Danish Ministry of the Environment
Environmental Protection Agency

Survey of Boric acid and sodium borates (borax)

Part of the LOUS review

Survey of chemical substances in consumer products No. 139, 2015

Title:

Survey of Boric acid and sodium borates (borax)

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Preface

Background and objectives

The Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) is intended as a guide for enterprises. It indicates substances of concern whose use should be reduced or eliminated completely. The first list was published in 1998 and updated versions have been published in 2000, 2004 and 2009. The latest version, LOUS 2009 (Danish EPA, 2011) includes 40 chemical substances and groups of substances which have been documented as dangerous or which have been identified as problematic based on quantitative structure activity relationship (QSAR) modelling or otherwise been considered of concern or in political focus. For inclusion in the list, substances must fulfil several specific criteria. Besides the risk of leading to serious and long-term adverse effects on health or the environment, only substances which are used in an industrial context in large quantities in Denmark, i.e. over 100 tonnes per year, are included in the list.

Over the period 2012-2015 all 40 substances and substance groups on LOUS will be surveyed. The surveys include collection of available information on the use and occurrence of the substances, internationally and in Denmark, information on environmental and health effects, on alternatives to the substances, on existing regulation, on monitoring and exposure, and information regarding ongoing activities under REACH, among others.

The main objective of this survey is to provide background for the Danish EPA's consideration regarding the need for further risk management measures. On the basis of the surveys, the Danish EPA will assess the need for any further information, regulation, substitution/phase out, classification and labelling, improved waste management or increased dissemination of information.

This survey concerns boric acid and sodium borates (borax) that are both subject to harmonised classification or registered under REACH. Thus the survey covers the substances:
Boric acid (CAS 10043-35-3);
Disodium tetraborate decahydrate (CAS 1303-96-4);
Disodium tetraborate anhydrous/pentahydrate (CAS 12179-04-3);
Disodium tetraborate, anhydrous / pentahydrate/decahydrate (CAS 1330-43-4);
Tetraboron disodium heptaoxide, hydrate (CAS 12267-73-1);
Diboron trioxide, boric oxide (CAS 1303-86-2);
Boric acid, crude natural, containing not more than 85 per cent of H3BO3 calculated on the dry weight (CAS 11113-50-1);
Orthoboric acid, sodium salt (CAS 13840-56-7);
Disodium octaborate (CAS 12008-41-2);
Disodium; boron; oxygen(2-); tetrahydrate (CAS 12280-03-4).

Boric acid and borax have been included on the LOUS list due to their classification as Repr. 1B, H360Df (May damage fertility. My damage the unborn child), and because they are marketed in quantities above 100 tonnes in Denmark.

The process

The survey has been undertaken by DHI from May 2013 to November 2014. The project participants from DHI were:

- Poul Bo Larsen, project manager
- Tina Slothuus, contributor
- Brian Svend Nielsen, contributor
- Peter Kortegaard , contributor
- Frank Leck Fotel, contributor
- Helle Buchardt Boyd, quality supervisor
- Jens Tørsløv, quality supervisor

The work has been followed by an advisory group consisting of:

- Peter Hammer Sørensen, Danish EPA, Chair of advisory group
- Thilde Fruergaard, Danish EPA
- Nikolai Nilsen, Confederation of Danish Industry
- Pia Vestergaard Lauridsen, Danish Working Environment Authority

Data collection

The survey and review is based on the available literature on the substances, information from databases and direct inquiries to trade organisations and key market actors.

The data search included (but was not limited to) the following:

- Legislation in force from Retsinformation (Danish legal information database) and EUR-Lex (EU legislation database);
- Ongoing regulatory activities under REACH and intentions listed on ECHA's website (incl. Registry of Intentions and Community Rolling Action Plan);
- Relevant documents regarding International agreements from HELCOM, OSPAR, the Stockholm Convention, the PIC Convention, and the Basel Convention.
- Data on harmonised classification (CLP) and self-classification from the C&L inventory database on ECHAs website;
- Data on ecolabels from the Danish ecolabel secretariat (Nordic Swan and EU Flower) and the German Angel.
- Pre-registered and registered substances from ECHA's website;
- Risk assessment report on the substances from ECHA´s website;
- Data on production, import and export of substances in mixtures from the Danish Product Register (confidential data, not searched via the Internet);
- Date on production, import and export of substances from the Nordic Product Registers as registered in the SPIN database;
- Monitoring data from the National Centre for Environment and Energy (DCE), the Geological Survey for Denmark and Greenland (GEUS), the Danish Veterinary and Food Administration, the European Food Safety Authority (EFSA) and the INIRIS database.
- Reports, memorandums, etc. from the Danish EPA and other authorities in Denmark;

This survey is mainly based on a compilation of existing reports and evaluations that has been made over time. Thus information has especially been extracted from Danish EPA reports, information from the ECHA web-site and from the common Nordic product register database, SPIN.

Summary and conclusions

This survey covers boric acid (H3BO3); various forms of sodium borate (borax) and diboron trioxide B_2O_3 either registered under REACH or subjected to harmonised classification in the EU. Worldwide mining of boron mineral ore were 5,410,000 tons in 2006. It is expected that the EU-27 consumes around 20% of this production.

Regulation
Both EU and Danish regulations specifically address the use of boric acid and sodium borate. Thus specific rules apply for the use of the substances as food additive, food supplement, in food packaging material, as micronutrient e.g. in fertilisers, and in cosmetics. Further boric acid and sodium borate are approved as active agents in biocidal product for the purpose of wood preservation. The use in toys is restricted due to the strict classification as Repr. 1B; H360FD of the substances.

According to the CLP regulation, the substances (all ten CAS numbers) are classified as reproductive toxicant as Repr. 1B; H360FD (May damage fertility. May damage the unborn child). This has led the substances to be placed on the candidate list for authorisation under the REACH regulation.
Very recently The European Chemical Agency has proposed that the substances should be subjected to authorisation, however this awaits further evaluation and decision making by the EU-Commission.

At present, some uncertainties remain to the classification limits of the substances as two disodium octaborate substances recently were recommended by the Risk Assessment Committee at ECHA to be classified using generic concentration limit unlike the other boric acid and sodium borate substances where specific classification limits have been applied. If the specific concentration limit for the other substances should be challenged/removed and the generic classification limit of 0.3% should apply for all the boron substances this would call for a lowering of the current specific classification limits by factors in the range of 10-30 for the substances.

Due to the classification as Repr. 1B; H360FD, chemical preparations are not to be sold to the public if they contain the substances at concentration levels above the current classification limit. In relation to occupational regulations the use and handling of the substances are regulated according to the generic rules for handling dangerous substances with a Repr. 1B classification. Furthermore, specific Danish occupational exposure limit values in the range of 1-10 mg/m^3 apply for the substances.

National guidance values also pertain to the industrial emission into ambient air. Thus a guideline value of 0.003 mg B/m^3 applies for the ambient air (a C-value). The content of boron in drinking water is regulated by the EU drinking water directive (limit value of 1 mg B/L) and the national legislation (limit value of 1 mg B/L but a maximum level of 0.3 mg B/L is recommended).

Criteria for eco-labelling restrict the use of the substances in eco-labelled products (due to their classification as Repr. 1B H360FD).

In the context of the old chemical regulation a risk assessment document has been elaborated on boric acid/borax. However, when REACH entered into force this was not formally agreed upon. No

specific risk assessment was undertaken (due to lack of data) for consumer exposure to the substances, neither alone nor in combination with the background exposure from the natural content in food and drinking water.

Uses

Boric acid (CAS 10043-35-3) and disodium tetraborate (CAS 1330-43-4) including its various hydrated forms) are by far the most widely used boron substances covered in this report as each of these substances are REACH-registered in the use tonnage band of 100,000 - 1,000,000 tonnes per year.

As indicated in chapter 3 boric acid and borax are used in many industries and for many purposes. The majority of the use (>50%) are used in the production of glass products (including glass fibre and glass wool) and ceramics where boric acid/borax is incorporated into and thus is a part of the glass/ceramic material. Other uses are in cosmetics, in biocides and in various chemical products such as soap and detergents, fertilisers, paint, varnishes, adhesives, electroplating, as catalysts, antifreeze products, lubricants and in cellulose (paper wool) insulation.

In Denmark, there has been an increase in terms of tonnage used during the last decade. In 2000 the tonnage reported was just below 100 tonnes of boric acid. This value remained more or less unchanged until 2003 but increased markedly hereafter. In 2012 the reported tonnage was 610 tonnes. The specific use of nearly 600 tonnes of this volume was not indicated otherwise than as "raw material" in the Danish product registry and was thus not further accounted for. About 14 tonnes was used as cooling/lubricating oil for metals. Earlier, boric acid was also included in *non-agricultural pesticides and preservatives*. Disodium tetraborate decahydrate (CAS: 1303-96-4) were used in *anti-freezing agents* to a large extent. But since 2005 the use within this group decreased and in 2012 no tonnage was registered for this product group. *Cleaning and washing agents* are now the main product group where disodium tetraborate decahydrate is used and to a lesser extent *non-agricultural pesticides and preservatives*.

Further uses of the substances are as food additive, food supplement, and in food packaging material, as micronutrient e.g. in fertilisers, and in cosmetics.

Waste

No specific concern has been addressed in relation to boric acid/ borates in the waste stream. Waste containing more than 1% of boron in the form of boric acid/ borates should due to the classification as Repr. 1B be treated as hazardous waste.

A large fraction of borate may end up in the waste stream from glass and ceramics, however, due to transformation and tight binding of borate into the glass matrix the release potential of borate from glass/ceramics is considered very low during handling of waste. Furthermore, glass in the waste stream is to a very high extent recycled.

Cellulose (paper wool) insulation in the waste stream may contain a relative high content of loosely bound boric acid/ borax powder which is highly accessible and thus constitute a potential for environmental and human exposure. For qualities containing more than 1% of boron (typically qualities sold some years ago) the cellulose insulation should be considered as hazardous waste. Data are lacking on how cellulose insulation today is handled in the waste stream.

A substantial amount of boron (but much less than 1 %) is found in bottom ash from waste incineration and coal fly ash from energy production. Some of the boron may leach to the environment from the ashes or products containing the ashes, depending on how they are managed, The leaching of boron has not been subject to regulation in relation to utilisation or landfilling, although quality criteria for boron exists for both groundwater and surface water.

A major part of (if not all) of coal fly ash in Denmark is used in the production of cement. This means that most of the boron in the Danish coal fly ash eventually will end up into cement and concrete.

Environment

Borates are naturally present and widely distributed in the environment and boron is an important - if not essential- micronutrient to many species. Boric acid/ borax are inorganic compounds and not degradable but subject to chemical transformation processes once released into the environment which result in different borate containing salts. Ambient concentrations of borates are highly variable and significantly influenced by geological conditions. In European rivers monitoring data indicate arithmetic mean values of 3.3 µg B/L (Finland), 357 µg B/L (Portugal) and 95-percentile values of 17 µg B/L (Scotland) and 632 µg B/L (Germany).

In ground water in Denmark boron levels may exceed 300 µg B/L (the indicative drinking water limit value) as this was found in a total of 72 drinking water wells in 2012.

However, concentrations in the environment are reported higher for urban areas influenced by anthropogenic sources and especially at industrial sites. The environmental risk assessment included in the Annex XV Transitional Dossier was based on “reasonable worst-case” scenarios. The assessments indicated risks towards sewage treatment plants, and in water and sediment in local scenarios involving industrial uses and releases of boron. These finding need be refined and re-assessed based on more detailed and updated information.

In contrast no risk was identified on a regional scale from the use of liquid detergents in the Hera (2005) report.

In relation to PBT assessment boric acid / borax is classified as Repr. 1B and meet the criteria for toxicity (T). Borates being inorganic substances cannot be evaluated for biodegradation, and further the boron does not bioaccumulate significantly. Thus boric acid/borax does not fulfil the criteria for B or VB, and boric acid/ borax are not considered to be PBT or vPvB substances.

Human Health, effects

When exposed via the oral or inhalational route boric acid/ borax are easily taken up (up to 100%) into the blood stream and distributed throughout the tissues and organs of the body. By dermal exposure an uptake of 0.5% over intact skin is considered as a maximum uptake. Boric acid is not further metabolized in the body but is excreted mainly in the urine, with elimination half-life < 24 hours in humans. In general, under physiological conditions, the boron compounds are transformed into boric acid; hence read-across can be made from the data on the various boron compounds.

In humans, the critical effects following inhalation of dust containing boric acid/ borax are considered to be nasal and eye irritation, throat irritations, cough, and breathlessness. Data from experimental animal studies and human studies show that boron is a respiratory irritant and a NOEC of 0.8 mg B/m^3 has been established.

In humans, acute irritant effects on the eye are well documented in human workers exposed to boric acid/borax. In animal studies, data on boric acid show do not imply classification for skin irritation. Boric acid/ borax are eye irritants and should therefore be classified accordingly as eye irritant (Eye Irr. 2; H319).

In humans, acute poisoning can occur after oral and inhalation exposure as well as after dermal exposure via damaged skin. In humans the lethal dose for oral exposure is quoted to be 2-3 g boric acid for infants, 5-6 g boric acid for children and 15-30 g boric acid for adults.

However the most critical effects of boric acid and borates are effects in relation to fertility (adverse effects on the testis) and developmental effects (malformations and prenatal mortality of the foetus).

For reproductive toxicity, a NOAEL of 17.5 mg B/kg bw/day was derived from a three generation reproduction study in rats using boric acid or sodium borate (borax). Based on the identified NOAEL value, a $DNEL_{consumer}$= 0.175 mg B/kg bw/day could be established using an assessment factor of 100. Several occupational studies are available on the effects of boric acid and boron on workers, mainly through inhalation. Although negative with respect to reproductive effects these studies were not considered conclusive for this end-point.

A NOAEL of 9.6 mg B/kg bw/day has been established from a prenatal developmental rat study on boric acid as increased mortality of fetuses, malformations and deceased body weight were seen at higher dose levels. Based on this identified NOAEL value, a $DNEL_{consumer}$ = 0.096 mg B/kg bw/day for oral exposure has been established using an assessment factor of 100. No human data exist with regard to developmental toxicity.

The effects of boric acid and borates on reproduction and development comply with a classification as Repr. 1B, H360FD ("May damage fertility and the unborn child"). This classification has recently been confirmed by The Risk Assessment Committee at ECHA in the committee's opinion on a new proposal for harmonised classification and labelling of boric acid (ECHA/RAC opinion (2014)).

Human health, exposure
From the data found on exposure estimates, which are presented in section 6.2, it can be seen that the dominating exposure to boric acid/ borates stems from food and drinking water. The general back ground (typical and realistic worst case) exposure in EU has been estimated to:

Typical exposure:	2.3-2.74 mg B/person/day (0.038 – 0.046 mg B/kg bw/day)
Realistic worst case exposure:	3.5 – 3.94 mg B/person/day (0.058 – 0.066 mg B/kg bw/day)

Especially the use of boron in dietary supplements may result in additional exposure of up to 1.5-30 mg B/ day (0.02-0.4 mg B/kg bw/day).

In relation to use of boric acid/borates in cosmetics a daily dose of 1.2 mg B/day (0.02 mg B/kg bw/day) has been estimated.

Further contribution to the exposure to boric acid/ borates may come from various other products e.g. laundry detergents, fertilisers, biocides, cellulose insulation, and furniture.

Health impact
Occupational exposure: In some situations, when working with boric acid/borax, protective measures such as technical measures or personal protective equipment may be necessary in order to reduce exposure and ensure safety. This may be relevant for e.g. industrial biocide impregnation processes, loading or unloading batches of boric acid/ borax powder, blowing cellulose wool insulation into constructions, or in connection with cleaning operations.

Consumer exposure
In 2013 the European Food Authority, EFSA, established a group ADI for boric acid and sodium tetraborate, expressed as boron equivalents to be 0.16 mg B/kg bw/day, i.e. 10 mg from all food sources for an adult weighing 60 kg (EFSA, 2013). Further EFSA concluded that exposure to boron from its natural occurrence in the diet and from other sources (dietary supplements, food contact materials, feed for food-producing animals, cosmetics, oral hygiene products, etc.) already may lead to exposures beyond the ADI.

Thus, the background exposure from food and drinking water has to be considered when assessing additional exposure sources for boric acid/ borax exposure. As the background exposure for some individuals in the populations may be quite close to the acceptable daily intake (or the DNEL of 0.09 mg B/kg bw/day) additional boron exposure from dietary supplements, cosmetics, biocides, detergents, cellulose insulation, furniture etc. may result in a total exposure exceeding the safe levels.
One example of this has recently been identified by the Risk Assessment Committee at ECHA that found that the extra contribution from specific uses of boron containing chemicals for photographic applications actually resulted in a total exposure exceeding the DNEL value.

