Annex XV dossier

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1 OR 2, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance name: Disodium tetraborate, anhydrous

EC number: 215-540-4

CAS number: 1330-43-4

In addition, the proposal covers substances / hydrates with the following CAS numbers which are covered by the EINECS entry of anhydrous form:

CAS number 12179-04-3: Disodium tetraborate pentahydrate, [CAS name: boron sodium oxide ($B_4Na_2O_7$), pentahydrate]

CAS number 1303-96-4: Disodium tetraborate decahydrate, [CAS name: Borax ($B_4Na_2O_7.10H_2O$)]

and the following substance with EC number 235-541-3 and CAS number 12267-73-1:

Tetraboron disodium heptaoxide, hydrate [CAS name: Boron sodium oxide ($B_4Na_2O_7$), hydrate].

- *It is proposed to identify the substance as a CMR according to Article 57 (c).*

Submitted by: Denmark

Version: February 2010

CONTENTS

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- *It is proposed to identify the substance as a CMR according to Article 57 (c).*

Summary of how the substance meets the CMR (Cat 1 or 2), PBT or vPvB criteria or is considered to be a substance giving rise to an equivalent level of concern

This dossier covers disodium tetraborate anhydrous (CAS 1330-43-4) and the hydrates disodium tetraborate pentahydrate (CAS 12179-04-03), disodium tetraborate decahydrate (CAS 1303-96-4) and tetraboron disodium heptaoxide, hydrate (CAS 12267-73-1). In aqueous solution, the hydrates form the same substances as disodium tetraborate anhydrous and are therefore comparable in their toxicological properties.

The harmonised classification according to Regulation (EC) No 1272/2008 as amended by Regulation (EC) No 790/2009 (Annex VI, part 3, Table 3.1) of disodium tetraborate (anhydrous, pentahydrate and decahydrate forms) and tetraboron disodium heptaoxide, hydrate is:

Toxic to reproduction, Repr.1B, H360FD.

The classification of disodium tetraborate (anhydrous, pentahydrate and decahydrate forms) and tetraboron disodium heptaoxide, hydrate according to part 3 of Annex VI, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 as amended by Regulation (EC) No 790/2009 is:

Toxic for reproduction, Repr. Cat 2, R60-61.

The disodium tetraborate in all three forms, anhydrous, pentahydrate and decahydrate, and tetraboron disodium heptaoxide, hydrate is meeting the criteria of Article 57 (c) of the REACH regulation.

Registration number(s) of the substance or of substances containing a given constituent/impurity or leading to the same transformation or degradation products:

No registration dossiers for the substances were submitted to ECHA by the publication date of this dossier (*March 2010*).

PART I

JUSTIFICATION

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Three disodium tetraborates are covered by the EINEC entry of the anhydrous form:

Disodium tetraborate anhydrous, CAS number 1330-43-4; EC number 215-540-4

Disodium tetraborate pentahydrate, CAS 12179-04-3

Disodium tetraborate decahydrate, CAS 1303-96-4.

This dossier covers also the substance with the EC number 235-541-3, Tetraboron disodium heptaoxide, hydrate, CAS number 12267-73-1.

EC number:	215-540-4	---	---	235-541-3
CAS number:	1330-43-4	12179-04-3	1303-96-4	12267-73-1
Chemical name:	Disodium tetraborate, anhydrous; boric acid, disodium salt	Disodium tetraborate pentahydrate; borax pentahydrate	Disodium tetraborate decahydrate; borax decahydrate	Tetraboron disodium heptaoxide, hydrate
IUPAC name:	Disodium tetraborate anhydrous	Disodium tetraborate pentahydrate	Disodium tetraborate decahydrate	Tetraboron disodium heptaoxide, hydrate
Synonyms:	Anhydrous borax; Sodium tetraborate; Boron sodium oxide ($B_4Na_2O_7$); Boric acid ($H_2B_4O_7$), disodium salt; Sodium borate, Borax, fused	Borax 5-mol; Sodium borate ($Na_2B_4O_5(OH)_4$) trihydrate; Sodium tetraborate pentahydrate; Boron sodium oxide ($B_4Na_2O_7$), pentahydrate; Boric acid ($H_2B_4O_7$), Disodium salt, pentahydrate	Borax; Sodium tetraborate decahydrate; Borax decahydrate; Sodium biborate decahydrate; Sodium pyroborate decahydrate; Boron sodium oxide ($B_4Na_2O_7$), decahydrate; Boric acid ($H_2B_4O_7$), Disodium salt decahydrate; Tetrasodium salts, decahydrate	$Na_2B_4O_7 \cdot xH_2O$ Boric acid ($H_2B_4O_7$), disodium salt, hydrate; Boron sodium oxide ($B_4Na_2O_7$), hydrate
Index number in Annex VI of the CLP Regulation	005-011-00-4	005-011-02-9	005-011-01-1	005-011-00-4

1.2 Composition of the substance

EC number:	215-540-4	---	---	235-541-3
CAS number:	1330-43-4	12179-04-3	1303-96-4	12267-73-1
EC name:	Disodium tetraborate, anhydrous; boric acid, disodium salt	Disodium tetraborate pentahydrate; borax pentahydrate	Disodium tetraborate decahydrate; borax decahydrate	Tetraboron disodium heptaoxide, hydrate
IUPAC name:	Disodium tetraborate anhydrous	Disodium tetraborate pentahydrate	Disodium tetraborate decahydrate	Tetraboron disodium heptaoxide, hydrate
Molecular formula:	$Na_2B_4O_7$	$Na_2B_4O_7 \bullet 5H_2O$	$Na_2B_4O_7 \bullet 10H_2O$	$Na_2B_4O_7 \bullet xH_2O$
Molecular weight range:	201.22	291.35	381.37	201.22 + x •18.02
Typical concentration (% w/w)	100	100	100	No information

1.3 Physico-chemical properties

The physico-chemical properties for tetraboron disodium heptaoxide, hydrate are considered herein to be described by the physico-chemical properties for the pentahydrate (CAS 12179-04-3) and the decahydrate (CAS 1303-96-4) forms of disodium tetraborate.

