Plastic (Polypropylene, High density polyethylene)<br>Unsuitable container materials: Base metals | | | | | | | |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 20-Sept-05 |
| **Materials and methods** | Section 3.1.1. Melting point, disodium tetraborate anhydrous<br><br>a. One study was summarized by the notifier (Kirk-Othmer). The melting point value of 742.5 °C from this study was used in the RAR for boric acid and tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh). Because no indications on methods were available, the study is given reliability 4. The study can however be used as confirmation study.<br><br>b. The melting point study submitted for disodium tetraborate pentahydrate (Cordia et al., 2003) can also be used for disodium tetraborate anhydrous, because during heating disodium tetraborate pentahydrate is converted into disodium tetraborate anhydrous. This study is considered as key study by the RMS because this study was carried out under GLP according to EC method A1 (= ASTM E 537-1) and with known purity.<br><br>c. Although GLP was indicated for the key study, the report submitted, did not contain any authorisation signatures. An authorised report is not required as there is no hard GLP requirement.<br><br>d. Experiments were carried out with batch number BRT 2463 [redacted] The purity of the active substance is given as 101.7%-103.1%. The purity of disodium tetraborate pentahydrate in the key study complies with the minimum purity indicated in chapter IIIA2.7 for both manufacturers. However, minimum and maximum purity cannot be higher than 100%. Data on impurities are not available.<br><br>e. In the key study differential thermal analysis (DTA) was used in the temperature range 25-1000 °C.<br><br>f. In the key study (Cordia et al, 2003) a phase transition was found at 131/132 °C, due to loss of water, which will not be found for disodium tetraborate anhydrous. At 525/527 °C a phase transition occurs, which might also be found for disodium tetraborate anhydrous. The melting point for disodium tetraborate anhydrous was found to be 737 °C. The melting point value found in study 1 (Kirk-Othmer) for disodium tetraborate anhydrous was 742.5 °C, which confirms the value found in the key study.<br><br>g. The reference is stated wrong in the table for disodium tetraborate pentahydrate. The full reference for the key study should be stated as: [redacted] |
| **Conclusion** | Melting point is 737 °C. A phase transition is found at 525/527 °C. |
| **Reliability** | study 1 is reliability 4; study 2 is reliability 1 (key study) |
| **Acceptability** | acceptable. |
| **Remarks** | - |

| | COMMENTS FROM ... |
|---|---|
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 29-Apr-05 |
| **Materials and methods** | Section 3.1.2. Boiling point, disodium tetraborate anhydrous.<br>a. One study was summarized (CRC handbook). This study was an encyclopedia without indications of methods and was given reliability of 4. The decomposition temperature at 1575 °C for disodium tetraborate anhydrous from this study was stated in the RAR for boric acid and tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh).<br>b. That a boiling point is not applicable, can be deduced from the melting point study (section A3.1.1) where a melting point was found at 737 °C. A phase transition was found at 525/527 °C. Therefore additional data are not required. |
| **Conclusion** | A boiling point is not applicable because the melting point lies above 360 °C. |
| **Reliability** | study 1 set at reliability 4. |
| **Acceptability** | acceptable. |
| **Remarks** | - |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 20-Sept-05 |
| **Materials and methods** | Section 3.1.3. Relative density, disodium tetraborate anhydrous.<br>a. Two studies were summarized by the notifier. Study 1 is a sheet with internal product specifications which was not submitted and is given reliability 4. Study 2 is considered as key study by the RMS and is given reliablity of 1 because the study was carried out according to GLP and according to EEC guideline A3 using a multi volume pycnometer.<br>b. The value of 2.37 at 20 °C from study 1 is the same value as stated in the RAR for boric acid and tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh). The data are considered not reliable by the RMS.<br>c. The key study was carried out for batch number BRt3001A[redacted] The purity was reported to be >99.0%. The purity of disodium tetraborate anhydrous in the key study complies with the minimum purity indicated in chapter IIIA2.7 for Borax Europe Ltd, but does not comply with the minimum purity for Etimine s.a. (99.9%). Data on impurities are not available.<br>d. The physical state of the measured substance in the key study is a solid.<br>e. The relative density to water at 4 °C was calculated by dividing the absolute density with 1000.00 kg/$m^3$.<br>e. The relative density is expressed as $D^{26}_4$ whereas it should be expressed as $D^{20}_4$. This temperature difference is not expected to cause a large deviation and the value is considered acceptable by the RMS.<br>f. The full reference for the key study should be stated as: [redacted] |
| **Conclusion** | Relative density $D^{26}_4 = 2.354 \pm 0.007$ |
| **Reliability** | reliability 1 |
| **Acceptability** | acceptable |
| **Remarks** | - |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 29-Apr-05 |
| **Materials and methods** | Section 3.2. Vapour pressure, disodium tetraborate anhydrous.<br>The notifier submitted two studies where the vapour pressure has been determined for boric acid (Tremain, 1998) or for disodium octaborate tetrahydrate (Howarth et al., 1995). Both studies are considered not relevant by the RMS for disodium tetraborate anhydrous. Both studies are set at reliability of 4. |
| **Conclusion** | Not applicable, because the melting point lies above 300 °C.<br>At ambient temperature the vapour pressure is expected to be less than $10^{-5}$ Pa . |
| **Reliability** | study 1 and 2, reliability 4. |
| **Acceptability** | acceptable. |
| **Remarks** | - |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 29-Apr-05 |
| **Materials and methods** | Section 3.1.1, Henry's law constant, disodium tetraborate anhydrous<br>The Henry's law constant can only be derived from the vapour pressure in combination with the aqueous solubility. Because the vapour pressure for disodium tetraborate anhydrous is expected to be less than $10^{-5}$ Pa, no additional data are required. |
| **Conclusion** | Not applicable. At ambient temperature, vapour pressure is expected to be less than $10^{-5}$ Pa. |
| **Reliability** | - |
| **Acceptability** | acceptable. |
| **Remarks** | - |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 20-Sept-05 |
| **Materials and methods** | Section 3.3, appearance, disodium tetraborate anhydrous<br>a. Physical state, color and odour is stated without specification of the purity of the active substance, impurities present, temperature and pressure.<br>b. Physical state corresponds with data in the RAR for boric acid and disodium tetraborate (d.d. 17 December 2003, document TR417+423_1203_env_hh). |
| **Conclusion** | as indicated by the notifier |
| **Reliability** | as indicated by the notifier. |
| **Acceptability** | acceptable. |
| **Remarks** | - |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |

| Evaluation by Competent Authorities | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | 20-Sept-05 |
| **Materials and methods** | Section 3.4 Spectra, disodium tetraborate anhydrous<br><br>a. One study was submitted. The study is considered as key study by the RMS and is given reliablity of 1 because the study was carried out according to GLP and according to guidelines.<br><br>b. The study was carried out for batch number BRt3001A [redacted] The purity was reported to be >99.0%. The purity of disodium tetraborate anhydrous in the key study complies with the minimum purity indicated in chapter IIIA2.7 for Borax Europe Ltd, but does not comply with the minimum purity for Etimine s.a. (99.9%). Data on impurities are not available.<br><br>c. UV/VIS spectra were recorded between 200-750 nm according to OECD 101. Test solution was 3.3422 g/L as disodium tetraborate anhydrous. The spectrum is equal to the spectrum of disodium tetraborate pentahydrate, which was recorded between 190-500 nm. No absorption maximum or minimum was found.<br><br>d. FTIR spectra were recorded between 400-4000 $cm^{-1}$. The test substance was recorded as KBr pellet. Peaks were observed at 702 (broad), 945 (broad), 1002 (broad), 1347 (broad) and 3420 (broad) $cm^{-1}$.<br><br>e. A statement was given that $^{13}$C-NMR spectra are not applicable, because disodium tetraborate anhydrous does not contain carbon atoms. Although $^{11}$B-NMR or $^{17}$O-NMR are more appropriate, these instruments are not available in most laboratories.<br><br>f. A statement was given that MS spectra from HPLC-MS with electrospray ionisation are unsuccessful because solutions of disodium tetraborate anhydrous cannot be ionised in this system.<br><br>h. Another technique which is appropriate to elucidate the structure of disodium tetraborate anhydrous is Raman spectroscopy or X-ray spectroscopy. Spectral data for these techniques are welcome. See also Mellor's Comprehensive, submitted for IIIA3.1.<br><br>i. The full reference of the newly submitted key study is: [redacted] |
| **Conclusion** | No absorption maxima or minima are observed in the UV/VIS spectrum in the range 190-750 nm of disodium tetraborate anhydrous or pentahydrate solution in water, basic medium or acidic medium.<br><br>FTIR spectra of disodium tetraborate anhydrous recorded as KBr pellet revealed peaks at 702 (broad), 945 (broad), 1002 (broad), 1347 (broad) and 3420 (broad) $cm^{-1}$.<br><br>$^{13}$C-NMR spectra are not applicable, because disodium octaborate tetrahydrate does not contain carbon atoms.<br><br>MS spectra could not be obtained because solutions of disodium tetraborate anhydrous could not be ionised in a HPLC-ES-MS system. |

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| **Reliability** | set at 1 for the key study |
| **Acceptability** | acceptable. |
| **Remarks** | Raman spectroscopy and X-ray spectroscopy data are desirable. |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Results and discussion** | *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* |
| **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** | |