Alternatives
ECHA has recently (September 2014) made a recommendation for including the boric acid/ borax from the candidate list on the authorisation list (Annex XIV). This of course put additional pressure on the industry in order to find alternatives for use of boric acid and sodium borate.
However, no single substance or specific technical measure can be a one-for-all alternative to the wide range of applications and processes in which boric acid and sodium borate are used.

For the use of borates in the glass industry there seems not for the majority of the applications to be a suitable alternative as the borate incorporated in the glass provides the materials with quite unique properties such a physical resistance and resistance towards thermal chock. Further boric acid/borax is bound into the glass matrix and the exposure potential from glass ware may be considered as negligible.

Also in relation to use of boric acid/ borax in starch and dextrin adhesives no appropriate alternatives have been found, as use of alternatives either may affect the production processes to a great extent and increase the cost or result in substitution to synthetic petrochemical based adhesives.
As boron is an essential micronutrient, substitution in fertiliser is not considered possible.
In lubricating oil it may be difficult to find alternatives for borate for some applications.

However, there seems to be alternatives in other areas, e.g. surface coatings and paints, insulation materials, welding processes, pH buffer solutions and in diagnostic applications.

Overall conclusions
From a regulatory and chemical safety perspective the following findings may be highlighted:

- *Boric acid/borax* are reprotoxic substances classified as Repr. 1B, H360Df (May damage fertility. My damage the unborn child)

- The use of boric acid/ borax is subject to strict regulation within several regulatory areas in relation to e.g. food; cosmetics, biocides.

- In REACH the substances are on the candidate list for authorisation and the European Chemical Agency has recently recommended the substances to be included on Annex XIV i.e. substances subject to authorisation.

- At present there is an inconsistency in the classification in-between the substances with respect to the classification limits used for mixtures.

- Boric acid/borax is used widely in a variety of industrial processes and a wide range of chemical products and articles, especially in the glass/ceramic production.

- In Denmark boric acid has an annual tonnage use level of 600-700 tonnes of which the specific use is known for about 40 tonnes only, according to data from the Danish Product Registry.

- In relation to handling of waste containing boron a potential for exposure may be present when handling cellulose insulation impregnated with boric acid/ borax powder.

- Boric acid/ borax are of low toxic potential in the environment and do not seem to be of environmental concern.

- Humans are exposed to boric acid/borax from several and variable sources e.g. food and drinking water (as natural constituent) from food supplements, from cosmetics and from various chemical products.

- The human exposure from food and drinking water alone may result in an exposure that exceeds the Derived No Effect Level of 0.09 mg B/kg bw/day.

- Thus the background exposure to boron should be considered when making risk assessment of specific sources (e.g. from chemical products) containing boric acid /borax.

Sammenfatning og konklusion

Denne undersøgelse omfatter borsyre (H_3BO_3), forskellige former for natriumborat (borax) og dibortrioxid B_2O_3 enten registreret under REACH eller underlagt den harmoniserede klassificering i EU.
Udvinding af mineralsk bor fra miner var på verdensplan 5.410.000 tons i 2006. Det forventes, at EU-27 forbruger omkring 20% af denne produktion.

Regulering
Både EU og danske lovgivning regulerer brugen af borsyre/borax på en række områder. Der gælder der særlige regler for brugen af stofferne som tilsætningsstoffer til mad, kosttilskud, i fødevareemballage, som mikronæringsstoffer fx i gødning, og i kosmetik. Endvidere er borsyre/ borax godkendt som aktivstoffer i biocidholdige produkter beregnet til træbeskyttelse. Anvendelse i legetøj er begrænset på grund af stoffernes strenge klassificering som Repr. 1B;H360FD.

Ifølge CLP-forordningen er stofferne (de ti CAS-numre der er omfattet i denne rapport) klassificeret som reproduktionstoksiske Repr. 1B;H360FD (Kan skade forplantningsevnen. Kan skade det ufødte barn). Dette har medført, at stofferne er sat på kandidatlisten til godkendelsesordningen i henhold til REACH-forordningen.
For ganske nylig har Det Europæiske Kemikalieagentur, ECHA foreslået, at stofferne bør videreføres til godkendelsesordningen under REACH, men dette afventer yderligere vurdering og endelig beslutning fra EU-Kommissionens side.

For øjeblikket er der stadig en vis usikkerhed om de specifikke klassificeringsgrænser for stofferne, da Risikovurderingskomiteen under ECHA for nylig anbefalede, at to dinatriumoktaborat stoffer skulle Repr. 1B klassificeres ud fra den generelle koncentrationsgrænse i modsætning til de øvrige borsyre/ borax stoffer, der har en væsentligt højere specifik koncentrationsgrænse. Hvis den specifikke koncentrationsgrænse for borsyre/ borax stofferne fjernes, og erstattes af den generelle klassificeringsgrænse på 0,3%, ville dette betyde en sænkning på 10-30 gange af de nuværende klassificeringsgrænser for stofferne.

På grund af klassificeringen som Repr 1B;H360FD må kemiske blandinger ikke sælges til offentligheden, hvis de indeholder stofferne i koncentrationsniveauer over den nuværende klassificeringsgrænse. For arbejdsmiljøet er der særlige forholdsregler for håndtering og arbejde med stoffer med en Repr. 1B klassificering. Derudover gælder der i Danmark konkrete grænseværdier i arbejdsmiljøet for stofferne (i intervallet 1-10 mg/m^3 afhængigt af stoffet).

For virksomheders udledning til udeluft er der fastsat grænseværdi for bor (B-værdi på 0.03 mg/m^3) i forbindelse med den danske B-værdivejledning. I drikkevand er der fastsat grænseværdi for borindhold i forbindelse med EUs drikkevandsdirektiv (1 mg bor/L) og i forbindelse med den nationale bekendtgørelse for drikkevandskvalitet (1 mg bor/L; men 0.3 mg bor/L bør tilstræbes).

Kriterier for miljømærkning hindrer brugen af stofferne i miljømærkede produkter, da stoffer med klassificering som Repr 1B;H360FD generelt ikke må anvendes i miljømærkede produkter.

I forbindelse med den tidligere kemikalielovgivning blev der udarbejdet en EU-risikovurdering for stofferne for borsyre og borax, men risikovurderingerne blev ikke formelt afsluttede inden REACH trådte i kraft. I disse rapporter blev der pga. mangel på data i forbindelse med udsættelse af forbrugere ikke foretaget nogen specifik risikovurdering for forbrugereksponering for stofferne.

Anvendelser
Borsyre (CAS 10043-35-3) og dinatriumtetraborat (CAS 1330-43-4), er langt de mest anvendte af de borstoffer, der er dækket af denne rapport. Hvert af disse stoffer er REACH-registreret i mængdeintervallet 100.000 - 1.000.000 tons pr. år.

Som det fremgår af afsnit 3, anvendes borsyre og borax i mange industrier og til mange formål. Størstedelen af anvendelsen (> 50%) går til fremstilling af glas (herunder glasfiber og glasuld) og keramik, hvor borsyren udgør en del af strukturen af glasset/det keramisk materiale. Andre anvendelser er i kosmetik og biocider samt i forskellige kemiske produkter, såsom sæbe og rengøringsmidler, gødning, maling, lak, lim, til galvanisering, som katalysatorer, i antifrost-produkter, smøremidler og til cellulose (papiruld) isolering.

I Danmark har der været en markant stigning i anvendt tonnage af borsyre i det seneste årti. I 2000 var den rapporterede tonnage lige under 100 tons. Dette forbrug forblev mere eller mindre uændret indtil 2003, men steg markant herefter. I 2012 var den rapporterede tonnage på 610 tons. Den specifikke brug af næsten 600 tons af denne mængde blev ikke angivet på anden måde end *"råmateriale"* i Produktregistreret, og der kan derfor ikke umiddelbart redegøres for anvendelsen. Omkring 14 tons blev anvendt som køle/smøreolie til metaller. Tidligere var der også borsyre i *ikke-landbrugsmæssige pesticider og konserveringsmidler*. Dinatriumdecahydrat (CAS: 1303-96-4) anvendtes før i tiden i *antifrostmidler* i stort omfang. Men siden 2005 er anvendelsen inden for denne gruppe faldet, og i 2012 blev der ikke registreret nogen tonnage for denne produktgruppe. *Rengørings- og vaskemidler* er nu den primære produktgruppe, hvor der anvendes dinatriumtetraborat decahydrat, og i mindre grad *ikke-landbrugsmæssige pesticider og konserveringsmidler*.

Stofferne anvendes yderligere i kosttilskud, i fødevareemballage, som mikronæringsstoffer fx i gødning og i kosmetik.

Affald
Der er ikke rapporteret om konkrete problemstillinger vedrørende borsyre/borax i affaldsstrømmen.
Affald, der indeholder mere end 1% bor i form af borsyre/borax skal på grund af klassificeringen som Repr. 1B behandles som farligt affald.

En stor del af den anvendte borsyre/borax vil optræde i affaldsstrømmen i forbindelse med indhold i glas og keramik. Her vurderes borsyren/ boraxen dog ikke at udgøre noget problem på grund af indlejring og binding i selve glasstrukturen. Glasholdigt affald genanvendes i meget udstrakt grad.

Cellulose (papir) isolering i affaldsstrømmen kan have et relativt højt indhold af løst bundet borsyre/borax pulver, som er meget tilgængeligt og således udgør et eksponeringspotentiale for mennesker og miljø. Mht til affald der udgøres af cellulose isolering med mere end 1% bor (gælder typisk ældre produkter), skal dette betragtes som farligt afflad. Der savnes imidlertid konkrete data mht. hvordan affald fra papirisolering håndteres.

Miljø
Der er adskillige tilgængelige studier af bors toksicitet overfor vand- og jordlevende organismer. Disse data tyder ikke på høj toksicitet.

Borater er naturligt til stede og vidt udbredt i miljøet, og bor er et vigtigt mikronæringsstof for mange arter. Borsyre/borax er uorganiske forbindelser og er ikke nedbrydelige, men de udsættes for kemiske omdannelsesprocesser, når de frigives i miljøet, hvilket resulterer i forskellige boratholdige salte. Udendørs koncentrationer af borater er meget varierende og væsentligt påvirket af geologiske forhold. I europæiske floder indikerer kontroldata aritmetiske middelværdier på 3,3 ug B/L (Finland), 357 ug B/L (Portugal) og 95-percentiler af 17 ug B/L (Skotland) og 632 ug B/L (Tyskland) .

I grundvand i Danmark kan borniveauer overstige 300 mg B/L (den vejledende drikkevandsgrænseværdi), da dette blev fundet i 72 drikkevandsboringer i 2012.

I miljørisikovurderingen i Det Europæiske Kemikalie-agenturs Transitional Dossier blev der indikeret risiko i vand og sediment for næsten alle lokale scenarier hvor der var industriel anvendelse af bor. Der gøres opmærksom på at disse indikationer er baseret på konservative og foreløbige estimater, og at mere detaljerede evalueringer bør baseres på yderligere opdateret information. Der blev ikke identificeret nogen risiko for regionale delmiljøer fra anvendelse af flydende rengøringsmidler i Hera (2005) rapporten.
I forbindelse med PBT-vurdering er borsyre/borax klassificeret som Repr. 1B, og derfor er kriterierne for toksicitet (T) opfyldt. Borater er uorganiske stoffer og det giver ikke mening at vurdere bionedbrydeligheden. Endvidere bioakkumuleres borater ikke i væsentligt omfang. Derfor opfylder borsyre/borax ikke kriterierne for B eller VB, og borsyre/borax betragtes ikke som PBT- eller vPvB-stoffer.

Sundhed, skadelige effekter
Ved oral indtagelse eller ved indånding af støv optages borsyre/borax let (op til 100%) i blodet og fordeles i væv og organer i kroppen. Ved hudeksponering angives en optagelse på 0,5% gennem intakt hud som en øvre grænse for optagelse i kroppen. Borsyre omdannes ikke yderligere i kroppen, men udskilles hovedsageligt i urinen, med en halveringstid for udskillelse på under 24 timer i mennesker. Under normale fysiologiske betingelser omdannes de forskellige borforbindelser til borsyre; og der kan derfor foretages en analogislutning fra oplysningerne om de forskellige borforbindelser.

Hos mennesker er de kritiske effekter efter indånding af støv indeholdende borsyre/borax næse- og øjenirritation, halsirritation, hoste og åndenød. Humane data og data fra dyreeksperimentelle undersøgelser angiver at borsyre/borax virker irriterende i luftvejene ved niveauer over 0,8 mg B/m^3, som anses for at være ikke-effekt-niveauet.

Hos mennesker er akut øjenirritation velkendt fra arbejdere, der udsættes for borsyre/borax. Dyreeksperimentelle data peger ikke på at stoffernes skal klassificeres som hudirriterende. Da stofferne er øjenirriterende, bør de derfor klassificeres i overensstemmelse hermed (Eye Irr. 2, H319).

Hos mennesker kan akut forgiftning forekomme efter oral indtagelse og indånding samt efter hudeksponering via beskadiget hud. I mennesker er den dødelige dosis for oral eksponering angivet til at være 2-3 gram borsyre for spædbørn, 5-6 gram borsyre for børn og 15-30 gram borsyre for voksne. De akuttoksiske effekter er baggrunden for at flere virksomheder anvender klassificeringen Acute Tox4; H302.

De mest kritiske effekter af borsyre og borax er imidlertid effekter i relation til fertilitet (skadelige effekter på testiklerne) og fosterets udvikling (misdannelser og øget fosterdødelighed).

Mht. effekter på forplantningsevnen er der blevet fastsat en NOAEL-værdi på 17,5 mg B/kg legemsvægt/dag på baggrund af en tre-generations reproduktionsundersøgelse i rotter doseret med borsyre. Baseret på denne NOAEL-værdi, har EU's Risikovurderingskomité fastsat en DNEL værdi (et tolerabelt eksponeringsniveau) på 0,175 mg B/kg legemsvægt/dag ved at anvende en usikkerhedsfaktor på 100. Der forelligger flere befolkningsundersøgelser, hvor arbejdere har været eksponeret for borsyre/borax, men selvom der ikke er fundet negative effekter på fertiliteten i disse undersøgelser anses disse data ikke at være pålidelige nok til at frikende borstofferne for disse effekter. Dvs. data fra dyrestudier anses for at være afgørende for vurderingen af fertilitetseffekter.

Mht. skadelige effekter på fosterudviklingen er der fastsat en NOAEL-værdi på 9,6 mg B/kg legemsvægt/dag ud fra oral dosering af borsyre i et teratogenforsøg med rotter. Ved højere dosisniveauer fremkom der øget fosterdødelighed, misdannelser og nedsat kropsvægt af de nyfødte unger. Baseret på denne NOAEL-værdi, har EU's Risikovurderingskomité fastsat en DNEL værdi (et tolerabelt eksponeringsniveau) på 0,096 mg B/kg legemsvægt/dag ved at anvende en usikkerhedsfaktor på 100. Der foreligger ingen humane data for udviklingstoksicitet.

Disse effekter på reproduktion og udvikling medfører klassificeringen Repr 1B, H360FD (Kan skade forplantningsevnen og det ufødte barn) for borsyre/borax. Dette blev for nylig bekræftet af risikovurderingskomitéen i ECHA i deres udtalelse om harmoniseret klassificering og mærkning af borsyre (ECHA/RAC udtalelse (2014)).

Sundhed, eksponering
Fra data fundet på eksponeringsestimater, som er præsenteret i afsnit 6.2, kan det ses, at den dominerende eksponering for borsyre/borater stammer fra fødevarer og drikkevand. Den generelle baggrundseksponering (Typisk og Realistisk Worst Case) i EU anslås til:

Typisk: 2,3-2,74 mg B/person/dag (0,038 – 0,046 mg B/kg legemsvægt/dag)
RWC: 3,5 – 3,94 mg B/person/dag (0,058 – 0,066 mg B/kg legemsvægt/dag)

Især anvendelsen af bor i kosttilskud kan resultere i yderligere eksponering på op til 1,5 - 30 mg B/dag (0,02-0,4 mg B/kg legemsvægt/dag).

I forbindelse med brug af borsyre/borax i kosmetik er der estimeret en daglig dosis på 1,2 mg B/dag (0.02 mg B/kg legemsvægt/dag).