Disodium tetraborate anhydrous			
REACH ref Annex, §	**Property**	**Value**	**Comment/reference**
VII, 7.1	Physical state at 20°C and 101.3 kPa	White, crystalline, odourless solid	
VII, 7.2	Melting/freezing point	737°C	Cordia JA *et al.* (2003b) cited in Austria 2008
VII, 7.3	Boiling point	Not required	Melting point is >300°C
VII, 7.5	Vapour pressure	Not required	Melting point is >300°C
VII, 7.7	Water solubility (mg/L)	27.0 ± 2.7 g/L at 20 ± 0.5°C Derived from studies with the pentahydrate and decahydrate	The water solubility for disodium tetraborate anhydrous as such cannot be determined because the substance is converted into boric acid/borate upon dissolution in water: $Na_2B_4O_7 + 7\ H_2O \rightarrow 2\ NaB(OH)_4 + 2\ B(OH)_3$. The water solubility found will be the water solubility for boric acid in the presence of sodium ions. The water solubility for disodium tetraborate anhydrous is equal to an equivalent amount of disodium tetraborate pentahydrate or disodium tetraborate decahydrate. Cordia JA *et al*. (2003b and c) cited in Austria, 2008.
VII, 7.14	Granulometry	d_{50} = 210 – 850 µm	Disodium tetraborate anhydrous is sold in both granular and powder forms. The range given here describes both granular and powder products.
VII, 7.16	Dissociation constant	Boric acid is a Lewis acid (hydroxide ion acceptor) rather than a Brønsted acid (proton donator). For this purpose the formula for boric acid is best written as $B(OH)_3$. pKa = 9.0 at 25°C for boric acid in dilute solutions only (B ≤ 0.025 M). At higher boron concentrations, polynuclear complexes are formed and several dissociation/formation constants apply.	The dissociation constant for disodium tetraborate anhydrous as such cannot be determined because disodium tetraborate anhydrous is converted into boric acid/borate upon dissolution in water: $Na_2B_4O_7 + 7H_2O \rightarrow 2\ NaB(OH)_4 + 2\ B(OH)_3$. The dissociation constant found will be the dissociation constant for boric acid in the presence of sodium ions. At low boron concentrations (B ≤ 0.025 M), the following equilibrium is found: $B(OH)_3 + 2H_2O \leftrightarrow [B(OH)_4]^- + H_3O^+$ pKa = 9.0 at 25°C At these concentrations, boric acid exists as undissociated boric acid $B(OH)_3$ at pH < 5, whereas at pH > 12.5, the metaborate ion -$[B(OH)_4]^-$ becomes the main species in solution. Both species are present at pH 5-12.5 at concentrations B ≤ 0.025 M. At higher boron concentrations (B > 0.025 M), an equilibrium is formed between $B(OH)_3$, polynuclear complexes of $B_3O_3(OH)_4^-$, $B_4O_5(OH)_4^{2-}$, $B_3O_3(OH)_5^{2-}$, $B_5O_6(OH)_4^-$ and $B(OH)_4^-$. In short: $B(OH)_3 \leftrightarrow$ polynuclear anions $\leftrightarrow B(OH)_4^-$. Again at pH<5, boron is mainly present as $B(OH)_3$ and in alkaline solution at pH>12.5, boron is mainly present as $B(OH)_4^-$. At in between values (pH 5-12), polynuclear anions are found as well as $B(OH)_3$ and $B(OH)_4^-$. The dissociation constant depends on temperature, ionic strength and presence of group I metal ions (Na, K, Cs). In the presence of metal ions (e.g. Na, Mg, Ca), ion pair complexes are formed, which

Disodium tetraborate anhydrous			
			further reduce the undissociated boric acid concentration: $M^{n+} + B(OH)_4^- \leftrightarrow MB(OH)_4^{(n-1)+}$ These ion pair complexes are expected to be present in solutions of disodium tetraborate, disodium octaborate and buffered solutions of boric acid and boric oxide. Ingri N (1963) cited in Austria 2008.

Disodium tetraborate pentahydrate			
REACH ref Annex, §	**Property**	**Value**	**Comment/reference**
VII, 7.1	Physical state at 20°C and 101.3 kPa	White, crystalline, odourless solid	
VII, 7.2	Melting/freezing point	No melting point can be defined because of decomposition of the substance	When disodium tetraborate pentahydrate is heated, it gradually loses water of crystallisation, forming disodium tetraborate anhydrous, $Na_2B_4O_7$. An endothermal peak is observed at 131°C due to the loss of water. Due to a phase transition, an exothermal peak is observed at 524/527°C. The crystal form of $Na_2B_4O_7$ melts at 737°C. Cordia JA *et al.* (2003b) cited in Austria 2008.
VII, 7.3	Boiling point	Not required	Melting point of disodium tetraborate anhydrous is >300°C
VII, 7.5	Vapour pressure	Not required	Melting point of disodium tetraborate anhydrous is >300°C
VII, 7.7	Water solubility (mg/L)	40.06 ± 2.70 g/L at 20 ± 0.5°C 35.9 g/L at 20°C (literature value)	The difference between the determined water solubility (Cordia JA *et al*. (2003b)) and the literature value (35.9 g/L, Mellor (1980)) could be explained by the fact that the two protocol methods used in each case were different. Mellor's Comprehensive Treatise on Inorganic and Theoretical Chemistry, Volume V Boron, Part A: Boron-Oxygen Compounds, Longman London and New York, (1980), ISBN 0-582-46277-0, page 254.
VII, 7.14	Granulometry	d_{50} = 460 – 520µm	
VII, 7.16	Dissociation constant	Boric acid is a Lewis acid (hydroxide ion acceptor) rather than a Brønsted acid (proton donator). For this purpose, the formula for boric acid is best written as $B(OH)_3$. pKa = 9.0 at 25°C for boric acid in dilute solutions only (B ≤	The dissociation constant for disodium tetraborate pentahydrate as such cannot be determined because disodium tetraborate pentahydrate is converted into boric acid/borate upon dissolution in water: $Na_2B_4O_7{\cdot}5H_2O + 2H_2O \rightarrow 2\ NaB(OH)_4 + 2\ B(OH)_3$. The dissociation constant found will be the dissociation constant for boric acid in the presence of sodium ions. At low boron concentrations (B ≤ 0.025 M), the following equilibrium is found: $B(OH)_3 + 2H_2O \leftrightarrow [B(OH)_4]^- + H_3O^+$ pKa = 9.0 at 25°C At these concentrations, boric acid exists as undissociated boric acid $B(OH)_3$ at pH < 5,

Disodium tetraborate pentahydrate			
		0.025 M). At higher boron concentrations, polynuclear complexes are formed and several dissociation/formation constants apply.	whereas at pH > 12.5, the metaborate ion -$[B(OH)_4]^-$ becomes the main species in solution. Both species are present at pH 5-12.5 at concentrations B ≤ 0.025 M. At higher boron concentrations (B > 0.025 M), an equilibrium is formed between $B(OH)_3$, polynuclear complexes of $B_3O_3(OH)_4^-$, $B_4O_5(OH)_4^{2-}$, $B_3O_3(OH)_5^{2-}$, $B_5O_6(OH)_4^-$ and $B(OH)_4^-$. In short: $B(OH)_3$ ↔ polynuclear anions ↔ $B(OH)_4^-$. Again at pH<5, boron is mainly present as $B(OH)_3$ and in alkaline solution at pH>12.5, boron is mainly present as $B(OH)_4^-$. At in between values (pH 5-12), polynuclear anions are found as well as $B(OH)_3$ and $B(OH)_4^-$. The dissociation constant depends on temperature, ionic strength and presence of group I metal ions (Na, K, Cs). In the presence of metal ions (e.g. Na, Mg, Ca), ion pair complexes are formed, which further reduce the undissociated boric acid concentration: $M^{n+} + B(OH)_4^- \leftrightarrow MB(OH)_4^{(n-1)+}$ These ion pair complexes are expected to be present in solutions of disodium tetraborate, disodium octaborate and buffered solutions of boric acid and boric oxide. Ingri N (1963) cited in Austria 2008.