Yderligere bidrag til eksponering for borsyre/borax kan komme fra forskellige andre produkter, fx vaskemidler, gødningsstoffer, biocider, cellulose isolering og møbler.

Erhvervsmæssig eksponering: I visse situationer i arbejdsmiljøet når der håndteres borsyre/borax, kan det være nødvendigt med særlige tekniske foranstaltninger eller anvendelse af personlige værnemidler for at reducere eksponeringen og opnå øget sikkerheden. Dette vurderes at være særligt relevant i forbindelse med støvende processer eller ved dannelse af aerosoler fx i forbindelse med industrielle biocid-imprægneringsprocesser, lastning eller losning af borsyre/borax pulver, ved indblæsning af celluloseuld-isolering i konstruktioner, eller i forbindelse med rengøringsprocesser.

Forbrugereksponering: I 2013 fastsatte Det Europæiske Fødevareagentur, EFSA, et samlet acceptabelt dagligt indtag (ADI) til 0,16 mg B/kg legemsvægt/dag for borsyre/borax, udtrykt som bor-ækvivalenter. Dette svarer til 10 mg bor fra alle fødevarekilder for en voksen, der vejer 60 kg (EFSA , 2013). EFSA konkluderede yderligere, at eksponering for bor fra naturlig forekomst i kosten og fra evt. andre kilder (kosttilskud, materialer i berøring med fødevarer, foder til fødevareproducerende dyr, kosmetik, mundhygiejne-produkter, osv.) tilsammen kan føre til en eksponering, der overstiger ADI-værdien.

Det er derfor vigtigt at baggrundseksponeringen fra især fødevarer og drikkevand tages i betragtning ved vurdering af yderligere kilder hvor eksponering med borsyre/borax kan forekomme. Da baggrundseksponeringen for nogle personer kan være ganske tæt på det acceptable daglige indtag (eller DNEL-værdien på 0,09 mg B/kg legemsvægt/dag fastat af EU's

risikovurderingskomité), kan yderligere boreksponering fra kosttilskud, kosmetik, biocider, rengøringsmidler, cellulose isolering, møbler osv. resultere i en samlet eksponering, som overskrider de sikre niveauer.
Et eksempel på dette er for nylig blevet identificeret af risikovurderingskomiteen i ECHA, som fandt, at ekstra bidrag fra en konkret anvendelse af fotokemikalier indeholdende borsyre/borax kunne medføre en samlet eksponering som oversteg DNEL-værdien.

Alternativer
ECHA har for nylig (September 2014) foreslået at videreføre borsyre/ borax fra kandidatlisten til godkendelseslisten under REACH (bilag XIV). Dette lægger naturligvis yderligere pres på industrien for at finde alternativer til anvendelsen af borsyre/borax.
Imidlertid kan der ikke peges på et én-for-alle alternativ eller en konkret teknisk foranstaltning som kan afløse brugen af borsyre/borax.
For anvendelse af borsyre/borax i glasindustrien synes der ikke for de fleste af anvendelser at være et egnet alternativ, da borsyre/borax indgår i glassets struktur og giver glasmaterialet særlige tilstræbte egenskaber, såsom øget fysisk styrke samt modstand mod termisk chok. Det er vigtigt at påpege at borsyren/boraxen er indlejret i glasmatricen, og et evt. eksponeringspotentiale herfra kan betragtes som ubetydeligt.

I forbindelse med anvendelse af borsyre/borax i stivelse- og dextrin- klæbemidler er der heller ikke fundet umiddelbart egnede alternativer, da anvendelse af alternativer enten vil påvirke produktionsprocesserne mærkbart og dermed øge omkostningerne eller resultere i substitution til syntetiske, organisk kemiske klæbestoffer.

Da bor er et essentielt mikronæringsstof, anses substitution i gødning heller ikke for muligt. Ligeledes kan der ikke for alle anvendelser i smøreolier umiddelbart findes alternativer til brugen af borsyre/borax.

Der synes imidlertid at være alternativer på andre områder, fx overfladebehandling og maling, isoleringsmaterialer, svejseprocesser, pH-buffer løsninger og i diagnostiske anvendelser.

Samlet konklusion
Ud fra en regulatorisk og sundhedsmæssig tilgang kan følgende observationer i forbindelse med denne rapport fremhæves:

- *Borsyre/borax* er reproduktionstoksiske stoffer klassificeret som Repr. 1B, H360Df (Kan skade forplantningsevnen. Kan skade det ufødte barn.)

- Anvendelsen af borsyre/borax er strengt reguleret inden for flere regulatoriske områder i forbindelse med fx fødevarer, kosmetik, biocider.

- I REACH er stofferne på kandidatlisten til godkendelse, og Det Europæiske Kemikalieagentur har for nylig anbefalet, at stofferne skal overføres til bilag XIV og dermed omfattes af godkendelsesordningen..

- På nuværende tidspunkt er der uoverensstemmelse imellem visse af borsyre/borax stofferne og deres til klassificeringsgrænserne for Repr 1B til brug i blandinger.

- Borsyre/borax har udbredt anvendelse i en række industrielle processer samt i en lang række kemiske produkter og artikler, især i glas-/keramikproduktion.

- I Danmark anvendes borsyre i en årlig mængde på 600-700 tons, men den specifikke anvendelse er kun kendt for omkring 40 tons, ifølge de offentligt tilgængelige data fra det danske produktregister.

- I forbindelse med håndtering af borsyre/borax holdigt affald vurderes håndtering af borsyre/borax holdigt cellulose isoleringsmateriale at kunne udgøre et potentiale for eksponering.

- Borsyre/borax har lavt toksisk potentiale i miljøet og synes ikke at være af miljømæssigt betænkeligt.

- Mennesker eksponeres for borsyre/borax fra flere og variable kilder, fx fødevarer og drikkevand (som naturlig bestanddel) fra kosttilskud, fra kosmetik og fra forskellige kemiske produkter.

- Den humane eksponering fra fødevarer og drikkevand alene kan medføre en eksponering, der overskrider Derived No Effect Level på 0,09 mg B/kg legemsvægt/dag.

- Således bør baggrundseksponering for bor medregnes, når der foretages en risikovurdering af specifikke kilder (fx kemiske produkter), der indeholder borsyre/borax.

1. Introduction to the substance

1.1 Identification of the substances

This survey covers boric acid (H_3BO_3) and various forms of sodium borate that are either registered under REACH or subjected to harmonised classification in the EU. Thus, other oxidation states of boron, e.g. perboric acid (HBO_3) and sodium perborates, are not included. The same applies to the dehydrated form of boric acid, i.e. metaboric acid (HBO_2) and sodium metaborates plus pentaboron sodium octaoxide (Table 1.1).

TABLE 1.1: IDENTIFICATION OF SUBSTANCES COVERING BORIC ACID AND SODIUM BORATE

Name/ CAS	CAS	Molecular formula	Molecular Weight (g/mol)	Conversion factor to boron content
Boric acid	10043-35-3	H_3BO_3	61.83	0.175
Boric acid, crude natural, containing not more than 85 per cent of H_3BO_3 calculated on the dry weight	11113-50-1	H_3BO_3	-	-
Disodium tetra borate anhydrous	1330-43-4	$Na_2B_4O_7$	201.22	0.215
Disodium tetra borate pentahydrate	12179-04-3	$Na_2B_4O_7 \cdot 5H_2O$	291.35	0.148
Disodium tetra borate decahydrate	1303-96-4	$Na_2B_4O_7 \cdot 10H_2O$	381.37	0.113
Tetraboron disodium heptaoxide, hydrate	12267-73-1	$Na_2B_4O_7 \cdot xH_2O$	201.22 + x • 18.02	0.215 (for x=1)
Diboron trioxide, boric oxide	1303-86-2	B_2O_3	≥69.62	0.155
Orthoboric acid, sodium salt	13840-56-7	Na_3BO_3	127.8	0.085
Disodium octaborate	12008-41-2	$B_8Na_2O_{13}$	340.4	0.253
Disodium; boron; oxygen(2-); tetrahydrate	12280-03-4	$B_8Na_2O_{13} \cdot 4H_2O$	412.4	0.210

The *conversion from substance content to boron content* is often practical in order to compare the concentrations between the substances. Also in relation to measurement of borate content in e.g. food items and environmental media (and in relation to limit values) the content of boric acid/borate is given as the boron content, as it is actually the content of elemental boron that is measured. *This should be kept in mind when reading the following chapters as the terms boric acid, borate/borax and boron may be used according to the term used in the references.*

1.2 Purity and impurities

The purity for boric acid is indicated to be in the range of 99.9 – 100.34%. Purity above 100% is due to the variation of crystal water in boric acid. Since boric acid consists of diboron-trioxide and water (H3BO3 <-> 1/2B2O3 + 3/2H2O), even a slight decrease in the structural water content will yield to a higher diboron-trioxide content, which will increase the purity (ECHA/transitional annex XV report (2009a).

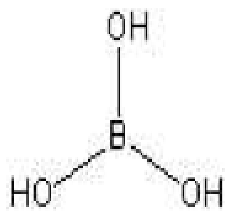
For disodium tetraborates the following degrees of purity were given:

Disodium tetraborate anhydrous: 99.0 – 101.9%
Disodium tetraborate pentahydrate: 101.6 – 103.1%
Disodium tetraborate decahydrate: 101.0 – 104.6%
(ECHA/Transitional Annex XV dossier, 2009b).

In the public part of the REACH registration dossiers on boric acid (CAS 10043-35-3); disodium tetraborate, anhydrous/pentahydrate/decahydrate (CAS 1330-43-4); diboron trioxide (CAS 1303-86-2), and disodium octaborate (CAS 12008-41-2) are the only four registrations on the substances. No further information could be found with respect to the impurity content.

1.3 Physical and chemical properties

Chemical structure of boric acid, H3BO3:



Chemical structure of sodium tetraborate (anhydrous), Na2B4O7:

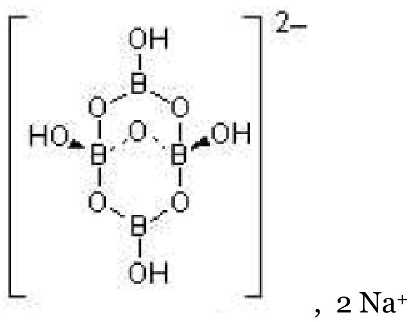


TABLE 1.2: PHYSICO-CHEMCIAL PROPERTIES (DATA FROM (ECHA/ TRANSITIONAL ANNEX XV REPORT 2009A+B)

Property	Boric acid	Disodium tetraborate, anhydrous	Disodium tetraborate, decahydrate
Physical state at 20°C and 101.3 kPa	White, crystalline, odourless solid	White, crystalline, odourless solid	White, crystalline, odourless solid
Melting/freezing point	No melting point can be defined in the range 25-1000°C due to the decomposition of the substance.	737°C	No melting point detected below 1000°C.
Relative density	D23/4 °C = 1.489	D23/4 °C = 2.354	D23/4 °C = 1.74
Water solubility	49.2 g/l at 20 °C; 47.2 g/l at 20 °C	27.0 ± 2.7 g/l at 20 ± 0.5°C Derived from studies with the pentahydrate and decahydrate	49.7 ± 3.6 g/l at 20 °C 47.0 g/l at 20 °C
Partition coefficient octanol/water (log value)	-1.09 ± 0.16 (22± 1°C)	-	-1.53 ± 0.05 (22 ± 1°C)
Flammability	non-flammable	Non-flammable	non-flammable
Granulometry	d50 = <75 – 680 µm	d50 = 210 – 850µm	d50 = 90 – 400µm
Dissociation constant	pKa = 9.0 at 25 °C for boric acid in dilute solutions only (C ≤ 0.025 M).	pKa = 9.0 at 25 °C for boric acid in dilute solutions only (≤ 0.025 M).	pKa = 9.0 at 25 °C for boric acid in dilute solutions only (C ≤ 0.025 M).

1.4 Summary

This survey covers boric acid (H_3BO_3); various forms of sodium borate (borax) and diboron trioxide B_2O_3 (boric acid consists of diboron-trioxide and water: $H_3BO_3 \leftrightarrow 1/2B_2O_3 + 3/2H_2O$) either registered under REACH or subjected to harmonised classification in the EU.
Boric acid and the sodium borates (borax) appear as white crystalline powders that are readily soluble in water.

2. Regulatory framework

This chapter gives an overview of how it is addressed in existing and forthcoming EU and Danish legislation, international agreements, eco-label criteria, etc. The overview reflects the findings from the data search.

Appendix 1 provides a brief overview of and connections between legislative instruments in the EU and Denmark. The appendix also gives a brief introduction to chemicals legislation, explanation for lists referred to in Chapter 3, as well as a brief introduction to international agreements and the aforementioned eco-label schemes.

2.1 Existing legislation

The Danish EPA has included boric acid and sodium borates on the LOUS list 2009 based on its classification as Repr. 1B; H360D and because the substances are placed on the Danish market in a quantity > 100 tonnes (Danish EPA 2011).

The current regulation, listed in Table 2.1 below, includes registration under REACH, classification according to the CLP regulation, regulation according to the biocides directive. Further regulations of the use and handling of chemicals apply in the working environment (e.g. OEL-values). The exposure of consumers is addressed through EU-regulation e.g. in relation to content in drinking water, to the use as food additive and to the use in cosmetic products.

TABLE 2.1: LEGISLATION ADRESSING BORIC ACID AND SODIUM BORATE

Legal instrument	Reference	Requirement as concerns NMP and national implementation
Regulation on chemical substances and mixtures		
REACH regulation REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	EU	Boric acid; Registration of production import and uses. Tonnage band: 100,000- 1000,000 tonnes per year Included on Annex XVII to REACH due to classification as Repr. 1B and may not be used in products to be sold to the public
CLP regulation (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures Danish Statutory Order No. 1075 of 24/11/2011 on "classification, packaging,	EU	EU harmonised classification is available for Boric acid and sodium borate, see Table 2.2 of this report

Legal instrument	Reference	Requirement as concerns NMP and national implementation
labelling, sale and storage of substances and mixtures". (Klassificeringsbekendtgørelsen)	DK	
COMMISSION DIRECTIVE 2009/91/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include disodium tetraborate as an active substance in Annex I thereto	EU	Disodium tetraborate EC No: 215-540-4 CAS No (anhydrous): 1330-43-4 CAS No (pentahydrate): 12267-73-1 CAS No (decahydrate): 1303-96-4 added to Annex 1 in Directive 98/8/EC, as wood preservative, product type 8 with expiry date, 31 august 2021
Commission Directive 2009/94/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include boric acid as an active substance in Annex I thereto	EU	Boric acid added to Annex 1 in Directive 98/8/EC, as wood preservative, product type 8 with expiry date, 31 august 2021
COMMISSION DIRECTIVE 2009/96/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include disodium octaborate tetrahydrate as an active substance in Annex I thereto	EU	Disodium octaborate tetrahydrate added to Annex 1 in Directive 98/8/EC, as wood preservative, product type 8, with expiry date, 31 august 2021
COMMISSION DIRECTIVE 2009/98/EC of 4 August 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include boric oxide as an active substance in Annex I thereto	EU	Boric oxide added to Annex 1 in Directive 98/8/EC, as wood preservative, product type 8, with expiry date, 31 august 2021
DIRECTIVE 98/8/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 February 1998 concerning the placing of biocidal products on the market	EU	Under article 5(2), a biocidal product classified as Reprotoxic Category 2 (Repr 1B under CLP)shall not be authorised for marketing, or use by the general public
Commission Decision 2008/681/EC 2008/809/EC 2009/322/EC 2009/809/EC 2010/72/EC 2012/78/EU	EU	Lists the dates for when boric acid should be phased out for use as a biocide in the product types; 1,2,3,6,7,9,10,12,13,18 and 22
Danish Statutory Order;	DK	Annex 1, Set up the conditions for use of boric acid and other borates as wood

Legal instrument	Reference	Requirement as concerns NMP and national implementation
BEK nr 628 af 13/06/2014 Bekendtgørelse om brug af kemiske stoffer og blandinger i bekæmpelsesmidler		preservatives Annex 2 list the borates not included in Annex 1, 1a and 1b of the biocidal directive Disodiumoctaborate tetrahydrate product type 1,2,3,6,7,9,10,11,12,13 18 Disodium tetraborate anhydrous product type 1,2,7,9,10,11,13, 18 Boric acid product type 1,2,3,6,7,9,10,11,12, 13 18,22
Environment and waste regulation		
DIRECTIVE 2000/60/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 October 2000 establishing a framework for Community action in the field of water policy	EU	Boric acid and sodium borate is not listed in the directive
DIRECTIVE 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain directives	EU	Boric acid and sodium borate are as a consequence of their classification as Repr. 1B included in ANNEX III: Properties of waste which render it hazardous.
Danish regulation on waste "Affaldsbekendtgørelsen" 1309/18/12 (Danish regulation on waste)	DK	Boric acid and sodium borate are as a consequence of their classification as Repr. 1B included in Annex 4: Properties and weight % which classifies waste as hazardous
Basel Convention ON THE CONTROL OF TRANSBOUNDARY MOVEMENTS OF HAZARDOUS WASTES AND THEIR DISPOSAL	Global	Boric acid and borates are as a consequence of the classification covered by Annex III of the Basel Convention regarding the control of transboundary moments of hazardous wastes and their disposal.
Working environment		
COUNCIL DIRECTIVE 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work.	EU	'Hazardous chemical agent' means: any chemical agent or chemical product which meets the criteria for classification as a dangerous substance according to the criteria in Annex VI to Directive

Legal instrument	Reference	Requirement as concerns NMP and national implementation
Implemented by the Danish executive order: Bekendtgørelse nr. 292 af 26. april 2001 om arbejde med stoffer og materialer (kemiske agenser).	DK	67/548/EEC
Directive 2009/161/EU establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directive 2000/39/EC	EU	Establishes indicative occupational exposure limits for chemical agents. Boric acid and sodium borate are not listed No SCOEL recommendation regarding OEL values is available for boric acid and sodium borate.
Danish Statutory Order; Bekendtgørelse nr. 507 af 17. maj 2011 om grænseværdier for stoffer og materialer med senere ændringer	DK	For disodium tetraborate decahydrate the OEL of 2 mg/m³ (8 hour average) applies For disodium tetraborate pentahydrate , and disodium tetraborate anhydrous, the OEL of 1 mg/m³ (8 hour average) applies For boron oxide an OEL of 10 mg/m³ (8 hour average) applies.
Danish executive Order on derivation of code numbers: Beskæftigelsesministeriets bekendtgørelse nr. 301 af 13/05/1993 om fastsættelse af kodenumre.	DK	According to this executive order the code number for boric acid/borate would be: 00-1 for up to 0.2% in a product 00-3 above 0.2% in a product : The number before the hyphen (from 00 up to 5) reflect volatility and need for ventilation/ inhalational protection). The number after the hyphen (from -1 up to -6) reflects the toxicity of the substance.
Danish executive order concerning young people at work: Bekendtgøres nr. 239 af 6. april 2005 om unges arbejde.	DK	Annex 4 contains a list of substances which workers below the age of 18 years most not handle. This covers substances classified as Repr 1A and Repr 1B.
Council Directive 92/85/EEC (Measures to encourage improvements in the safety and health at work of pregnant workers and workers who recently given birth or are breastfeeding)	EU	Boric acid is as a consequence of its classification as Repr. 1B included. The directive provides further measures, which ensure a safe use
Consumer regulation		

Legal instrument	Reference	Requirement as concerns NMP and national implementation
REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products	EU	Annex 3 Limit the use of boric acid/ sodium borates in cosmetic products Max. concentration (as boric acid) in; Talc; 5% Oral products; 0.1% Other products, excluding bath and hair waving products; 3% Tetraborates; Max. concentration in; Bath products; 18% (as boric acid) Hair products; 8% (as boric acid)
DIRECTIVE 2009/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 June 2009 on the safety of toys	EU	Boric acid/borates are not allowed in toys in components of toys or in micro-structurally distinct parts of toys due to its classification as toxic for reproduction (CMR) of category Repr. 1B (EC) No 1272/2008.
COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food	EU	Boric acid and sodium tetraborate are listed for 1. Use as additive or polymer production aid 2. Use as monomer or other starting substance or macromolecule obtained from microbial fermentation With a combined specific migration limit (SML) value of 6 mg B/kg
COMMISSION REGULATION (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements	EU	Boric acid and sodium borate are listed in annex 2, as substances (minerals) for use in food supplements. No limits are specified.
Danish Statutory Order; BEK nr 1440 af 15/12/2009 Bekendtgørelse om kosttilskud	DK	Boric acid and sodium borate are listed in annex 2, as substances for use in food supplements
COMMISSION REGULATION (EU) No 1129/2011 of 11 November 2011	EU	Boric acid is listed as a food additive, with the E number 284

Legal instrument	Reference	Requirement as concerns NMP and national implementation
amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives		Sodium tetraborate is listed as a food additive with the E number 285 Both only permitted for use in caviar from sturgeon only, with a maximum level of 4000 mg/kg, expressed as boric acid
Danish Statutory Order; BEK nr 862 af 27/08/2008 Bekendtgørelse om gødning og jordforbedringsmidler m.v.	DK	Boric acid is listed as a micronutrient
Council Directive 98/83/83/EC on the quality of water intended for human consumption	EU	Limit value for boron 1 mg/l.
BEK 1024 af 31/10/2011 Bekendtgørelse om vandkvalitet og tilsyn med vandforsyningsanlæg	DK	Sets limit value for boron in drinking water to 1 mg/l, however, it is encouraged to keep the content below 0.3 mg/l.
Other regulation		
Danish guidance document: Vejledning fra Miljøstyrelsen Nr. 2 2002 "B-værdivejledningen"	DK	B-value (contribution value) of 0.003 mg B/m^3, as a limit value for each company's contribution to the air pollution in the environment, for elemental boron, the borates covered in this survey do not have a B-value.

2.2 Classification and labelling

2.2.1 Harmonised classification in the EU

HARMONISED CLASSIFICATION AND LABELLING ARE APPOINTED TO BORIC ACID AND SODIUM BORATES ACCORDING TO ANNEX VI OF REGULATION (EC) NO 1272/2008 (CLP REGULATION), SEE

Table 2.2.

TABLE 2.2: HARMONISED CLASSIFICATION ACOORDING TO ANNEX VI OF REGULATION (EC) NO 1272/2008 ACCORDING TO CLP REGULATION (AND ACCORDING TO DSD DIRECTIVE 67/548/EEC, IN BRACKETS)

Name/ CAS	CAS	Chemical formula	Classification	
			Hazard Class and Category Code(s)	Specific concentration limit
Boric acid	10043-35-3	H3BO3	Repr. 1B; H360FD	C ≥ 5.5 %
Boric acid, crude natural, containing not more than 85 per cent of H3BO3 calculated on the dry weight	11113-50-1	H3BO3	Repr. 1B; H360FD	C ≥ 5.5 %
Disodium tetra borate anhydrous	1330-43-4	Na2B4O7	Repr. 1B; H360FD	C ≥ 4.5 %
Disodium tetraborate pentahydrate	12179-04-3; 1330-43-4	Na2B4O7 • 5H2O	Repr. 1B; H360FD	C ≥ 6.5 %
Disodium tetra borate decahydrate	1303-96-4; 1330-43-4	Na2B4O7 •10H2O	Repr. 1B; H360FD	C ≥ 8.5 %
Tetraboron disodium heptaoxide, hydrate	12267-73-1	Na2B4O7 • xH2O	Repr. 1B; H360FD	C ≥ 4.5 %
Diboron trioxide, boric oxide	1303-86-2	B2O3	Repr. 1B; H360FD	C ≥ 3.1%
Orthoboric acid, sodium salt	13840-56-7	Na3BO3	Repr. 1B; H360FD	C ≥ 4.5%
Disodium octaborate*	12008-41-2	B8Na2O13	Repr. 1B; H360FD*	- *
Disodium; boron; oxygen(2-); tetrahydrate*	12280-03-4	B8Na2O13 • 4H2O	Repr. 1B; H360FD*	- *

H360FD : May damage fertility. My damage the unborn child.

*In process, a proposed harmonised classification agreed by the Risk Assessment Committee at ECHA in March 2014 (ECHA/ RAC opinion 2014a+b).

The substances classified with the specific concentration limit in the range of 3.1% to 8.5% are classified according to an overall specific concentration limit for the boron content of 1% and thus, the various individual concentration limits for the substances reflect the differences in the boron content as indicated in Table 1.1 showing the boron conversion factors for the substances.

HOWEVER, IT SHOULD BE NOTED THAT CLASSIFICATIONS OF THE LAST TWO SUBSTANCES IN

Table 2.2 (disodium octaborate and disodium; boron; oxygen(2-); tetrahydrate) recently have been concluded by the Risk Assessment Committee that did not agree to base the classification on the specific concentration limit for the boron content. RAC instead followed the new guidance on applying a specific concentration limit from 2013 and from this they found no rationale from the data to deviate from using the generic classification limit for the substances. Thus, RAC applied the generic limit of 0.3% for the two substances*. This view was also stated by RAC in connection with a classification opinion on boric acid in March 2014 (ECHA/RAC opinion 2014c); however here the aim in this opinion was not to discuss and conclude on a classification limit.

(*If disodium; boron; oxygen(2-); tetrahydrate (CAS 12280-03-4) with a boron conversion factor of 0.210 was to be classified according to the boron content of 1% this would mean a specific concentration limit of 4.8% for the substance. Thus the conclusion of RAC using the generic limit of 0.3% for the substance is a limit that is 16 times lower than the limit based on the boron content).

IT REMAINS, HOWEVER, TO BE SEEN WHETHER THE COMMISSION AGREES ON THIS VIEW, AS THIS WOULD CALL FOR A REVISION OF THE CLASSIFICATION LIMITS OF ALL THE SUBSTANCES IN

Table 2.2 using the generic limit instead of the specific limits based on a boron content of 1%.

In connection with the classification the substances should furthermore be labelled with the warning pictogram:

Health Hazards

2.2.2 Notified classification in the EU

According to the current CLP regulation companies placing chemical substances or chemical mixtures on the market in EU are obliged to notify the classification they use for the substances to the European Chemicals Agency, ECHA. The classifications used (and notified) by the companies can be searched at the ECHA website in the CLP inventory database, see Table 2.3.

TABLE 2.3: NOTIFIED CLASSIFICATIONS ACCORDING TO THE CLP INVENTORY DATABASE

Name	CAS	No. of notifications	Classification used in notifications (numbers) - used either alone or in combination -
Boric acid	10043-35-3	37	Repr. 1B; H360 (31) Repr. 1A ; H360 (1) H360 (2) Skin Irr 2; H315 (1) STOT SE 3; H335 (1) STOT SE1 (1); H370 STOT RE1 (1); H372 No classification (1)
Boric acid, crude natural, containing not more than 85 per cent of H3BO3 calculated on the dry weight	11113-50-1	3	Repr. 1B; H360(3)
Disodium tetra borate anhydrous	1330-43-4;	30	Repr. 1B; H360(26) Repr 2;H360 (1) Eye Irr 2; H319 (12)

Name	CAS	No. of notifications	Classification used in notifications (numbers) - used either alone or in combination -
			Eye Dam 1; H318 (1) Acute Tox4; H302 (2) No classification (1)
Disodium tetraborate pentahydrate	1330-43-4	30	Repr. 1B; H360(26) Repr 2;H360 (1) Eye Irr 2; H319 (12) Eye Dam 1; H318 (1) Acute Tox4; H302 (2) No classification (1)
Disodium tetra borate decahydrate	1330-43-4	30	Repr. 1B; H360(26) Repr 2;H360 (1) Eye Irr 2; H319 (12) Eye Dam 1; H318 (1) Acute Tox4; H302 (2) No classification (1)
Disodium tetra borate decahydrate	1303-96-4	20	Repr. 1B; H360(14) -; H360 (2) Repr. 1A; H360 (1) Repr 2;H360 (1) Eye Irr 2; H319 (4) Skin Irr 2; H315 (1) No classification (1)
Tetraboron disodium heptaoxide, hydrate	12267-73-1	4	Repr. 1B; H360 (4) Eye Irr 2; H319 (1)
Diboron trioxide, boric oxide	1303-86-2	15*	Repr. 1B; H360 (12)

Name	CAS	No. of notifications	Classification used in notifications (numbers) - used either alone or in combination -
			Repr. 1A ; H360 (1) H360 (1)
Orthoboric acid, sodium salt	13840-56-7	5	Repr. 1B; H360(5) H350 (1)
Disodium octaborate*	12008-41-2	4	Repr. 1B; H360 (4)
Disodium; boron; oxygen(2-); tetrahydrate*	12280-03-4	3	Repr. 1B; H360 (1) Eye Irr 2; H319 (1) Skin Irr 2; H315 (1)

*one notification considered as mistake and excluded due to classification of 11 different end-points.

Besides the classification as Repr. 1B, the most widely used additional classifications are Eye Irr. 2, H319 and Skin Irr. 2. It should be noted that a few notifications do not classify at all and also a few notifications lack a classification for reproduction toxicity.

2.3 REACH

Under REACH the following registrations within the following tonnage bands have been made:

CAS	Name	Tonnage
1303-86-2	diboron trioxide	1,000 - 10,000 tonnes per annum
1303-86-2	diboron trioxide	100 - 1,000 tonnes per annum
1330-43-4	disodium tetraborate, anhydrous *	100,000 - 1,000,000 tonnes per annum
10043-35-3	boric acid	100,000 - 1,000,000 tonnes per annum
12008-41-2	disodium octaborate	1,000 - 10,000 tonnes per annum

*this registration also covers the hydrated forms of disodium tetraborate.

Restriction

According to Annex XVII of REACH substances classified as Repr.1A or 1B shall not be placed on the market, or used, — as substances, — as constituents of other substances, or, — in mixtures, for supply to the general public when the individual concentration in the substance or mixture results in a classification as Repr.1A or 1B.

Candidate list for authorisation

Boric acid/borax have been identified as substances of very high concern (SVHC) due to the classification as Repr. 1B; H360 DF.
In the period June 2010- June 2012 the following substances were included on the Candidate List (ECHA/MSC 2010(a+b+c) and ECHA/MSC 2012):

Boric acid (CAS 233-139-2 and CAS 10043-35-3);
Disodium tetraborate (-anhydrous CAS 1330-43-4); (-pentahydrous CAS 12179-04-3);

(-decahydrate CAS 1303-96-4); and
Tetraboron disodium heptaoxide, hydrate (CAS 12267-73-1)
Diboron trioxide (CAS 1303-86-2)

This gives further obligations for the suppliers of chemical mixtures or articles containing the substances. For chemical mixtures even if they do not meet the criteria for hazard classification the suppliers – on request – have to provide a safety data sheet if the mixture contains boric acid/borax at a level above ≥ 0.1% (w/w).
Suppliers of articles containing substances on the Candidate List in a concentration above 0.1% (w/w) have to provide sufficient information to allow safe use of the article to their customers - or upon request, to a consumer within 45 days of the receipt of the request. This information must contain as a minimum the name of the substance. Further there is an obligation to make notification to ECHA if the substance is present in the articles in quantities of more than one tonne per producer or importer per year and if the substance is present above a concentration of 0.1% (w/w).
The placing of a substance on the REACH Candidate List is the first step towards the authorisation process for a substance.

ECHA has recently (September 2014) made recommendations to include the boron substances from the candidate list on the authorisation list (Annex XIV).

EU-risk assessment
Under the previous chemical regulation (EEC) No 793/93, EU- risk assessment reports on boric acid and sodium borate have been elaborated by Austria. The work was, however, not finalised before REACH turned into force, and thus no risk management measures were concluded from the work. Therefore transitional Annex XV reports were made in order to feed the work into the REACH regulation (ECHA/transitional annex XV report (2009a+b).

In the risk assessment part of the reports it was concluded that "There is a need for better information to adequately characterise the risks to workers and consumers from boron exposure via boric acid and sodium tetraborates".

Thus a risk characterisation for boron exposure via consumer products was not made due to the lack of information on all possible applications as indicated in the consumer exposure section of the report.

As a follow-up on this, a study on borates in consumer products was carried out on behalf of the commission (RPA 2008). This report identified further uses of boric acid and borates in relation to consumer use. However, no overall risk assessment for consumer exposure or combined exposure considering indirect environmental background exposure was undertaken.

The Risk Assessment Committee in 2010 made an assessment of consumer use of boric acid and borates in photographic applications (developer and fixer). In the opinion no risk was identified for the specific uses alone; however, when background exposure from food and drinking water risk was included in the assessment, risk was identified for some worst case scenarios (ECHA/RAC opinion 2010a+b).

2.4 Other initiatives

Boric acid is listed in the EU SUBSPORT substance database. According to the Subsport database boric acid is listed in Chemsec SIN list, which is a non-governmental organisation driven project that aims to identify Substances of Very High Concern. The aim of the project is to push the legislative process and provide tools for business and other actors to identify alternatives.