Disodium tetraborate decahydrate			
REACH ref Annex, §	**Property**	**Value**	**Comment/reference**
VII, 7.1	Physical state at 20°C and 101.3 kPa	White, crystalline, odourless solid	
VII, 7.2	Melting/freezing point	No melting point detected below 1000°C	Cordia JA (2003c) cited in Austria 2008
VII, 7.3	Boiling point	Not required	Melting point of disodium tetraborate anhydrous is >300°C
VII, 7.5	Vapour pressure	Not required	Melting point of disodium tetraborate anhydrous is >300°C
VII, 7.7	Water solubility (mg/L)	49.74 ± 3.63 g/L at 20 ± 0.5°C 47.0 g/L at 20°C (literature value)	The difference between the determined water solubility (Cordia JA (2003c) cited in Austria, 2008) and the literature value (47.0 g/L, Mellor (1980) cited in Austria 2008) could be explained by the fact that the two protocol methods used in each case were different. Mellor's Comprehensive Treatise on Inorganic and Theoretical Chemistry, Volume V Boron, Part A: Boron-Oxygen Compounds, Longman London and New York, (1980), ISBN 0-582-46277-0, page 254.
VII, 7.8	Partition coefficient n-octanol/water (log value)	-1.53 ± 0.05 (22 ± 1°C)	Although not required as this is an inorganic substance, an end point has been derived in Cordia JA (2003c) Cited in Austria 2008

Disodium tetraborate decahydrate			
VII, 7.14	Granulometry	d_{50} = 90 – 400µm	Disodium tetraborate decahydrate is sold in both granular and powder forms. The range given here describes both granular and powder products.
VII, 7.16	Dissociation constant	Boric acid is a Lewis acid (hydroxide ion acceptor) rather than a Brønsted acid (proton donator). For this purpose the formula for boric acid is best written as $B(OH)_3$. pKa = 9.0 at 25 °C for boric acid in dilute solutions only (B ≤ 0.025 M). At higher boron concentrations, polynuclear complexes are formed and several dissociation/formation constants apply.	The dissociation constant for disodium tetraborate decahydrate as such cannot be determined because disodium tetraborate decahydrate is converted into boric acid/borate upon dissolution in water: $Na_2B_4O_7 \cdot 10H_2O \rightarrow 2\ NaB(OH)_4 + 2\ B(OH)_3 + 3H_2O$. The dissociation constant found will be the dissociation constant for boric acid in the presence of sodium ions. At low boron concentrations (B ≤ 0.025 M), the following equilibrium is found: $B(OH)_3 + 2H_2O \leftrightarrow [B(OH)_4]^- + H_3O^+$ pKa = 9.0 at 25°C At these concentrations, boric acid exists as undissociated boric acid $B(OH)_3$ at pH < 5, whereas at pH > 12.5, the metaborate ion $-[B(OH)_4]^-$ becomes the main species in solution. Both species are present at pH 5-12.5 at concentrations B ≤ 0.025 M. At higher boron concentrations (B > 0.025 M), an equilibrium is formed between $B(OH)_3$, polynuclear complexes of $B_3O_3(OH)_4^-$, $B_4O_5(OH)_4^{2-}$, $B_3O_3(OH)_5^{2-}$, $B_5O_6(OH)_4^-$ and $B(OH)_4^-$. In short: $B(OH)_3 \leftrightarrow$ polynuclear anions $\leftrightarrow B(OH)_4^-$. Again at pH<5, boron is mainly present as $B(OH)_3$ and in alkaline solution at pH>12.5, boron is mainly present as $B(OH)_4^-$. At in between values (pH 5-12), polynuclear anions are found as well as $B(OH)_3$ and $B(OH)_4^-$. The dissociation constant depends on temperature, ionic strength and presence of group I metal ions (Na, K, Cs). In the presence of metal ions (e.g. Na, Mg, Ca), ion pair complexes are formed, which further reduce the undissociated boric acid concentration: $M^{n+} + B(OH)_4^- \leftrightarrow MB(OH)_4^{(n-1)+}$ These ion pair complexes are expected to be present in solutions of disodium tetraborate, disodium octaborate and buffered solutions of boric acid and boric oxide. Ingri N (1963) cited in Austria 2008.

2 HARMONISED CLASSIFICATION AND LABELLING

2.1 Classification in Annex VI of Regulation (EC) No 1272/2008

Disodium tetraborate anhydrous has index number 005-011-00-4 in Annex VI, part 3, Tables 3.1 and 3.2 of Regulation (EC) No 1272/2008 amended by Regulation (EC) No 790/2009.

The classification of disodium tetraborate (anhydrous, pentahydrate and decahydrate forms) and tetraboron disodium heptaoxide, hydrate according to Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 as amended by Regulation (EC) No 790/2009 is:

Toxic for reproduction, Repr. Cat 2, R60-61.

See Table 2.1 for further details and specific concentration limits.

Table 2.1: Classification of disodium tetraborates according to Annex VI, part 3, Table 3.2 of Regulation (EC) No. 1272/2008 amended by Regulation (EC) No 790/2009

Substance	CAS no	Index no	Classification	Concentration limits
Disodium tetraborate, anhydrous	1330-43-4	005-011-00-4	Repr. Cat 2, R60-61	Repr. Cat 2, R60-61 C≥4.5%
Disodium tetraborate, pentahydrate	12179-04-3	005-011-02-9	Repr. Cat 2, R60-61	Repr. Cat 2, R60-61 C≥6.5%
Disodium tetraborate, decahydrate	1303-96-4	005-011-01-1	Repr. Cat 2, R60-61	Repr. Cat 2, R60-61 C≥8.5%
Tetraboron disodium heptaoxide, hydrate	12267-73-1	005-011-00-4	Repr. Cat 2, R60-61	Repr. Cat 2, R60-61 C≥4.5%
Key: Repr. Cat 2: Toxic for reproduction in category 2 R60-61: May impair fertility. May cause harm to the unborn child				

The harmonised classification of disodium tetraborate (anhydrous, pentahydrate and decahydrate forms) and tetraboron disodium heptaoxide, hydrate according to Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008, as amended by Regulation (EC) No 790/2009, is:

Toxic to reproduction, Repr.1B, H360FD.

See Table 2.2 for further details and specific concentration limits.

Table 2.2: Classification of disodium tetraborates according to Annex VI, part 3, Table 3.1 of Regulation (EC) No. 1272/2008 amended by Regulation (EC) No 790/2009

Substance	CAS no	Classification		Labelling		Specific Conc. Limits M-factors
		Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(S)	Hazard statement Code(s)	
Disodium tetraborate, anhydrous	1330-43-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD	Repr. 1B; H360FD: C≥4.5%
Disodium tetraborate, pentahydrate	12179-04-3	Repr. 1B	H360FD	GHS08 Dgr	H360FD	Repr. 1B; H360FD: C≥6.5%
Disodium tetraborate, decahydrate	1303-96-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD	Repr. 1B; H360FD: C≥8.5%
Tetraboron disodium heptaoxide, hydrate	12267-73-1	Repr. 1B	H360FD	GHS08 Dgr	H360FD	Repr. 1B; H360FD: C≥4.5%
Key: Repr.1B: Toxic to reproduction; H360-FD: May damage fertility. May damage the unborn child; GHS08: Health hazard; Dgr: Danger						

3 ENVIRONMENTAL FATE PROPERTIES

Not relevant for this dossier

4 HUMAN HEALTH HAZARD ASSESSMENT

Information on hazard to human health relevant for the assessment as to whether disodium tetraborate (anhydrous, pentahydrate and decahydrate forms) and tetraboron disodium heptaoxide, hydrate meet criteria of Article 57 of the REACH-Regulation is provided in section 2 of this report (classification information).

5 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

Not relevant for this dossier

6 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for this dossier

7 PBT, VPVB AND EQUIVALENT LEVEL OF CONCERN ASSESSMENT

Not relevant for this dossier

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

Information on use and exposure is based on data from the transitional Annex XV dossier for disodium tetraborate anhydrous (Austria, 2008) and the report from RPA (2008) on Assessment of the risk to consumers from borates and the impact of potential restrictions on their marketing and use. Information is supplemented by more recent data obtained from USGS (USGS, 2008).

The term tetraborates covers the disodium tretraborates, anhydrous, pentahydrate and decahydrate, whereas the term “borates” is wider and includes e.g. boric acid and perborates.