Boric acid is on the Trade Union priority List of substances of Very High Concern, which from a trade union perspective should have priority for inclusion in the REACH candidate list and potentially in the authorisation list. Boric acid is also listed in the German UBA list, the master list contains substances and groups of substances that are considered of concern by the German Federal Environment Agency and should not be present in mixtures and articles.
The NOKIA substance list that identifies substances, which the company has banned, restricted, or targeted for reduction with the aim of phasing out their use, lists boric acid. The Swiss blue sign system also lists boric acid. The Swiss enterprise blue sign claims that it includes all harmful substances listed in relevant restricted substances lists of the textile sector. Boric acid is listed in the Swedish PRIO tool, which is a list of phase out substances that are considered of such concern that they should not be used, and the list of Priority Risk-Reduction Substances, which have properties to which special attention should be paid.

2.5 International agreements

Boric acid and the borates are not specifically addressed in any of the following international conventions: Ospar convention; Helcom convention; Stockholm convention; Rotterdam convention; Basel convention.

2.6 Eco labels

The general approach taken in eco-label criteria (the Nordic Swan, the EU Flower and the German Blue Angel) adopted to date is to exclude eco-labelling when the products contain chemicals which have certain specific properties (classification and risk phrases).
Boric acid is classified with H315, H319, H335 and H360D. Criteria documents covering the product groups referred to in Section 3.3 were consulted. Most of these documents state that "The materials used for the manufacture of the ecolabelled product shall not contain substances or preparations that are assigned the classification Repr. 1B H360 (DF) (May damage fertility. May damage the unborn child). Furthermore, some criteria documents state that "The final product formulation, including all intentionally added ingredients present at a concentration of greater than 0.010 %, shall not contain substances or mixtures classified as toxic, hazardous to the environment, respiratory or skin sensitisers, or carcinogenic, mutagenic or toxic for reproduction in accordance with Regulation (EC) No 1272/2008 or Council Directive 67/548/EC".

2.7 Summary and conclusions

Both the EU and Danish regulations specifically address the use of boric acid and sodium borate. Thus specific rules apply for the use of the substances as food additives, food supplements, and in food packaging material, as micronutrients e.g. in fertilisers, and in cosmetics. Furthermore, boric acid and sodium borate are only approved as active agents in biocidal product for the purpose of wood preservation. The use in toys is restricted due to the strict classification as Repr. 1B; H360FD of the substances.

According to the CLP regulation the substances (all ten CAS numbers) are classified as reproductive toxicants as Repr. 1B; H360FD (May damage fertility. My damage the unborn child). This has led the substances to be placed on the candidate list for authorisation under the REACH regulation. Very recently The European Chemical Agency has proposed that the substances should be subjected to authorisation; however this awaits further evaluation and decision making by the EU-Commission.

At present, some uncertainties remain to the specific classification limits of the substances as two disodium octaborate substances recently were recommended by the Risk Assessment Committee at

ECHA to be classified without a specific concentration limit comparable to the specific concentration limits for the other boric acid and sodium borate substances. If the specific concentration limit for the other substances should be challenged/removed and the general classification limit of 0.3% should apply, this would call for a lowering of the current classification limits by factors in the range of 10-30 for the substances.

Due to the classification as Repr. 1B; H360FD, chemical preparations are not to be sold to the public if they contain the substances at concentration levels above the current classification limit. In relation to occupational regulations the use and handling of the substances are regulated according to the generic rules for handling dangerous substances with a Repr. 1B classification. Furthermore, specific Danish occupational exposure limit values in the range of 1-10 mg/m^3 apply for the substances.

The content of boron in drinking water is regulated by the EU drinking water directive and the national legislation. National guidance values also pertain to the industrial emission of the substances into ambient air (C-values).

Criteria for eco-labelling restrict the use of the substances (due to their classification as Repr. 1B H360FD) in eco-labelled products.

In the context of the old chemical regulation, a risk assessment document has been elaborated on the substances. However, when REACH entered into force this was not formally agreed upon. Furthermore, no specific risk assessment was undertaken (due to lack of data) for consumer exposure to the substances, neither alone nor in combination with the background exposure from the natural content in food and drinking water.

3. Manufacturing

3.1 Manufacturing processes

Borates are manufactured from minerals mined in boron mineral ores. Boric acid is manufactured by reacting inorganic borate minerals with sulphuric acid in an aqueous solution. Borax pentahydrate and decahydrate are manufactured by dissolving sodium borate minerals in hot liquor followed by recrystallisation. The anhydrous form is produced from its hydrated forms (ECHA/ transitional annex XV report (2009b)).
Worldwide mining of boron mineral ores were 5,410,000 tons in 2006. Turkey accounts for half of the mined tonnage. Second most is mined USA (approx. 1/5 of worldwide tonnage). It is expected that the EU-27 consumes around 20% of this production (RPA, 2008).

Import and export

There is no mining of boron within the EU. Hence all the reported tonnage in the EU is imported. Listed tonnage in the REACH registration dossier is 100.000 to 1.000.000 tonnes and the number of registrants is 45 companies (REACH Registration data, 2014).
According to RPA (2008), three companies account for 95% of total imported tonnage.
Top three importing EU-countries are Belgium, Germany and The Netherlands. The same three countries are the main exporters though in export The Netherlands tops the list in front of Belgium. (RPA, 2008)

3.2 Use

3.2.1 Identified uses in the EU

Several uses of borates have been identified within the EU. The table below (Table 3.1) summarises the findings reported by RPA (2008). According to this information, glass, glass products and ceramics account for more than half (55.8%) of the used tonnage of borates and are thus by far the largest users of boron. Second most is soap and detergent products which account for 16.8% of the total volume used. The remaining categories each only account for smaller volumes (0.1%-8.2%) compared to the two topmost uses.

TABLE 3.1: USES OF BORATES IDENTIFIED WITHIN THE EU (MODIFIED AFTER RPA, 2008)

Product application or industry sector	%	Tonnes
Glass, glass products and ceramics	55.8	334,800
Soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	16.8	100,800
Fertilisers and nitrogen compounds	4.7	28,200
Chemical and fertiliser minerals	2.4	14,400
Paper and paper products (incl. currogated paper)	1.5	9,000
Basic pharmaceutical products and preparations	1.4	8,400
Wood products (e.g. veneer sheets and wood based panels) except furniture	1.0	6,000
Paints, varnishes, coatings, printing inks and mastics	0.5	3,000

Product application or industry sector	%	Tonnes
Furniture (e.g. mattresses)	0.1	600
Other chemicals and chemical products: Various chemical processes incl. metallurgy, antifreeze, brake fluids, buffers, wallboards, lubricants	8.2	49,200
Others: Steel slag stabilisation, flame retardants, cellulose insulation, nuclear, electroplating	7.6	45,600
Total	**100**	**600,000**

Other uses not specified in the above table are the use in biocides (as wood preservatives), in adhesives, and as pH buffer in solutions.

3.2.2 Glass and glass products

Borates increase the mechanical strength of glass and its resistance to thermal shock, different chemicals including acids and alkaline fluids, and water. In insulation and textile fibre glass, borates help lower glass batch melting temperature and control the relationship between temperature, viscosity and surface tension which is important when creating optimal glass fiberisation. Information provided by the Glass Fibre Producers Association and presented in RPA (2008) states that approximately 84,000 tonnes of borates are used by their members to manufacture glass products, and they estimate that on an EU level the glass fibre production is around one million tonnes/year. All are sold for industrial application (RPA, 2008).
The use of glass fibres within the EU is increasing 3-4%; however the trend is to apply purer forms of borates and use other materials of lower costs (RPA, 2008).

3.2.3 Insulation

Glass wool and rock (stone) wool have together met just over half of the world's demand for insulation. 75% of the world's insulation materials are used in North America and Europe. According to The European Insulation Manufacturers Association there has been an increasing demand for glass mineral wool, which is partly due to improved building standards and environmental awareness (RPA, 2008).

TABLE 3.2: APPLICATION OF GLASS WOOL AND ROCK (STONE) WITHIN CONSTRUCTION (RPA, 2008)

	% applied in residential and commercial building	% applied in industrial application
Glass wool	88	12
Rock (stone) and slag wool	80	20

In cellulose insulation, for cellulose fibre fire resistance, 12% boric acid is added. For mould and fungus resistance, 6% borax decahydrate is added (RPA, 2008).

3.2.4 Soap and detergents

Different forms of borates are used to produce laundry detergents, household or industrial cleaners as well as personal care products.

Boric acid and disodium tetraborate are used as enzyme stabilisers in liquid laundry detergents and several cosmetics and oral hygiene products (RPA, 2008). Boric acid and borax are added to some liquid fabric detergents up to 2% concentration to stabilise the protease and other enzymes in the formulation. The annual consumption of boric acid and borax as enzyme stabilisers in detergents on the European market was estimated to be 3,000 tonnes B_2O_3 equivalent in 2004, equivalent to 932 tonnes of boron. This use represents approximately 1% of the total borate consumption in Europe.

The more significant use of borates in the European detergent market is for the manufacture of sodium perborate. Modern laundry detergents contain around 15% sodium perborate or increasingly sodium percarbonate (RPA, 2008). Sodium perborate is used as an oxidising and bleaching agent in detergent products. Over the last years the content of sodium perborate in detergents marketed in Western Europe has decrease due to the replacement with sodium percarbonates. In 2007 CEFIC indicated that the manufacture of perborates was around 196,000 tonnes, which is used in soaps and detergents (RPA, 2008); of this 28% is sold within Europe, the remaining 72% are exported.

3.2.5 Cosmetics
Borates also serve to control bacteria and fungi in personal care products (ECHA/transitional annex XV report 2009a). Boric acid and disodium tetraborate decahydrate are according to the EU cosmetic regulation (EC no 1223/2009) allowed for use in cosmetic products in Europe at various concentration levels (0.1-18%) depending on the type of cosmetic.

3.2.6 Fertiliser minerals
Boron is a micronutrient essential to plant growth. Fertilisers which are applied to a diverse range of crops, both commercially and by consumers, therefore contain boron. Boron fertilisers with a typical content of 2-14% boron include boric acid, sodium borate, calcium borate and boron ethanol amine (RPA, 2008).

3.2.7 Other food products
Natural levels of boron are found in food products. However, boron is also available as a dietary supplement with claims for different health improvements (RPA, 2008).

3.2.8 Use in Adhesives, paper, veneer sheets and pressed panels
Dextrine/starch based adhesives are made from natural polymers derived from roots tubers and seeds from higher plants. The wet tack of these polymers, however, is too low, and therefore borax is added in the presence of sodium hydroxide in order to change the polymer to a more highly branched polymer with a higher molecular weight which improved the wet tack. The precise composition of adhesives varies, but borate is applied in concentrations up to 10% (RPA, 2008).

When used in paper and paperboard products as well as veneer sheets and pressed panels, borates serve as multifunctional additives with adhesive, flame retardant and fungicidal properties.
In gypsum board panels between 0.03% and 0.15% by weight is applied (RPA, 2008).

3.2.9 Mattresses
When applied in mattresses borates are applied in the wadding for flame resistance but also for smoulder resistance (RPA, 2008).

3.2.10 Paints and coatings
In paints and coatings borates are applied as coating additives with flame retardant, corrosion inhibiting and buffering properties. It is estimated that the use of borates within this sector in EU is around 3,000 tonnes/year (RPA, 2008).

3.2.11 Pharmaceutical preparations
Borates are used as antiseptics in medicaments and to combat rheumatoid arthritis and osteoarthritis. It is also used as an eye wash (RPA, 2008).

3.2.12 Basic metals

Different forms of boron are added to alloys such as ferrous, aluminium, lead, zinc, tin, copper, nickel and uranium. These alloys are used in a range of products e.g. motor vehicles (RPA, 2008).

3.2.13 Nuclear reactors.

Boron is used to control and limit the neutron flux within nuclear reactors (RPA, 2008).

3.2.14 Electronics, optical products and lightning equipment

Borosilicate is used in TV, computer monitors and optical instruments (RPA, 2008).
Boric oxide is often applied in the production of optical glass (RPA, 2008).
Borosilicate glass is used for light in harsh environments such as automobile light and traffic lights. (RPA, 2008).
Borates are also used to prevent surface oxidation during welding, brazing or soldering (RPA, 2008)

3.2.15 Registered uses according to ECHA's database of REACH registered substances

As mentioned in Section 2.3 under REACH, the following registrations within the following tonnage bands have been made:

CAS	Name	Tonnage
1303-86-2	diboron trioxide	1,000 - 10,000 tonnes per annum
1303-86-2	diboron trioxide	100 - 1,000 tonnes per annum
1330-43-4	disodium tetraborate, anhydrous *	100,000 - 1,000,000 tonnes per annum
10043-35-3	boric acid	100,000 - 1,000,000 tonnes per annum
12008-41-2	disodium octaborate	1,000 - 10,000 tonnes per annum

*this registration also covers the hydrated forms of disodium tetraborate.

Data from the five REACH registrations of boric acid, diboron trioxide (2 registrations), disodium tetraborate, and disodium octaborate indicate registration for the following products and uses (given as a condensed list to avoid too much overlap between the indicated uses):

Adhesives, sealants
Antifreeze and de-icing products
Base metals and alloys
Biocidal products (e.g. disinfectants, pest control)
Borate PVA solutions
Borates in metallurgy
Catalysts
Cellulose insulation
Coatings and paints, thinners, paint removes
Cosmetics, personal care products
Fillers, putties, plasters, modelling clay
Fertilisers, micronutrients
Flame retardants
Formulation into cement
Formulation in refractory mixtures
Glass production (borosilicate and crystal glass)
Glass fibre production
Heat transfer fluids

Hydraulic fluids
Ink and toners Metal surface treatment products, including galvanic and electroplating products
Intermediate
Intermediate use in the production of non-oxide ceramic powders Laboratory chemicals
Leather tanning, dye, finishing, impregnation and care products (e.g. as flame retardant).
Lubricants, greases, release products
Metal-surface treatment products
Metal working fluids
Non-metal-surface treatment products
Paper and board dye, finishing and impregnation products: including bleaches and other processing aids
Pharmaceuticals
Photo-chemicals
Polymer preparations and compounds
Production of frits
Production of glass wool
Production of high alkali glass
Production of low alkali glass
Production of metal powders
Products such as pH-regulators, flocculants, precipitants, neutralisation agents)
Reagent chemicals
Swimming pool tablets production
Water treatment chemicals
Washing and cleaning products
Welding and soldering products

The long list of the various product applications and uses illustrates the wide and dispersive use of boric acid/borates both in relation to industrial use as well as for consumer use.

3.2.16 Data from ECHA

ECHA has recently recommended the boron substances from the candidate list to be included on the authorisation list (September 2014).

For *boric acid* (CAS 10043-35-3; CAS 11113-50-1) ECHA estimated the total volume *within the scope for the authorisation* to be in the range of 10,000 – 100,000 tonnes/year.

For *disodium tetraborate* (CAS 1330.43-4; CAS 12179-04-3; CAS 1303-96-4) ECHA estimated the total volume *within the scope for the authorisation* to be > 10,000 tonnes/year.

For *diboron trioxide* (CAS1303-86-2) ECHA estimated the total volume *within the scope for the authorisation* to be in the range of 100 – 1,000 tonnes/year.

For all of these substances some uses were considered to be outside the scope of authorisation, e.g. uses as intermediates in the manufacture of other substances (including in the glass and ceramic/frit sectors) and uses of mixtures below the specific concentration (SCL) limit for classification, uses in cosmetic/medicinal/biocidal products, and uses in scientific research and development.

For t*etraboron disodium heptaoxide* (CAS 12267-73-1) ECHA noted that the substance has not been registered under REACH, i.e. at present no registered uses.

(ECHA 2014 a+b+c+d)

3.2.17 The Nordic countries

The Nordic SPIN database (Substances in Preparations in the Nordic Countries) is the result of a common Nordic initiative to gather non-confidential data. The database summarised information from the Nordic product registers on the common use of chemical substances in different types of products and industrial areas.

Information on use volumes and information on the tonnage of substances in preparation in the period 1999-2012 in the four Nordic countries has been retrieved from the SPIN database as of August 2014. Table 3.3 sums up the trends in the use of all 10 substances. More specific data for each individual substance is presented graphically in Figure 3.1 to Figure 3.3 and in Appendix 2 where relevant.

TABLE 3.3: USE AS REPORTED TO THE SPIN DATABASE. SUBSTANCES MARKED WITH * HAVE SPIN DATA PRESENTED GPRAPHICALLY IN APPENDIX 2

Substance	CAS	Use [Numbers for DK only]
Boric acid	10043-35-3	See also Figure 3.1 and Figure 3.2. The total tonnage of boric acid in DK has increased over the past 10 years. In 2011 618 tons were reported to SPIN. SPIN lists 16 categories of use. *"Cutting fluids", "Non-agricultural pesticides and preservatives"* and *"Surface treatment"* are the top-3 reported uses in 2011, but all together theses uses only account for a tonnage of 10 tons. Unfortunately SPIN does not account for the use of the remaining 608 tonnes.* The total number of products with boric acid is slightly decreasing by 25% over the years to end at 150 products in 2011.
Boric acid, crude natural, containing not more than 85 per cent of H3BO3 calculated on the dry weight	11113-50-1*	Up to 30 tonnes yearly were reported in 2005-2010, but almost no tonnage is reported for 2011. The numbers of products are decreasing over year. Use reported from 2005-2010 is solely in the category *"Non-agricultural pesticides and preservatives"*.
Disodium tetraborate, anhydrous	1330-43-4*	Up to 10 tonnes per year over the last decade, but only two tonnes reported in 2011. No uses are reported after 2004. Until then *"Anti-freezing agents"* and *"Photochemicals"* were the two only reported uses.
Disodium tetraborate pentahydrate	12179-04-3	Below 7 tonnes per year for the last ten years. Only three tonnes were reported to SPIN in 2011. Almost all tonnage was reported used as *"Anti-freezing agents"*.
Disodium tetraborate decahydrate	1303-96-4*	Tonnage in has decreased gradually from almost 200 tons in 2000 to 27 tons in 2011. Reported uses for the last five years in SPIN is given in Figure 3.3.
Tetraboron disodium heptaoxide, hydrate	12267-73-1	There is no information on tonnage, number of products or use for this substance.
Diboron trioxide, boric oxide	1303-86-2*	There is no reported use for DK. Yearly tonnage is close to zero.
Orthoboric acid, sodium salt	13840-56-7	There is no reported use for DK. No yearly tonnage is reported.

Substance	CAS	Use [Numbers for DK only]
Disodium octaborate	12008-41-2	There is no reported use for DK. Yearly tonnage is close to zero.
Disodium; boron; oxygen(2-); tetrahydrate	12280-03-4	There is no reported use for DK. Yearly tonnage is close to zero.

*As indicated in Table 3.1, a large use volume (608 tonnes) of the Danish consumption of boric acid could not be accounted for in the SPIN database. An updated recent search in the Danish product registry (2014) indicates a total use volume 737 tonnes of which 125 was exported. About 47.5 tonnes was used for biocides (45 tonnes for export); 14 tonnes for cooling agents/ lubricants; 66 tonnes for process agents (exported). However, for a total annual volume of 578 tonnes the specific use could not be accounted for as only the use as raw material was indicated.

Tonnages are varying a lot from country to country. In general the reported tonnage for Denmark is lower than the other Nordic countries – presumably due to the size of the industries in the respective countries.

Boric acid (10043-35-3) is used in several hundred tonnes/year in all four Nordic countries. In line with Denmark (as mentioned in Table 3.3), the reported tonnages for specific uses in the other Nordic countries do not nearly add up to the total reported tonnage in each country. In addition the majority of the tonnage is unspecified as it is reported in the category *"Others", "Cutting fluids", "Non-agricultural pesticides and preservatives"* are other main categories. It is not possible to explain two very high single-year reportings for Norway and Finland (Table 3.1).

Sweden and Norway have reported highest tonnages for three of the disodium tetraborates – the anhydrous, the pentahydrate and the decahydrate (See also Appendix 2).

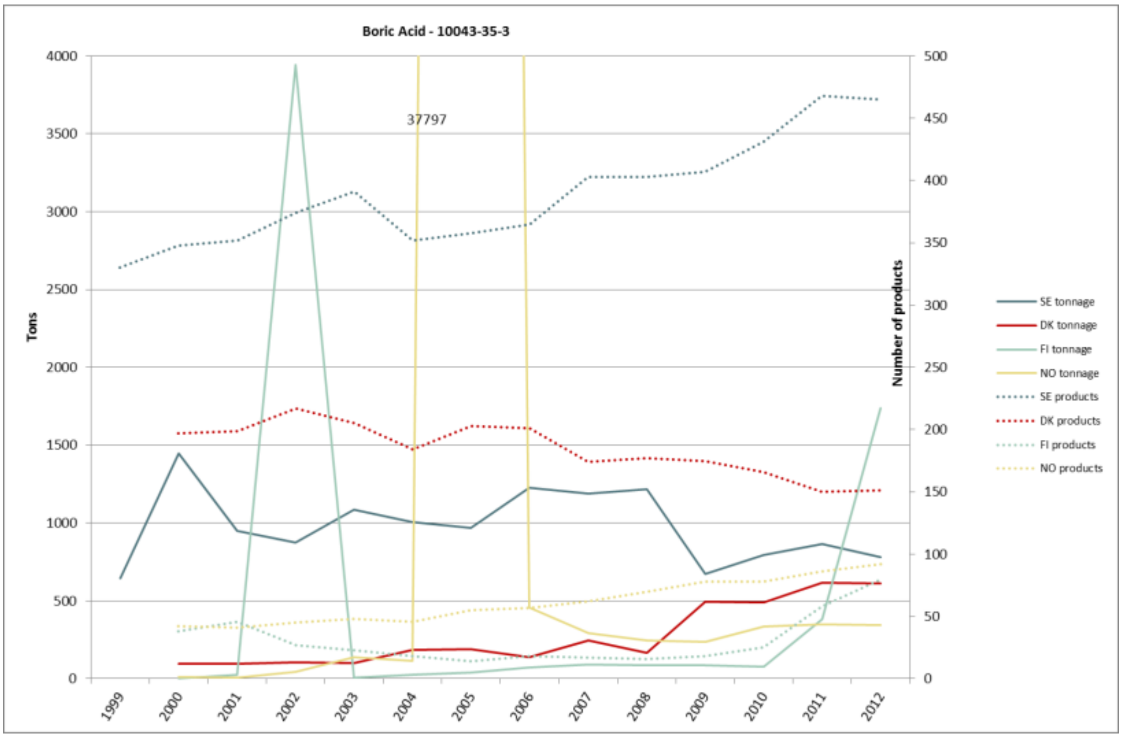


FIGURE 3.1: : REPORTED TONNAGES AND NUMBER OF PRODUCTS PR. YEAR (SPIN, 2014)

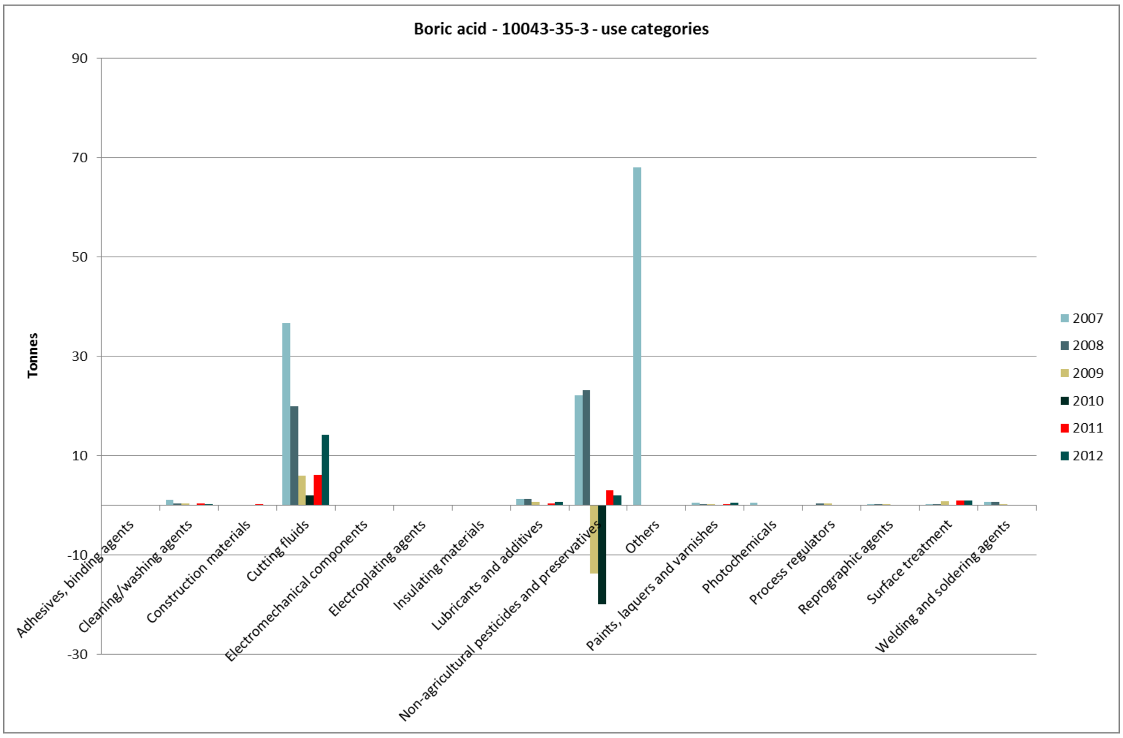


FIGURE 3.2: REPORTED USES OF BORIC ACID IN DENMARK (SPIN, 2014).

As seen from Figure 3.2 the total *identified* uses of boric acid in Denmark in 2012 sums up to around 18 tonnes (the orange bars) which is far below the total use of 610 tonnes. (Negative volumes may be due to export).

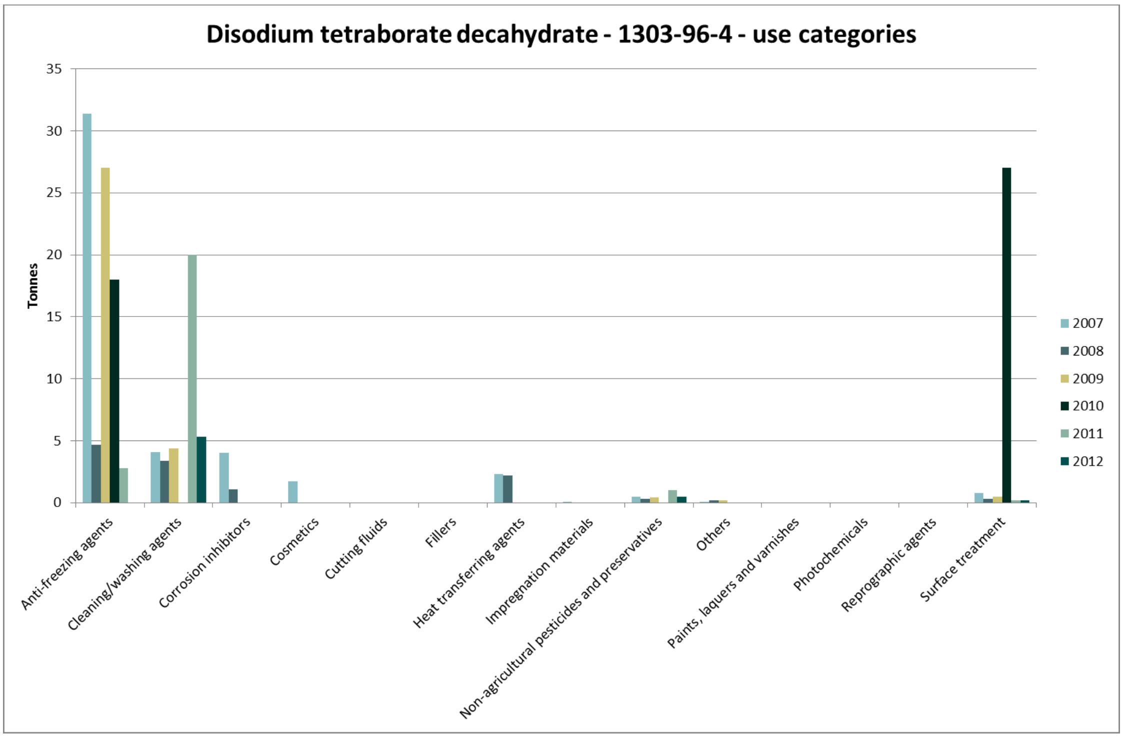


FIGURE 3.3: REPORTED USES OF DISODIUM TETRABORATE DECAHYDRATE IN DENMARK (SPIN, 2014).

In a survey on the use of boric acid and borax in cellulose/paper wool insulation, at least 4 products were found on the Danish market using a content of 3-14% of boric acid and borax in the paper insolation material (Larsen, 2012). This use cannot be seen from the SPIN data.

3.3 Historical trends in use

When considering the tonnage of boric acid (CAS 10043-35-3) which is being used in Denmark, there has been a marked increased during the last decade. In 2000 the tonnage reported was just below 100 tonnes this value remained more or less unchanged until 2003 but increased markedly hereafter. In 2012 the reported tonnage was therefore 610 tonnes. The last few years *cutting fluids* have been reported as the main product group for the use of boric acid. Earlier boric acid was also included in *non-agricultural pesticides and preservatives* (SPIN, 2014)

Disodium tetraborate decahydrate (CAS: 1303-96-4) used to be applied in *antifreeze agents* to a large extent. But since 2005 the use within this group decreased and in 2012 no tonnage was registered for this product group. *Cleaning and washing agents* are now the main product group to apply Disodium tetraborate decahydrate and to a lesser extent *non-agricultural pesticides and preservatives* (SPIN, 2014).

3.4 Summary and conclusions

Boric acid (CAS 10043-35-3) and disodium tetraborate including its various hydrated forms (CAS 1330-43-4) are by far the most widely used boron substances covered in this report as each of these substances are REACH-registered in the use tonnage band of 100,000 - 1,000,000 tonnes per year.

As indicated in Chapter 3 boric acid and borax are used in many industrial processes and for many purposes. The majority of the use (>50%) is in the production of glass products (including glass fibre and glass wool) and ceramics where borate is incorporated into and thus is a part of the glass/ ceramic material. Other uses are in cosmetics and biocides and in various chemical products such as soap and detergents, fertilisers, paint, varnishes, adhesives, electroplating, as catalysts, antifreeze products, lubricants and in cellulose (paper wool) insulation.

In Denmark, there has been a marked increased during the last decade. In 2000 the tonnage reported was just below 100 tonnes; this value remained more or less unchanged until 2003 but increased markedly hereafter. In 2012 the reported tonnage was therefore 610 tonnes. The specific use of nearly 600 tonnes of this volume was not indicated otherwise than “raw material” in the product registry and was thus not further accounted for. About 14 tonnes was used as cooling/lubricating oil for metals. Earlier boric acid was also included in *non-agricultural pesticides and preservatives,* disodium tetraborate decahydrate (CAS 1303-96-4) used to be applied in *antifreeze agents* to a large extent. But since 2005 the use within this group decreased and in 2012 no tonnage was registered for this product group. *Cleaning and washing agents* are now the main product group to apply disodium tetraborate decahydrate and to a lesser extent *non-agricultural pesticides and preservatives*.

Further uses for the substances are as food additives, food supplements, and in food packaging material, as micronutrients e.g. in fertilisers, and in cosmetics.

4. Waste management

4.1 Waste from manufacture and use of borates

Waste generated during manufacturing or from industrial use has according to the EU waste directive and the Danish statutory order on waste to be treated as hazardous waste, if the waste contains substances in an amount that according to classification rules for chemical substances and preparations would result in classification for either physico-chemical, toxicological or environmental properties (Danish MoE, 2012; DIRECTIVE 2008/98/EC).
Waste is considered hazardous if it exhibits one or more of the characteristics listed in Table 1 (Annex 4) of the Danish statutory order on waste (Bek. 1309 of 18/12/2012), as indicated in Table 2 (Annex 4) of the order, where limits in relation to the old classification (SDS) system are given.

Below is indicated the concentration limit in waste for the classification as Repr. Cat 2; R60-61 that has been applied for boric acid and sodium borates. The specific classification limit for these substances is in the range of 3.1% to 8.5% as seen in Table 2.2; however, this is based on an overall specific classification limit of 1% based on the boron content of the substances, thus waste should be considered as hazardous according to:

Repr. Cat. 2; R60-61 C ≥ 1 % (as Boron content)

As discussed in Section 2.2.1, it may be an open question whether these specific classification limits in the range of 3.1%-8.5% would still apply for boric acid and sodium borates in the future as arguments have been put forward to use the generic classification limit for the substances (0.3% in the new CLP system and 0.5% in the old classification system).

4.2 Waste treatment

In the comprehensive reviews on boric acid/borates and boron (ECHA/transitional Annex XV report (2009a+b) and ATSDR 2010), no specific data have been found regarding boric acid/ borates. The ATDSR (2010) provides some data on boron trichloride and trifluoride in relation to waste, but no other information regarding disposal of boron or other boron compounds was located.