According to IMA-Europe (2010), the hydrated forms of disodium tetraborate are identified by the CAS numbers for the pentahydrate form (12179-04-3) and the decahydrate form (1303-96-4) whereas the CAS number (12267-73-1) covering all the hydrates of disodium tetraborates are not used by the borate industry. Therefore, information in this section of the dossier includes all the hydrates of disodium tetraborate.

1 INFORMATION ON MANUFACTURING, IMPORT AND EXPORT

1.1 Manufacturing sites

No manufacture of tetraborates takes place within the EU. The only manufacturing of borates is reported to take place in Larderello, Italy, where boric acid is produced from geothermal springs. However, the contribution to the world’s production of borates is insignificant.

Two facilities within EU: Borax Francais S.A.A. in Coudekerque, France, and Società Chimica Larderello in Ravenna, Italy, are refining imported tetraborates to remove trace levels of impurities. Also, they manufacture other borates from the imported tetraborates.

The oldest known form of boron is the disodium tetraborate decahydrate. It is a naturally occurring mineral salt mined commercially under the name tincal. The main commercial active deposits of boron are in Turkey and the USA with smaller deposits in South America, Russia and China. The Turkish industry is dominated by Eti Mine Works, which has mines at several locations in Turkey. The US industry is dominated by Rio Tinto Borax with mining at Boron, California (RPA, 2008).

The hydrated forms (penta and decahydrates) of sodium tetraborate are manufactured by dissolving the sodium borate minerals in hot liquid followed by recrystallising. Also production from brine pumped from salt layers and refined is taking place (USGS, 2008). The anhydrous form is produced from the hydrates.

1.2 Manufacturing volumes

In 2008, the total world production of boron was 4.1 million tonnes, an increase of approx. 7% from 2007 (excludes the US production for which data were withhold) (USGS, 2008). The latest disclosed volume for US production was 1.15 million tonnes in 2005 and presuming a stable production size for the US, the global boron production is at a current level of over five million tonnes per annum (USGS, 2008).

According to Eti Maden (2009) representing the Turkish boron-mining industry, the global boron market grew significantly in 2008 compared to the previous year. The demand for boron products increased in traditional markets as well as developing economies compared to 2007. The increase in demand was slow in traditional markets such as USA and Western Europe but high in terms of annual rate, in the Eastern European and the Asian markets. It is estimated that global boron demand in 2008 increased by approx. 8% from 2007.

1.3 Import and export volumes

Tetraborates are not mined within the EU but imported as raw or refined materials or in the form of finished products. In the EU, imports and distribution of boric acid and tetraborates are done by three companies: Eti Mine Works, Rio Tinto Minerals and Società Chimica Larderello. Together the three companies are responsible for more than 95% of the EU supply of these substances (Austria, 2008).

Data from the Harmonized Commodity Description and Coding System (HS) indicates the size of the import to and the export of borates from the EU countries (see Table 1). However, such trade data may be connected with considerable uncertainties. Also, it should be noted that the quantities data in Table 1 cover a range of borates (from raw materials and refined products) and thus are not necessarily expressed on the same basis (ore, B_2O_3 or boron). The data indicate an annual import of borates to the EU of 0.6 million tonnes borates covering tetraborates, perborates and other borates (RPA, 2008). About 59% of the import comes from Turkey and 20% comes from the USA. The remaining part is from elsewhere outside the EU or trade between EU member states which is included in the statistics. The annual quantity of exports from individual EU countries is 0.2 million tonnes corresponding to 37% of the import. Part of the exports from the EU countries is to nearby countries, i.e. other EU countries.

Table 1 Import and export quantities based on data for 2007 covering borates (raw materials and refined products) (RPA, 2008)

Country	Total import (tonnes per year)	Total export (tonnes per year)
Top 5 Importers*	416,163	210,029
EU-27	615,323	227,293

*Top 5 Importers are Belgium, Germany, Netherlands, Spain and France

2 INFORMATION ON EXPOSURE

Uses of tetraborates as wood preservative are regulated under Directive 98/8/EC concerning the placing of biocidal products on the market and the exposure from this use is not covered in this report. Furthermore, exposure from uses covered by the Council Directive 76/768/EEC concerning cosmetic products is not included here.

2.1 Uses

Tetraborates have a multitude of different properties and are used in a variety of different products and processes. The main industrial uses include glass, ceramics, detergents, wood treatment, insulation fibreglass and various unspecified uses such as production of other borate compounds. An overview of applications of tetraborates is shown in Table 2.

Table 2 Overview of application of tetraborates (from Austria, 2008). Applications in *Italic* are from the 'Final list of borates uses' prepared by IMA-Europe aisbl (IMA-Europe, 2009a)

	Sodium tetraborate anhydrous	**Sodium tetraborate pentahydrate**	**Sodium tetraborate decahydrate**
Glass and glass fibres			
Insulation & Textile Fiber Glass		X	*X*
Light bulbs		*X*	
Photovoltaic solar panels	*X*	*X*	*X*
Borosilicate Glass	X	X	*X*
Refractories	X	*X*	X
Ceramics			
Glaze and enamels	X	X	*X*
Frits	X	*X*	*X*
Detergents and cleaners			
Soaps	*X*	*X*	X Powder hand soap
Liquid/laundry detergents	*X*	X Stabilizes enzymes	X
Bleach	*X*	X Sodium perborate precursor	*X*
Cleaning products	*X*	X	*X*
Additive (e.g. hand, cleaners, polishes waxes and industrial cleaning compounds)	*X*	X	X
Personal care products			
Cosmetics		*X*	X Lotions, creams & ointments
Toiletries			X
Pharmaceuticals			X
Industrial fluids			
Metal working fluids		X	
Lubricants		X Also used in dry powdered lubricants	X Also used in dry powdered lubricants
Water treatment chemicals		X	X
Anti-freeze (engine coolant)		*X*	*X*
Wire drawing-dipping bath & lubricants		*X*	
Brake fluids		*X*	*X*
Hardening salts		*X*	
Metallurgy			
Steel and non-ferrous metal production (flux agent)	X	X	X

	Sodium tetraborate anhydrous	**Sodium tetraborate pentahydrate**	**Sodium tetraborate decahydrate**
Galvanizing			*X*
Non-ferro smelting and precious metal refining		*X*	
Alloys	*X*		
Slag formation agent		*X*	
Metal surface refining			*X*
Adhesives			
Starch adhesive formulation (corrugated paper and paperboard)		X	X
Casein and dextrin based adhesive		X	X
Cardboard / glue			*X*
Cobalt carboxylate used in tyres+rubbers			*X*
Flame retardant			
Cellulose insulation	X	X	X
Wood products			*X*
Cotton batting in mattresses/futons			*X*
Paper		*X*	*X*
Other	*X*		*X*
Biocides			
Wood preservative		X	X
Non-professional remedial products		X	
Professional remedial products			X
Agriculture			
Fertilizers		X	X
Other			
Abrasives	X		
Cement		X	
Leather tanning		X	X
Photographic chemicals		X	X
Reagent chemicals	X	X	
Baltiboard (insulation board)			*X*
Production of other borates	*X*	*X*	*X*
Catalyst/inhibitor			*X*
Buffer		*X*	*X*
Buffering agent in formaldehyde resins			*X*
pH stabilizer in printing industry			*X*
Inorganic colour pigments in ceramics		*X*	
Construction materials		*X*	

	Sodium tetraborate anhydrous	**Sodium tetraborate pentahydrate**	**Sodium tetraborate decahydrate**
Manufacture of non-metallic mineral products		*X*	
Production of plastics, resins, rubbers, nylon, elastomers		*X*	

2.1.1 Use volumes

It is expected that about 20% of the global borate production is consumed by the EU. This leads to the consumption figures of the order of 1 million, 460,000 and 140,000 t/a expressed as ore, B_2O_3 and B, respectively (RPA, 2008).

The use volume of tetraborates is 166,346 tonnes calculated as B_2O_3 and based on data for 2007. The use volume of all the tetraborates are represented by 5.0% of the anhydrous form, 90.1% of the pentahydrate form and 4.9% of the decahydrate form (Austria, 2008).

Table 3 Overview of EU use volumes for the year 2007 (Austria, 2008)

Substance	**Quantity of substance (tonnes)**	**Quantity given as B_2O_3 (tonnes)**	**Part of total sodium tetraborates (%)**
Sodium tetraborate, anhydrous	12,151	8,384	5.0
Sodium tetraborate, pentahydrate	305,933	149,907	90.1
Sodium tetraborate, decahydrate	22,069	8,055	4.9
Total	340,153	166,346	100

Table 4 below shows the division of tetraborates by the end use application based on data for 2007 (Austria, 2008). The table also includes the perborates, which are the main borate compounds applied in detergency products. Tetraborates are used as raw material in manufacturing of perborates.

The group of “various chemical effects” corresponding to 5% includes miscellaneous unspecified uses as well as minor uses such as abrasives, cement, leather tanning, photographic chemicals and reagent chemicals.

Table 4 Overview of end use application of tetraborates (including perborates) (Austria, 2008)

End use of tetraborates	**Relative part of use (%)**
Glass and ceramics	65
Detergency	23
Various chemical effects	5
Biological (agriculture, wood preservation)	4
Flame retardancy	1
Industrial fluids	1
Metallurgy	1

Data on the 2008 use volume provided by the European Borates Association, EBA, are shown in Table 5. The data indicate that the use volume of the tetraborates was 340,000 tonnes in 2007 and it increased to 373,000 tonnes in 2008 (IMA-Europe, 2009b).

EBA estimates that 80% of the borates end up in consumer products, 5% in professional products and 15% in industrial products and applications (RPA, 2008).

Table 5 Overview of uses and associated volume for the reference year 2008 (IMA-Europe, 2009b)

Uses	**Sodium tetraborate anhydrous (tonnes)**	**Sodium tetraborate pentahydrate (tonnes)**	**Sodium tetraborate decahydrate (tonnes)**
Detergents and cleaners (soaps, liquid/laundry detergents, bleach, cleaning products)	0	68,114	849
Pharmaceuticals	0	0	55
Glass, glass fibres & refractories[1]	12,471	188,098	723
Ceramics (glaze, enamels, frits)[1]	4,155	47,961	14
Metallurgy[1] (steel & non-ferrous metal production, metal surface refining)	588	1,027	753
Industrial fluids[2] (metal working fluids, anti-freeze, lubricants, brake fluids, water treatment chemicals)	0	3,357	734
Adhesives/glue (starch adhesives formulation, casein & dextrin based adhesives, cardboard glue)	0	108	10,044
Flame retardants (cellulose insulation, wood products, papers, cotton batting in mattresses/futons)	61	5,871	2,482
Agriculture (fertilizer)	336	14,324	1,159
Chemicals and buffer[3]	0	5,778	2,000
Other Uses	264	1,055	499
Total volume (tonnes)	17,875	335,694	19,312
Total volume (tonnes, expressed as B_2O_3)	12,334	164,490	7,049

[1] sodium tetraborates used as intermediates

[2] sodium tetraborates used as intermediates in some applications

[3] sodium tetraborates used as intermediates in the synthesis of other chemicals

2.1.2 Glass and glass fibres

The function of borates in glass is to lower the melt temperatures, to inhibit devitrification, to increase the mechanical strength and to increase resistance to thermal shock, water and chemicals in the final product. Borosilicate glass is used in heat-resistant glass applications such as halogen light bulbs, cookware and Pyrex®.

Borates are used for the production of insulation and textile fibreglass used in e.g. circuit boards and surfboards. Borates act as a flux and lower the melting temperature, control the relationship between temperature, viscosity and surface tension to optimise the glass fiberization. In insulation fibreglass, borates impact air trapping to prevent heat loss and absorb infrared radiation adding to the insulation performance.

The amount of tetraborates used in the production of glass is approx. 47,000 tonnes per year (RPA, 2008). The amount covers the full range of borates used in glass (boric acid, boric oxide, borax pentahydrate, etc.). No information was available on how the quantities are expressed (substance, B_2O_3, or boron).

2.1.3 Ceramics

Borates are used in ceramic glazes and enamels. The function of the tetraborates is to initiate glass formation, reduce glass viscosity to help forming a smooth surface, reduce thermal expansion to facilitate a good fit between the glaze or enamel with the substrate. The use of borates in the formulations of glazes and enamels allows a wider range of clays to be used, increasing productivity and decreasing energy use. Ceramic frits are borate containing chemicals used as a flux in glaze and clay formulas, containing e.g. silica oxide, calcium oxide, sodium oxide and borates that are melted together and cooled rapidly and then ground to a fine powder (www.continentalclay.com).

2.1.4 Detergents

Sodium tetraborates are used in soaps, in liquid laundry detergents and as additive in cleaning products such as hand cleaners, polishes waxes and industrial cleaning products. The use of tetraborates in powdered detergents serves to enhance the cleaning effect. In liquid products, the tetraborates are used to provide alkaline buffering, soften water and boost surfactant performance in addition to stabilizing enzymes. Furthermore perborates are used in laundry detergents as bleaching agent.

Total consumption of boric acid and tetraborate (decahydrate) in liquid detergents is estimated by HERA (2005) (cited in RPA, 2008) to be 930 tonnes per year given (calculated as boron).

2.1.5 Personal care products

In personal care products, the tetraborates are used to control growth of bacteria and fungi. The personal care products are cosmetic creams, skin lotions, hair shampoos, dyes and gels, eye drops, bath salts and denture cleaners.

2.1.6 Metallurgy

Tetraborates are used in the production of steel and non-ferrous metals, alloys, rare earth magnets and amorphous metals. The tetraborates are used as flux agent during the smelting operation to dissolve metallic oxide impurities so that they can be removed with the slag in the steel and non-ferrous metal production. The detergency properties of borates also help to remove oxides, grease and foreign matter from the metal surface (Austria, 2008).

2.1.7 Industrial fluids

Tetraborates are used in metal working fluids, lubricants and in water treatment chemicals where they act as corrosion inhibitor and buffer. Other functions are freezing point reduction, boiling point elevation, lubrication, stabilization of thermal oxidation, prevention of sludge formation and reduction in moisture sensitivity (RPA, 2008).

2.1.8 Adhesives

In adhesives based on natural polymeric products such as maize, potato, wheat etc., the tetraborates are added to increase the viscosity, for a quicker tack and better fluid properties.

The function as adhesive is used in the production of corrugated paper and paperboard.

2.1.9 Flame retardants

Borates are able to suppress a fire by melting and covering the flammable material in a layer of char, excluding the oxygen from the flame. Cellulose from wood, cotton and other plant-derived materials is widely used as insulation material but it is inherently flammable in many of its forms. Tetraborates are added to cellulose insulation material to improve flame retardancy of the cellulose.

The function as flame retardant in corrugated paper and paperboards, other pressed boards such as fibreboards, fabrics and mattresses is mostly provided by the use of boric acid (Austria, 2008).