Thus no specific concern regarding boric acid/borate in the waste stream has been flagged in these reviews neither in relation to industrial or domestic waste. Thus the description here will as a starting point look at the most important uses in relation to industry and the consumers.

According to Chapter 3 regarding uses of boric acid/borates the substance may enter the waste stream according to the use of the substances in various products and articles .

TABLE 4.1: USES OF BORATES IDENTIFIED WITHIN THE EU (MODIFIED AFTER RPA, 2008)

Product application or industry sector	%	Tonnes
Glass, glass products and ceramics	55.8	334,800
Soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	16.8	100,800
Fertilisers and nitrogen compounds	4.7	28,200
Chemical and fertiliser minerals	2.4	14,400
Paper and paper products (incl. corrugated paper)	1.5	9,000
Basic pharmaceutical products and preparations	1.4	8,400
Wood products (e.g. veneer sheets and wood based panels) except furniture	1.0	6,000
Paints, varnishes, coatings, printing inks and mastics	0.5	3,000
Furniture (e.g. mattresses)	0.1	600
Other chemicals and chemical products: Various chemical processes incl. metallurgy, antifreeze, brake fluids, buffers, wallboards, lubricants	8.2	49,200
Others: Steel slag stabilisation, flame retardants, cellulose insulation, nuclear, electroplating	7.6	45,600
Total	**100**	**600,000**

The overall use of boric acid and borax in the EU as indicated in the table may give a fairly good impression of where to find boric acid and borate in the waste stream. This may also be reflected in the waste stream in Denmark as the products above represent widely used and rather commonly used products.

As indicated in the above section, all types of waste fractions containing boric acid/borax above their specific classification limits (corresponding to a boron content of 1%) should be considered as hazardous waste. Some specific considerations may be mentioned:

Glass
A large fraction of the substances used in products may be found in glass products, including glass fibres.
Glass fibres may contain up to 5% boron (w/w) as diboron trioxide. Glass fibres for insulation contain between 1.5% and 3.6% boron (w/w) (RPA 2008).

In boron containing glass, the boron content has gradually been reduced from 8-10% diboron trioxide to around 5% (1.5% boron); however, the concentration is much higher in some specialised applications.

Some of these special applications may be the use of borosilicate glass for:
· laboratory equipment, including pharmaceutical equipment;
· pharmaceutical packaging material;
· glass fibre insulation material;
· light bulbs (and other electrical lighting);
· textile glass fibre composites (fibre glass);
· enamel frit and other enamelling products;
· glass for liquid crystal display screens (LCDs);
· radiation shielding for the nuclear industry and hospital x-ray equipment;
· solar panels;

· ophthalmic lenses, especially for high prescription eyesight correction; and
· heat resistant glass panels (e.g. in cookers).

RPA (2008)

It could be argued that formalistically glass with higher amount of borate comparable to a boron content of 1% should be considered as hazardous waste. However, it should be recognised that borate is bound into the glass matrix and as such does not have a potential for release. Thus, infrared spectroscopy of various types of boron containing glass has disclosed various boron structures incorporated in the glass matrix. This may be units of: symmetric $(BO_3)_3$– triangles, BO_4^- tetrahedral units, and asymmetric $(BO_3)^{3-}$ units. The pure diboron trioxide glasses consist of BO_3 and BO_4 groups attached together by B-O-B bands where the structure consists of a random network of planar BO_3 triangles with a certain fraction of sixmembered (boroxol) rings. In other mixed types of glass the B-O-B band structures may be replaced by B-O-Metal oxide bands (Gautam et al. 2012). This complexity adds to the view that the inherent properties of borate as bound into a glass matrix may be considered as quite different from the inherent properties of the boric acid/ borate used as raw materials which may support the view that classification of glass waste as hazardous waste based on the content of boron would not make any sense.

Soap and detergents
Soap and detergents are in connection to the intended use mainly released into waste water, but a part of the products may also end up in the waste stream as chemical waste and domestic waste. However, these types of products cannot be sold to the public if they contain boric acid/borax in a concentration that requires classification based on the boron content. However, these products are often classified for irritation which would imply that waste from these products should be considered as hazardous.

Cosmetics
Also cosmetics may end up particularly in domestic use. However, waste from cosmetics would generally not be considered as hazardous. An exception may be some types of bath and hair products which are allowed to contain boric acid/borax in a content exceeding the specific classification limit of the substances.

Cellulose insulation
Waste from insulation material - especially cellulose insulation - may cause concern during handling in the waste stream if not handled properly (by either professionals or consumers) as the insulation material may contain concentrated boric acid/borax powder loosely attached to the surface of the insulation material. Especially older types of cellulose insulation may contain high amounts of boric acid/borax (up to 25%), and thus this type of waste containing higher concentration than 1% of boron should be considered and treated as hazardous waste. Cellulose insulation on the market today cannot be sold to the public if the content of boron is higher than 1%. Thus this type of waste would not be considered as hazardous waste although the waste still would represent a high potential for exposure to concentrated boric acid/borax dust when handled. However, specific data regarding the potential for boric acid/borax exposure in relation to handling waste containing cellulose insulation is not available.

Articles
In relation to waste from various articles such as boron impregnated wood, furniture/mattresses, and paper/cardboard products, it may typically not be known how large a fraction of these types of waste streams that in fact contains boric acid/borate, as it is not known whether these substances have been used in the process of manufacturing.

4.3 Recycling

With respect to possible recycling, handling of the waste and waste treatment it is important to consult the local authorities in the municipality in order to follow their local instructions. Especially for glass products nearly 100% of recycling can be anticipated in Denmark (Danish EPA 2014).

For cellulose insulation waste the use as compost material on green areas has been described on the website by cellulose insulation manufacturers in Denmark. However, according to §10 of the statutory on the use of waste for agricultural purposes (Danish MoE, 2006) and the guidance associated to this (Danish EPA, 2010), such use has to be applied for and an approval has to be given by the local authorities.
If recycling cellulose insulation, consideration should be given to the relatively concentrated surface layer of boric acid/borax dust that impregnates the cellulose material and therefore poses a potential for release and exposure.

It should be noted that the major part of (if not all) coal fly ash in Denmark is used in the production of cement (Hjelmar, 2014). This means that most of the boron in the Danish coal fly ash will be carried over into cement and concrete.

4.4 Incineration and energy production

Ashes from waste incineration and coal energy production contain boron (probably mostly as borates).
The boron content in incinerator bottom ash (IBA) has been measured in several European countries (Belgium, Denmark, France, Ireland, Italy, The Netherlands, Sweden and UK). From a total of 191 measurements, a median value of 183 mg B/kg ash (average = 198 mg B/kg ash) and a 95-percentile value of 401 mg B/kg ash were found (Hjelmar *et al.* 2013). If it is assumed that the average for European IBA is also representative of Danish conditions, then approximately 0.64 million tonnes of IBA produced annually in Denmark (Hjelmar et al., 2012) correspond to a total of 127 tonnes of boron/year. If the IBA is utilised as aggregates or landfilled, some of this boron may eventually be released as part of the leachate produced. Since boron is not a commonly regulated substance in relation to utilisation or landfilling, very little information is available on the leaching of boron/borate from IBA. Data from 1986 indicate that the leaching of B from IBA may be in the order of 2 mg B/kg ash at L/S (liquid to soil ratio) = 2 l/kg and 4 mg B/kg of ash at L/S = 5 l/kg (measured on a mixture of 85% (w/w) IBA and 15% (w/w) fly ash from Vestforbrænding from 1985, VKI (1986). Whether or not this may constitute an environmental problem depends on the specific situation, but since there are quality criteria for the content of boron both in groundwater and surface water, this cannot be totally excluded.

From the database of the *Electric Power Research Institute* (*EPRI*), data on the boron content in coal fly ash indicate a 10 percentile content of 120 mg B/kg and a 90-percentile content of 1000 mg B/kg ash. Other data indicate a median value of 37 mg B/kg ash.

As a very rough estimate the Danish consumption of 5.3 million tonnes of coal per year would result in 335.000 tons coal fly ash. The total content of boron in this amount would then, with the above 90-percentil level of 1000 mg B/kg, contain 355 tonnes of boron. However, if more realistic the average content is considered to be about one order of a magnitude lower.

Leaching experiments from coal fly ash in Denmark have shown leaching of 4 to 17 mg B/kg ash at L/S = 2 l/kg and 9.2 mg B/kg ash and higher at L/S = 10 l/kg (VKI, 1986).

It should be noted that the major part of (if not all) of the coal fly ash in Denmark is used in the production of cement (Hjelmar, 2014). This means that most of the boron in the Danish coal fly ash will be carried over into cement and concrete, and as such it may eventually end up in construction and demolition waste (crushed concrete), from which part of it could potentially be released to the environment by leaching when the crushed concrete is used, e.g. in road construction. However, no data are available on the leaching of boron/borate from crushed concrete.

4.5 Summary and conclusions

No specific concern has been addressed in relation to boric acid/borates in the waste stream. Waste containing more than 1% of boron in the form of boric acid/borates should due to the classification as Repr. 1B be treated as hazardous waste.

A large fraction of borate may end up in the waste stream from glass and ceramics; however, due to transformation and tight binding of borate into the glass matrix the release potential of borate from glass/ceramics is considered very low during handling of waste. Furthermore, glass in the waste stream is to a very high extent recycled.

Cellulose (paper wool) insulation in the waste stream may contain a relatively high content of loosely bound boric acid/borax powder which is highly accessible and thus constitutes a potential for environmental and human exposure. For qualities containing more than 1% of boron (typically qualities sold some years ago) the cellulose insulation should be considered as hazardous waste. Data are lacking on how cellulose insulation today is handled in the waste stream.

A substantial amount of boron (but much less than 1 %) is found in bottom ash from waste incineration and coal fly ash from energy production. Some of the boron may leach to the environment from the ashes or products containing the ashes, depending on how they are managed. The leaching of boron has not been subject to regulation in relation to utilisation or landfilling, although quality criteria for boron exist for both groundwater and surface water.

A major part of (if not all) coal fly ash in Denmark is used in the production of cement. This means that most of the boron in the Danish coal fly ash eventually will end up into cement and concrete.

5. Environmental effects and exposure

5.1 Environmental hazard

Borates are naturally present and widely distributed in the environment and boron is an important - if not essential - micronutrient to many species (plants, algae, fish etc.). The concentration-response curve for boron is therefore likely to be U-shaped for many species, with adverse effects observed at very high and very low concentrations, while no adverse effects are observed at the intermediate concentrations (HERA, 2005).

5.1.1 Toxicity to aquatic organisms

Several studies on the toxicity of boron towards aquatic organisms are available. The table below (Table 5.1) summarises the results from aquatic toxicity studies, which showed the highest toxicity and which were reported in the HERA report (2005) and the ECHA/transitional Annex XV Reports (2009a+b). In the Transitional Annex XV Reports an added risk approach is applied.

TABLE 5.1: AQUATIC TOXICITY OF BORON. VALUE IN BOLD IS APPLIED FOR THE CALCULATION OF THE PREDICTED NO EFFECT CONCENTRATION (HERA, 2005; ECHA, TRANSITIONAL ANNEX XV REPORT, 2009A+B)

Organism	Duration [hours]	Endpoint	Result [mg-B/L]	Reference
Daphnia magna	48	LC50	133-229	HERA, 2005
Daphnia magna	21d	NOEC	6.4-10	HERA, 2005
Daphnia magna	48	LC50	95-133	Transitional Annex XV Report, 2009
Daphnia magna	21d	NOEC	10-32	Transitional Annex XV Report, 2009
Fish	96	LC50	14.2-725	HERA, 2005
Fish (*Brachydanio rerio*)	34d	NOEC LOEC	5.6 18	HERA, 2005
Fish (*Brachydanio rerio*)	34 d	NOEC	**1.8**	Transitional Annex XV Report, 2009
Alge *Chlorella pyrenoidosa*	96	NOEC	10-93	HERA, 2005
Alge *Selenastrum capricornutum*	72	NOEC	17.5	Transitional Annex XV Report, 2009

Organism	Duration [hours]	Endpoint	Result [mg-B/L]	Reference
Alge *Scenedesmus subspicatus*	96	EC50	34	Transitional Annex XV Report, 2009
Rana sylvatica (frog)	23d	NOEC	49.5	HERA, 2005
SSD*	Chronic	HC5**	**3.45**	HERA, 2005

*SSD: species sensitivity distribution

**HC5: Hazardous Concentration 5% (concentration which is protective of 95 % of the organisms)

Toxicity to sediment living organisms

A 28 day study with the sediment dwelling organism *Chironomus riparius* resulting in a NOEC = 180 mg B/ kg dw is available (ECHA, Transitional Annex XV Report (2009).

Predicted No Effect Concentration (PNEC) – Aquatic organisms

Based on the chronic 5th percentile concentration for aquatic species the calculated $PNEC_{aquatic}$ is 3.45 mg-B/L for the aquatic compartment (HERA, 2005).
Applying the $NOEC_{freshwater}$ of 1.8 mg/L for *Brachydanio rerio* and an assessment factor of 10 a $PNEC_{,add.,freshwater}$ of 0.18 mg/L is derived in the ECHA, Transitional Annex XV Report (2009). This value is in accordance with the $PNEC_{freshwater}$ derived in the Assessment Report on disodium tetraborate made for Product type 8 (wood preservatives) (Assessment Report, 2009)

The high natural boron background of approximately 5 mg B/L in the open sea indicates that marine species are likely to be less sensitive to boron toxicity than estuarine or freshwater organisms. In the Transitional report it is therefore assumed that the $PNEC_{freshwater}$ also protects the marine environment (open sea). In contrast to the open sea is not anticipated that the $PNEC_{,freshwater}$ will also protect estuarine species (ECHA, Transitional Annex XV Report, 2009).

Predicted No Effect Concentration (PNEC) – sediment organisms

A calculated $PNEC_{sediment}$ of 3.29 mg B/kg ww is reported for sediment in the HERA report (2005). In the ECHA, Transitional Annex XV Report (2009) a $PNEC_{sediment}$ = 1.8 mg B/kg d.w. is calculated. In the Assessment Report on disodium tetraborate a $PNEC_{sediment}$ of 0.24 mg B/kg ww is reported (Assessment Report, 2009).

5.1.2 Toxicity to microorganisms

Table 5.2 below summarises the result on the toxicity towards microorganisms.

TABLE 5.2: AQUATIC TOXICITY OF BORON TOWARDS MICROORGANISMS (HERA, 2005)

Study	Duration [hours]	Endpoint	Result [mg-B/L]	Reference
Activated Sludge, domestic sewage treatment plant (OECD 209)	3	EC20	112	HERA, 2005;
Activated Sludge, domestic sewage treatment plant (OECD 209)	3	NOEC	17.5	Transitional Annex XV Report, 2009
Photobacterium phosphorum	NA	EC20	18	Transitional Annex XV Report, 2009

Predicted No Effect Concentration (PNEC) – microorganisms

In the HERA document a $PNEC_{STP}$ = 112 mg B /L is reported; the calculations are however not stated in the report (HERA, 2005).

In the Transitional Report a NOEC of 17.5 mg B/L was divided by an assessment factor of 10 to derive a $PNEC_{add, STP}$ of 1.75 mg B/L (ECHA, Transitional Annex XV Report, 2009). This value is in accordance with the $PNEC_{STP}$ derived in the Assessment Report on disodium tetraborate (Assessment Report, 2009).

5.1.3 Toxicity to terrestrial organisms

Several studies on the toxicity of boron towards terrestrial organisms are available. Table 5.3 below summarises the results from these studies.