2.1.10 Biocides

The tetraborates are used as a protection against wood destroying organisms. The function is provided by treating solid wood, engineered wood composites and other interior building materials such as studs, plywood, joist and rafters.

2.1.11 Agriculture

As boron is an essential micronutrient to plants, the borates are used as fertilisers in order to enhance crop yields.

2.1.12 Other uses

Other uses of tetraborates are mostly miscellaneous unspecified and minor uses such as abrasives, cement, leather tanning, photographic chemicals and reagent chemicals.

Borates are furthermore used in fireworks to give a green colour and as igniters for various devices including airbags. Borates are also used in plasticizers including “slime” products for use as kids play dough.

Other uses are included in Table 2 as specified in the Transitional Annex XV dossier on disodium tetraborates anhydrous (Austria, 2008) and by the European boron industry (IMA-Europe, 2009a).

2.2 Estimated trends in uses

The overall demand for borates has declined in Europe over the past 5 years as a result of the decreasing demand for use of perborates as bleach in detergents. During the same time, the demand for borates for use in agriculture and for vitreous application such as insulation fibre glass, borosilicate glass and frits and ceramics has increased (Austria, 2008). Comparing data on market shares for 2005 with data for 2007, a decrease in use for detergency and cleaning of 7% is seen (from 26% in 2005 to 19% in 2007). In the same period the market share for the application of borates in glass and ceramics has increased by 4% and the use in agricultural applications increased by 2%. For the remaining uses, only small changes were seen (Austria, 2008).

According to EBA the demand for borates is expected to increase by 2-4% per year over the next five years. The forecast is based on an increasing demand for insulation products to meet climate change goals and ceramic frits and glaze for the general upgrading of housing stock throughout the EU. In addition, the borosilicate industry is expanding with substantial increases due to demands for pharmaceutical glass, tubing for heat collection in solar panels and e-glass (automobile and infrastructure). Use in agriculture is also expected to increase substantially. End-uses such as timber preservation, metallurgy, flame retardant and cleaning are forecasted to grow modestly (RPA, 2008).

The outlook made by USGS (2008) for boron in general is pointing to an increasing demand for borates within fire retardants as well as in production in flat glass, fibreglass and borosilicate glass. USGS also addresses the rapid developing technology using borates such as zinc borates in nano-form. The technology has been widely used in the fields as aerospace, home electrical appliances and in the light industry where improved fire resistance is required.

2.3 Exposure

In the transitional Annex XV dossier on disodium tetraborate, common occupational sources of exposure across different industries are considered e.g. discharging, loading, unloading, packaging of borates into bags, etc. Exposure via consumer products and indirectly exposure via the environment of humans are also estimated in the transitional Annex XV dossier (Austria, 2008).

Exposure of the environment is not considered in this dossier.

2.3.1 Occupational exposure

Disodium tetraborates are solids at room temperature. In the industry, they are either used as bulk materials or solutions. As the tetraborates are mostly handled as solids (powder), the predominant route of occupational exposure is inhalation of dust from handling. Dermal exposure may also occur from direct contact with the solid or with liquids containing tetraborates. Normally, oral exposure is not considered a significant route of exposure in working situations.

Occupational exposure limits (OEL) are not established at community level but several EU countries have their own OELs. Table 6 shows an overview of the OELs established by EU countries. The OELs are given as the Time Weighted Average (TWA) for a working day of 8 hours.

Table 6 OELs established by EU countries (Austria, 2008)

Country/ organisation (year)	8-hr TWA OEL (mg/m^3)		
	Sodium tetraborate anhydrous	**Sodium tetraborate pentahydrate**	**Sodium tetraborate decahydrate**
Belgium (2007)	2	2	2
Denmark (2008)	1	1	2
France (2008)	1		5
Germany - AGS (2007)	2.1	3	4
Greece (2001)	10		10
Ireland (2007)	1		5
Portugal (2004)	1		5
Spain - INSHT (2006)	1	1	5
Sweden (2007)			2
UK - HSE (2005)	1	1	5

Exposure levels from the practical handling of the substance through raw material handling and industrial and professional handling by downstream users have been calculated with EASE. RMMs were identified for each activity but the effectiveness was not determined. Local exhaust ventilation (LEV) was considered for inhalation, if present, but gloves were not considered for dermal exposure.

Table 7 summarises the exposure levels for reasonable worst case as the highest EASE value and for the typical value as the midpoint of the EASE range. For each of the addressed activities, the relevant industry is given in the table.

Table 7 Summary of occupational exposure levels given as reasonable worst case (RWC) and typical values for the inhalation and dermal route calculated by use of EASE (Austria, 2008)

Tasks		**Inhalation exposure**		**Dermal exposure**	
		EASE Exposure to disodium tetraborate (mg/m^3)	**Equivalent to boron for disodium tetraborate anhydrous (mg B/m^3)**	**EASE Exposure to disodium tetraborate (mg/day)**	**Equivalent to boron for disodium tetraborate anhydrous (mg B/day)**
Discharging borates from ships Relevant for M/I only	RWC Typical	50 27.5	10.75 5.91	960 528	206 114
Discharging borates from big bags (800-1200 kg) Relevant for glass, glass fibre, cellulose insulation, chemical synthesis, metallurgy, soap and detergents, fertilizers and the industrial fluids industries	RWC Typical	5 3.5	1.08 0.75	960 528	206 114
Loading/unloading borates into/from road tankers Relevant for M/I, distributors and DU such as glass, glass fibre, chemical synthesis, ceramics, industrial fluids, soap and detergents, metallurgy, fertilizers and other industries	RWC Typical	3.5 2	0.75 0.42	528 96	114 21
Packaging into big bags (1000-1500 kg) Relevant for M/I only	RWC Typical	5 3.5	1.08 0.75	960 96	206 21
Packaging into 25 kg bags/Discharging 25 kg bags or similar Relevant for glass, glass fibre, industrial fluids, metallurgy, refractory, industrial cleaning, ceramic frits, chemical synthesis, fertilizers, soap and detergents, adhesives and other industries	RWC Typical	4.5 3.5	0.97 0.75	864 528	186 114
Packaging liquid products Relevant for industrial fluids, buffer, chemical synthesis, additives in phenol-formaldehyde resins, corrosion inhibitors, soap and detergents and metal working fluids industries	RWC Typical	- -	- -	52 29	11 6
Cleaning, sweeping	RWC Typical	45 10	9.7 1.75	864 192	151 34
Cleaning, vacuuming	RWC Typical	0.5 0.1	0.11 0.02	86 9.6	19 2.1

Key: RWC: Reasonable worst case; B: Boron

2.3.2 Consumer exposure

Exposure to tetraborates from consumer products can arise from the substances themselves, preparations or articles containing the substance.

In the report by RPA (2008), the products are grouped depending on type (substance, preparation, article) and degree of consumer exposure (potential for significant exposure, potential for possible exposure and minimal potential for exposure). The products with a significant potential for exposure to borates include fertilizers, soap/detergents and other chemical products.

In the transitional Annex XV dossier on disodium tetraborates, the different exposure routes are described for relevant product groups and exposure is estimated based on literature information (Austria, 2008).

2.3.2.1 Glass and glass fibres

Glass wool consists of silicates but may contain smaller amounts of other elements including boron. Content of boron in glass wool may be in the range from 5 to 12% as B_2O_3 (1.5-3.6% as B) (Austria, 2008).

The level of respirable fibres in residential buildings, offices and institutions is normally very low (<0.005 fiber/cm^3). Therefore, the consumer exposure to tetraborates from glass wool would only occur during removal of glass wool insulation and installation as part of a do-it-yourself home improvement project. Also, just after installation or repair, the concentration of respirable fibres may increase. The most critical concentration of respirable fibres during handling of glass wool was reported by Jensen, 2007 (cited in Austria, 2008) to be 0.05-1 fiber/cm^3 resulting in a maximum daily exposure of 0.03-0.06 mg boron based on a total working day of 8 hours.

The migration of boron into water, acetic acid, ethanol and olive oil was studied in borosilicate glass, soda lime silica glass and lead crystal glass. The results from the study showed that in most cases boron was not detected (detection limit 0.03 ppm). Only one sample showed migration of boron from lead crystal glass to water resulting in a value of 0.06 ppm (Austria, 2008).

2.3.2.2 Ceramics

The migration of metals including boron has been studied from glazed ceramic ware. The reasonable worst case expose value of boron from glazed ceramic ware was estimated to be 0.116 mg B/day with a typical value of 0.017 mg B/day (Austria, 2008).

2.3.2.3 Detergents

The levels of tetraborates in household cleaning products are low (<1% boron). Primary exposure occurs trough skin contact. Consumer inhalation from liquid detergents is not expected as the tetraborates have negligible volatility at room temperature and no spray products exist according to HERA (2005) (cited in Austria, 2008). No information is given for inhalation from consumer handling of powdered detergents.

Dermal exposure of consumers from liquid detergents occurs by hand laundry washing or laundry pretreatment. The exposures for these two scenarios have been calculated by HERA (2005) (cited in Austria, 2008) to be 3.44 µgB/person/day and 102 µgB/person/day, respectively, for worst case dermal exposure. Occasional misuse of liquid detergents for hand dishwashing may result in skin exposure. The exposure in this worst case scenario has been estimated to be 2.17 µg B/person/day (Austria, 2008).

2.3.2.4 Personal care products

No information on consumer exposure is available for the use of tetraborates in personal care products.

2.3.2.5 Flame retardants

Cellulose insulation is usually applied by professionals. Although it is unlikely that consumers would apply such insulation themselves, laying such insulation into the floors and attics could be undertaken by consumers as bags of loose insulation designed for do-it-yourself use are available. Exposure to the borates through spreading the loose insulation by hand (without gloves) and/or through inhaling/ingesting particles in the air (particularly if working in confined areas in the roof space) may undoubtedly occur. However, this is not a regular or routine exercise and this kind of consumer exposure will be limited to occasional projects (RPA, 2008). The draft Annex XV dossier on boric acid prepared by Germany (2009) cites a study on personal dust monitoring in construction work, manual installation of cellulose insulation. Based on a documented respirable particle concentration of 2.75 mg/m^3, an inhalation exposure of 0.24 mg B/person/day from boric acid can be calculated. Another 0.15 mg B/person/day derives from disodium borate decahydrate. A boric acid concentration of 5% and another 5% of disodium borate decahydrate, 0.3 days exposure time and an inhalation rate of 33 m^3/day were used for calculation (Germany, 2009).

2.3.2.6 Agriculture

Fertilizers available for consumer use generally contain 0.02% boron as a concentrate solution or granules. Inhalation exposure from pouring the dilute solution (approx. 0.2 ppm of boron) in the garden is not expected. No information is available on inhalation exposure from handling the fertilizer in the granules form.

Dermal exposure is only expected from spill on the hands during use. A reasonable worst case dermal exposure from fertilizers is calculated to be 2 µg B/person/day of use and a typical value would be 0.2 µg B/person/day of use (Austria, 2008).

2.3.2.7 Other uses

Persons taking mineral supplements may have a daily boron intake of 1-10 mg B/person/day (Austria, 2008).

Exposure of consumers to borates in starch adhesives has been calculated by RPA (2008). The exposure scenario is set up for children playing with cardboard tubes (from kitchen/toilet rolls). Although exposure from handling would be expected to be minimal, chewing and/or eating a piece of tube would be a possibility. Taking 5% borates in the adhesive and 2% adhesives in the cardboard and eating 2 g of cardboard/adhesive would result in an uptake of: 2 g x 0.05 x 0.02 = 2 mg of borate (typically borax decahydrate) = 0.23 mg boron. This is well below the tolerable upper intake level of 3 mg B/day recommended by EFSA ((2004) cited in RPA) for toddlers (aged 1-3).

2.3.3 Human exposure via the environment

Boron enters the environment mainly through the weathering of rocks, boric acid volatilization from seawater and volcanic activities, but to a lesser extent also from anthropogenic sources. Anthropogenic sources include agriculture, refuse, fuel and wood burning, power generation using coal and oil, glass product industry, use of borates by consumers and industry, boron processing industry, leaching of treated wood/paper and sewage/sludge disposal (Austria, 2008).

Boron does not appear to be present in ambient air at significant levels (Sprague, 1972 cited in Austria, 2008). Levels of boron concentration in air have been estimated to be <0.5–80 ng/m^3 with a typical value of 20 ng/m^3. Assuming a respiration volume of 20 m^3 per day, a respiratory exposure of 400 ng/day can be calculated.

Boron represents an essential plant micronutrient with a total concentration of 10 mg B/kg in the earth's crust. Data on boron concentration in soils in the EU were collected and the concentration in topsoils ranged between 0.5 and 14.2 mg B/kg. An EU-PEC value of 5 mg B/kg was derived to represent the EU level of boron in soil. Incidental intake of soil of 20 mg soil/person/day results in an intake of 0.1 µg B/person/day (Austria, 2008).

Boron can be released into ground and surface water through weathering processes and to a much smaller extent from anthropogenic sources. Drinking water is derived from ground water or from surface water sources. A range of different levels of boron in drinking water is reported to be below 0.005 mg B/L and up to 5 mg B/L. A typical value of 0.4 mg B/L and a reasonable worst case of 1.0 mg B/L were estimated. The typical daily intake of boron from drinking water can be estimated to be 0.8 mg B/person/day assuming a daily intake of 2 litres per person. The reasonable worst case is estimated to be 2 mg B/person/day (Austria, 2008).

For mineral waters, boron contents of 0.75 mg/L (mean) and 4.35 mg/L (maximum) have been determined (references cited in Germany, 2009: Moore 1997, cited in BfR (2006a), BfR (2006b) and EFSA (2004)). Assuming a daily mineral water consumption of 2 litres per person, boron exposures of 1.5 mg B/person/day (mean) and 8.7 mg B/person/day (maximum) can be calculated.

The largest intake of boron comes from food. The boron uptake via food can vary significantly, due to individual nutrition behaviour and the origin of the food. The richest sources of boron are fruits, vegetables, pulses, legumes and nuts. Based on literature data, the higher mean daily dietary intake of 1.5 mg B/person/day for adult male and female is derived. Applying the TGD method (2003), the daily dietary intake is 1.94 mg B/person/day (Austria, 2008). Boron intakes in adults in the UK have been estimated by EFSA ((2004) cited in Germany, 2009) from analysis of samples from the 1994 Total Diet Study using consumption data from the 1986/87 Dietary and Nutritional Survey of British Adults as 1.5 mg B/person/day (mean) and 2.6 mg B/person/day (97.5 percentile).

The exposure from boron in house dust is considered in the draft Annex XV dossier on boric acid (Germany, 2009) as house dust represents an aggregate of boron exposure from various sources. In a representative study on settled dust in 3,282 living rooms, a median dust sink rate of 4.52 mg/m^2/day and a median boron sink rate of 0.13 µg/m^2/day were determined (Umweltbundesamt, 2001 cited in Germany, 2009). For a 10-kg child ingesting 100 mg house dust per day by hand-mouth contact a worst-case external boron exposure of 0.003 mg B/child/day can be calculated from these values. The typical case would be ingestion of 20 mg house dust per day, leading to an external boron exposure of 0.0006 mg/child/day.

The most important sources of exposure are food and drinking water. The total indirect exposure of man via the environment including dietary intake can be estimated to be typically 2.3 mg B/person/day and up to 3.94 mg B/person/day (Austria, 2008).

Table 8 below summarises the consumer exposure estimates including the exposure from consumer products and indirect exposure via the environment.

Table 8 Summary of estimates on consumer exposure levels given as reasonable worst case (RWC), typical values or as mean and maximum values

Consumer product		Estimated external exposure to humans	Unit	Route of exposure	Comments/assumptions/reference
Glass wool	RWC	0.06	mg B/person/day	Inhalation	Removal and installation of insulation, do-it-yourself work, 8 hours per day, occasionally (Austria, 2008)
Cellulose insulation	RWC	0.15	mg B/person/day	Inhalation	Manual installation of cellulose insulation, 8 hours per day, occasionally (Germany, 2009)
Detergents	RWC	0.11	mg B/person/day	Dermal	Hand laundry washing, laundry pretreatment, misuse of liquid detergent for hand dishwashing (Austria, 2008)
	Typical	0.06	mg B/person/day		
Fertilizers	RWC	0.002	mg B/person/day	Dermal	Exposure expected from spill on hands during use (Austria, 2008)
	Typical	0.0002	mg B/person/day		
Ceramic	RWC	0.116	mg B/person/day	Oral	Based on the measurement of migration into acetic acid. Use of ceramic ware for meal once a day/once a week is assumed (Austria, 2008)
	Typical	0.017	mg B/person/day		
Adhesive	RWC	0.23	mg B/person/day	Oral	Starch adhesive in cardboard, chewing and eating of 2 g by child (Germany, 2009)
Via the environment					
Ambient air	Typical	0.40	µg B/person/day	Inhalation	Typical air value of 20 ng/m^3 and a respiration volume of 20 m^3/day (Austria, 2008)
Drinking water	RWC	2.0	mg B/person/day	Oral	Daily intake of drinking water of 2 litres (Austria, 2008)
	Typical	0.8	mg B/person/day		
Mineral water	Maximum	8.7	mg B/person/day	Oral	Daily intake of mineral water of 2 litres (Germany, 2009)
	Mean	1.5	mg B/person/day		
Food	Maximum*	2.6	mg B/person/day	Oral	Intake in adults (Germany, 2009)
	Mean	1.5	mg B/person/day		
House dust	RWC	0.003	mg B/person/day	Oral	A 10 kg child ingesting 100 g house dust (Germany, 2009)
	Typical	0.0006	mg B/person/day		A 10 kg child ingesting 20 g house dust (Germany, 2009)
Soil intake	RWC	0.0001	mg B/person/day	Oral	Incidental intake of 20 mg soil (Austria, 2008)

Key: RWC: Reasonable worst case; B: Boron; * 97.5 percentile

3 INFORMATION ON ALTERNATIVES

3.1 Glass and glass fibres

The boron content has gradually been reduced from 8-10% B_2O_3 by weight to 5%. Furthermore, boron-free glass fibres are available. In the production of boron-free glass a different mix of oxides is used under different heat conditions but boron is not substituted by another additive (RPA, 2008).

The combination of the properties obtained through the addition of borates in the glass production is unique. There are no alternatives to the use of borates for the production of glass suitable for production of: Heat resistance cookware, glass panels, laboratory ware, LCD screens, solar panels, optical glass and radiation shielding glass.

By the industry, the borates for use in manufacturing of glass may be regarded as an isolated intermediate as it is manufactured with the purpose of producing another substance, i.e. glass.

3.2 Ceramic frits

There are no alternatives for use of borates in the production of ceramic frits as well as in glaze and enamel. By the industry, the borates used for producing the ceramic frits may be regarded as isolated intermediates as the ceramic frits are considered as a substance. Thus, the borates are intermediates in the production of frits.

3.3 Detergents

Tetraborate is used to produce perborate, which is used as an oxidizing and bleaching agent in detergent products (and cleaning products). Production of perborates has decreased significantly over the last ten years due to a replacement of sodium perborates by sodium percarbonates in detergent products. Percarbonates are technical suitable as alternative to the perborates in many applications. Some detergents manufacturers still apply perborates in the detergent products, either in order to minimise the risks inherent to changing the formula or because their products are sold in countries with hot and humid climate as the percarbonate have limited stability in such conditions (RPA, 2008).

The use of tetraborates to stabilize enzymes in liquid detergents is critical as no alternatives are available according to AISE (2008, cited in RPA, 2008).

3.4 Industrial fluids

Often the borates are used as a multifunctional additive in industrial fluids. This increases the demands for available alternative chemicals or alternative techniques. In general, for the uses in industrial fluids no direct alternatives exist with the same high level of performance in addition to fulfilling the demands on cost effectiveness.

According to downstream users of borates-based lubricants, the products cannot be replaced with the same level of performance and cost efficiency based on their experiences from working on finding a suitable replacement for these lubricants (RPA, 2008).

For buffering action, other buffering systems covering the same pH range are available. However, often the borates have more than one action, e.g biocidal action combined with a pH buffering action. Having these multifunctional functions, the borates may be difficult to replace to obtain same level of performance.

3.5 Flame retardant

Alternatives for the function as flame retardant are currently present. However, for the use of borates in the cellulose insulation industry, no alternatives have been identified. Cellulose from wood, cotton and most other plant-derived materials is widely used in the insulation industry, but cellulose is inherently flammable in many of its form. By use of borates in the cellulose insulation material, the flame retardancy is enhanced (Austria, 2008).

3.6 Agriculture

By definition, when a crop is boron-deficient, no alternatives to boron exist (RPA, 2008).

OTHER INFORMATION

A number of compounds related to boric acid, i.e. boric acid itself, boric oxide, sodium borate and sodium perborate are classified as toxic for reproduction in Category 2/ Repr. 1B.

It is clear from the available data and the known chemistry of borates that in aqueous solutions inorganic borate salts are likely to produce the borate ion, $B(OH)_4^-$, largely irrespective of the metal salt[4]. Thus, the toxicity of borates is largely independent of the identity of the solid state borate salts in question.

The borate ion, $B(OH)_4^-$, is the principal anion in solutions of 1:1 alkali borates. Mixtures of $B(OH)_3$ and $B(OH)_4^-$ appear to form classical buffer systems. When additional boric acid is added to borate solutions, polyborates are formed. These include the triborate ion, $B_3O_3(OH)_4^-$, the tetraborate ion, $[B_4O_5(OH)_4^{2-}]$ and the pentaborate ion, $B_5O_6(OH)_4^-$. A rapid equilibrium exists among the various polyborate species in aqueous solution (Kirk Othmar).

This dossier covers disodium tetraborate anhydrous (CAS 1330-43-4). However, since disodium tetraborate pentahydrate (CAS 12179-04-03) and disodium tetraborate decahydrate (CAS 1303-96-4) are hydrates of disodium tetraborate anhydrous, they are also addressed in this report. In aqueous solution, the latter two substances form the same substances as disodium tetraborate anhydrous. Since the presented borates differ only in their amount of water of crystallisation and contain disodium tetraborate as a compound, they can equally well be used for many applications.

[4] This anion can be produced from a number of different borate compounds, including triborates, tetraborates, pentaborates, octaborates, metaborates and perborates (Kirk Othmar)

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