TABLE 5.3: TERRESTRIAL TOXICITY OF BORON. VALUE IN BOLD IS APPLIED FOR THE CALCULATION OF THE PREDICTED NO EFFECT CONCENTRATION (HERA, 2005, ECHA, ANNEX XV TRANSITIONAL REPORT 2009)

Organism	Duration [hours]	Endpoint	Result	Reference
Eisenia fetida (earthworm)	14d	LC50/NOEC	>175 mg-B/kg dry soil	HERA, 2005
Lumbricus terrestris (earthworm)	14d	LC50 NOEC	501 mg-B/kg dry ref soil; 301 mg-B/kg dry artificial soil 875 (est.) mg-B/kg dry ref soil; 350 (est.) mg-B/kg dry artificial soil	HERA, 2005
Folsomia candida (collembollan)	14d	LC50	248 mg-B/kg dry reference soil	HERA, 2005
Onychiurus folsomi	35d	NOEC	22 mg-B/kg dry reference soil; 44 mg-B/kg dry artificial soil	HERA, 2005; Transitional Annex XV Report, 2009
Folsomia candida (springtail)	28	EC10 Geometric mean EC10	13.8 **15.4**	Transitional Annex XV Report, 2009
Eisenia andrei	56d	NOEC	5.2 mg-B/kg dry artificial soil	HERA, 2005; Transitional Annex XV Report, 2009
Phaseolus vulgaris (field beans)	NA	NOEC	**1.6 mg-B/kg**	HERA, 2005

Predicted No Effect Concentration (PNEC) – terrestrial organisms

A $PNEC_{terrestrial}$ of 0.16 mg-B/kg is reported for the terrestrial compartment in the HERA report for borate (HERA, 2005). Similarly a $PNEC_{add.,terrestrial}$ = 1.54 mg B/kg soil is derived in the Transitional Annex XV reports (2009) which is based on the geometric mean of the most sensitive endpoint of the most sensitive species (juvenile production, *Folsomia candida).* The assessment report on disodium tetraborate reports a higher value of 0.4 mg B/kg dw. and 0.35 mg B/kg ww . (Assessment Report, 2009).

5.2 Environmental fate

5.2.1 Bioaccumulation

Boric acid has a low measured P_{ow} value (Log P_{ow} = -1.09). However for inorganic chemicals, estimates of bioaccumulation potential are not reliably predicted by octanol/water partitioning data. The available data (i.e. reported BCF values of 0.7 to 1.4 L/kg for Pacific oysters (*Crassostrea gigas*); reported BCF < 0.1 in Chinook salmon fed boron-supplemented diets for 60 to 90 days) indicate that borates are not significantly bioaccumulated (ECHA, Transitional Annex XV Report, 2009).

5.2.2 Environmental degradation

Boron is a naturally occurring element and is not biodegradable. However, boron and inorganic boron-salts undergo chemical transformations.

Water

In the aquatic environment borates will form un-dissociated boric acid (H_3BO_3) and the borate anion. Their solubility defines that borates will be diluted and dispersed throughout the aquatic environment ultimately reaching the sea (HERA, 2005).

Hydrolysis

Hydrolysis is not a relevant degradation pathway since boron is inorganic and does not have chemical bonds which can undergo hydrolysis (ECHA, Transitional Annex XV Report, 2009).

Photochemical degradation

Boric acid is considered to be resistant to photochemical degradation (ECHA, Transitional Annex XV Report, 2009).

Sediment

There is some evidence that water-soluble borates have a slight tendency for adsorption to sediment particles, depending e.g. on pH, organic matter content and the number of active adsorption sites (HERA, 2005).

Soil

There is some evidence that water-soluble borates have a slight tendency for adsorption to soil depending e.g. on pH, organic matter content and the number of active adsorption sites (HERA, 2005).

Air

The vapour pressure for boric acid is very low; therefore volatilisation is expected to be minimal (HERA, 2005). The exception is over the oceans, where evaporation of aerosols leads to small but measured quantities of boric acid vapours in the marine atmosphere (ECHA, Transitional Annex XV Report, 2009).

5.2.3 PBT

The general criteria for performing a PBT assessment are described in the ECHA Guideline R.11 (ECHA, 2012). Based on these criteria it can be concluded that:

Boron is an inorganic element and does not biodegrade.

Measured BCF factors (BCF << 2,000) indicate no potential for bioaccumulation (B).

Boric acid/borates are classified as Repr. 1B, H360Df (May damage fertility. My damage the unborn child) and therefore the substances fulfil the criteria for toxicity (T).

Boric acid/borates therefore do not fulfil the criteria for PBT or vPvB.

(ECHA, Annex XV Transitional Report, 2009; Assessment Report, 2009).

5.3 Environmental exposure

5.3.1 Sources of release

Boron is present in the environment from both natural and anthropogenic sources. Anthropogenic sources include boron due to use of boric acid in detergents and boron from use of perborates in cleaning and laundry products, all products which are disposed of to the sewage system after use (HERA, 2005).

5.3.2 Monitoring data

There are some areas in Europe where boron levels are high due to local geological conditions. Furthermore, rainwater carrying boron from adjacent oceans may contribute boron to surface waters. An analysis of the concentration of boron in European rivers is summarised in **Fejl! Henvisningskilde ikke fundet.** below. The data was collected at river sites specifically intended to monitor the effects of inputs from sewage works and other anthropogenic discharges. In this study the average 95th percentile for every monitoring point is reported as "Mean 95 percentile". The mean concentrations reported are in the range 3.3-367 µg B/L; however the range of measurements are from below detection limit (nd.) to 7,490 µg B/L (HERA, 2005; ECHA, Annex XV Transitional Report, 2009).

Monitoring data (1996-1998) from 4 UK-rivers report boron concentrations in the range of 20-530 µg B/L (mean 90th percentile: 283-442 µg B/L). Background concentrations were reported as negligible; however in one river an excess of 100 µg B/L was reported (HERA, 2005; ECHA, Annex XV Transitional Report, 2009).

Furthermore, monitoring data from the Foregs Geochemical Baseline Programme are presented graphically in Figure 5.1 (ECHA, Annex XV Transitional Report, 2009).

TABLE 5.4: MONITORINGDATA DATA ON BORON CONCENTRATIONS (µG B/L) IN EUROPEAN RIVERS (HERA, 2005; ECHA, ANNEX XV TRANSITIONAL REPORT, 2009)

Country	Monitoring points	Time period	Total No. Values	Arithmetic Mean [µg B /L]	Range [µg B/L]	Mean site 95% percentile [µg B/L]
Austria	30	1998-2000	712	44	nd-690	80
Belgium	651	1998-2000	5,056	239	25-2,029	410
Denmark	0	-	-	-	-	-
Finland	463	1995	463	3.3	<1-46	44

Country	Monitoring points	Time period	Total No. Values	Arithmetic Mean [µg B /L]	Range [µg B/L]	Mean site 95% percentile [µg B/L]
(lakes only)						
France	25	1995-2000	1,304	146	nd-2,670	261
Germany	197	1980-95	197	171	nd-1,300	632
Greece	28	1997-99	Not known	144	4-2,330	-
Luxembourg	0	-	-	-	-	-
Ireland	185	1999-2000	185	26	nd-1,630	101
Italy	64	1998-1999	926	114	nd-894	84
Netherlands	9	1986-1999	1,842	111	38-878	218
Portugal	8	1999-2000	129	367	30-3,860	534
Spain	328	1991-2000	4,272	137	nd-7,490	288
Sweden	0	-	-	-	-	-
UK-England	98	1974-2000	22,329	65	nd-1,121	95
UK-Northern Ireland	0	-	-	-	-	-
UK-Scotland	10	1976-1997	3,437	9.7	nd-230	17
UK-Wales	39	1975-1999	4,965	13.0	nd-292	22

The majority of the available monitoring data for the aquatic compartment are above the $PNEC_{,add.,freshwater}$ of 0.18 mg/L which was derived in the RCHA, Transitional Annex XV Report (2009). The fact that the concentrations in the water environment most often exceed the derived PNEC value reflect that boron is a natural occurring element with a relatively high natural background concentration compared to the PNEC, which is also the justification for using an added approach in assessment of risks in the aquatic compartment. The available monitoring data often represent sites influenced by anthropogenic discharges. Thus the data reflect local sources as well as the natural background levels caused by the geological conditions.

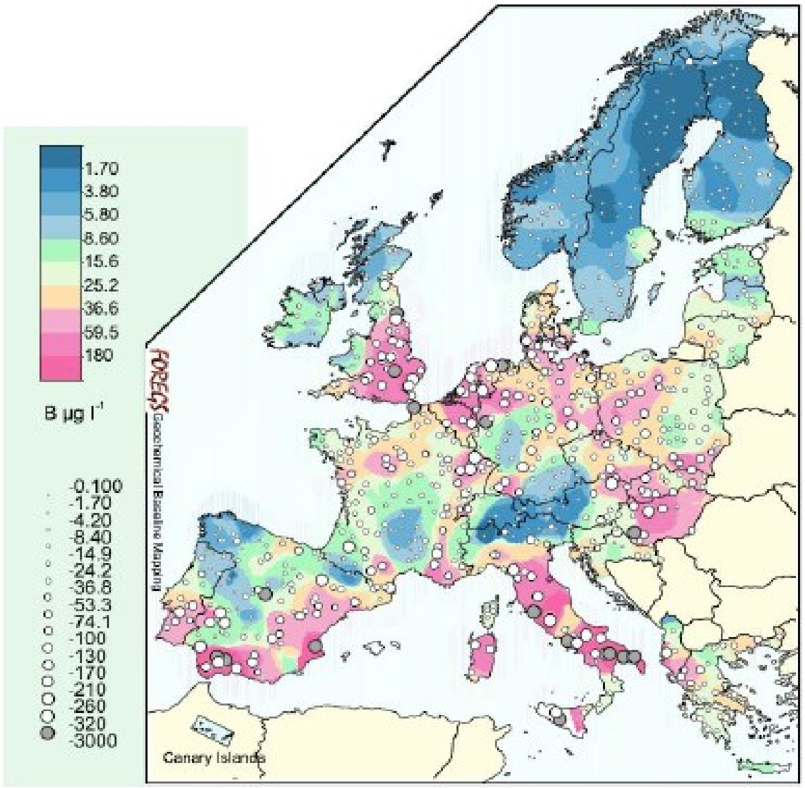


FIGURE 5.1: MONITORING DATA. BASELINE B-LEVELS (DISSOLVED) IN EUROPEAN SURFACE WATERS (FIGURE TAKEN FROM FOREGS GEOCHEMICAL BASELINE PROGRAMME) (ECHA, ANNEX XV TRANSITIONAL REPORT, 2009).

Sediment

No monitoring data are available.

In the HERA report an estimated PEC-sediment of 0.0080 mg-B/kg for the Regional PEC, 0.0033 mg-B/kg for the Continental PEC and 0.96 mg-B/kg for the Local area was calculated applying EUSES (HERA, 2005).

Air

The major source of boron in the atmosphere is from marine evaporation. Most of this is re-deposited into the oceans or as precipitation in coastal areas. The estimated value is presented in Table 5.5 together with the estimates for volcanic emissions and emissions from industry (HERA, 2005).

TABLE 5.5: ESTIMATED RELEASES OF BORON TO THE ATMOSPHERE (KG-B/YEAR) (HERA, 2005)

Source	Amount [kg-B/year]
Marine evaporation	1.3 to 4.5 * 10^9
Volcanic emission	3 * 10^8
Industry	1 * 10^7

Measurement of atmospheric boron levels from the analysis of rain water has shown levels of 0.002 to 0.0045 mg-B/L reported for France and 0.1 mg-B/L reported for Japan (HERA, 2005).

Effluent
Boron compounds are released to water in municipal sewage from perborates in detergents and in waste waters, from coal-burning power plants, copper smelters, and industries using boron. Borate levels above background may be present in runoff waters from areas where boron-containing fertilisers or herbicides were used (ATSDR, 2010). Most boron is not removed by conventional sewage treatment, and treated effluent will be discharged into surface waters or possibly as irrigation water. However, a fraction of the boron which is contained in sewage water will adsorb to and be removed with sewage sludge. Results of boron concentrations in sewage sludge from a study of 48 sewage treatment plants in Sweden showed a mean concentration of 61 kg-B/kg dw sludge and concentrations ranging from 2-391 mg/kg dw sludge.

In Europe reported levels of boron in sewage water are within the range 0.22-2.86 mg B/L (HERA, 2005). In Denmark (2011) an average concentration of 300 µg B/L was reported in the outlet from sewage treatment plants. The maximum concentration reported was 1,700 µg B/L (DCE, 2012). The PEC_{STP} estimated derived using EUSES and arising from use of boric acid in liquid detergents is 0.044 mg-B/L (HERA, 2005).
An average boron concentration of 1 mg/L was reported in sewage effluents in California. Furthermore, the boron concentrations in municipal sewage in a treatment plant in England was reported within the range 2.5 to 6.5 mg/L, releasing between 130 and 240 kg boron/day. Concentrations reported for a Dutch sewage treatment plant in 1994 were 0.41–1.2, 0.39–0.96, and 0.44–1.0 mg/L in raw sewage, settled sewage, and effluent, respectively. These data demonstrate that boron passes through the sewage treatment process virtually unchanged. Since boron cannot be degraded and is not substantially absorbed during processing, there is almost no removal during the sewage treatment process (ATSDR, 2010).

Soil
There is a natural level of boron in the soil derived from boron-bearing rocks as well as from decomposition of soil organic matter. The world-wide range is reported as 45 to 124 mg-B/kg soil. Boron may also be introduced into soils by the use of irrigation water containing sewage effluent with its associated boron. The extent to which sewage effluent is used for irrigation of agricultural crops within Europe has not been determined. However, it is anticipated that higher use will be in Southern European countries rather than in Northern Europe. Boron is mobile with water in soils, and in wetter areas boron is therefore unlikely to accumulate in soils, but will move with surface and groundwater flows. Accumulation is likely in dry soils where water evaporates leaving the boron to accumulate. The EUSES estimate of $PEC\text{-}_{soil\ porewater}$ associated with liquid detergent products was 0.016 mg-B/L (HERA, 2005).

Storage of treated wood after industrial treatment, in-service life and in-situ treatment of wood will result in a release of boron to soil (Assessment Report, 2009).

Ground water

MEASURED VALUES OF BORON IN GROUNDWATER ARE PRESENTED IN THE

Table 5.6 below. The ambient concentrations of boron in groundwater are highly variable and significantly influenced by geological sources (ECHA, Annex XV Transitional Report, 2009).

TABLE 5.6: REPORTED MEASURED CONCENTRATIONS (MG/L) OF BORON IN GROUND WATER (ECHA, ANNEX XV TRANSITIONAL REPORT, 2009)

Country	Number of locations	Numbers of data points	Concentration	Max concentration
France	1,589	11,499	Generally <0.5 mg B/L	1.3 mg B/L (urban area)
Italy	2,632	3,158	Low* (northern Italy)	>10 mg B/L (east Italy)
Cyprus	734	1,016	1-9 B mg/L (Igneous rocks containing glassy lavas) 2-8 mg B/L (Sedimentary rocks (chalks, chalky marls and gypsum))	

*not further elaborated in the report

In Denmark the quality criteria for boron in groundwater is 300 µg/L and the quality criteria for drinking water is 1,000 µg/L (indicative drinking water criteria is 300 µg/L).
In 2012, the drinking water criterion for boron (1000 µg/L) was exceeded in 3 wells out of 1,572, in eastern Zealand (Glostrup) and on Bornholm. All three intakes have also had a high level of boron in the analyses back in 2005. The indicative drinking water criterion of 300 µg/L was exceeded in 78 wells in 2012 (GEUS, 2013).

5.3.3 Calculated Predicted Environmental Concentrations (PEC)

PEC from use of boron in detergents

Predicted Environmental Concentrations (PECs) were calculated applying the EUSES model and reported in the HERA report (2005). Estimates were based on the use of boron in detergents and are shown in Table 1 of Appendix 3. For detailed information on the calculations, please consult the HERA report.

In the ECHA, Annex XV Transitional Report (2009) the local environmental exposure concentrations (STP, water and sediment) are calculated as generic "reasonable worst-case" exposure assessment based on modelling, to derive an EU environmental concentration (Table 2, Appendix 3). Furthermore, measured data, i.e. site-specific or monitoring information, are used to revise the calculated concentrations (Table 3, Appendix 3) according to the EU Technical Guidance Documents EUSES.

High PEC-values were estimated for the water compartment. Especially high were the values calculated for "Industry sector: Borosilicate, IFG/TFG and Ceramics" and "Life cycle stage: industrial use" (*generic approach*: $PEC_{add.\ water}$ = 4,561 µg/L; 4,834 µg/L and 5,907 µg/L respectively and *site specific approach*: $PEC_{add.\ water}$ = 16,262 µg/L; 5,834 µg/L and 9,800 µg/L respectively). The lowest value was found for Industry sector: cleaners and life cycle stage: formulation ($PEC_{add.\ water}$ = 124 µg/L).

The values calculated for the STP and sediment compartment were generally in the same range. The highest PEC values were found for the same industry sector and life cycle stages which were identified for the water compartment:

STP:

Generic approach: PEC_{STP} = 45 µg/L; 48 µg/L and 58 µg/L, and *site specific approach*: PEC_{STP} =162 µg/L; 57 µg/L and 97 µg/L for borosilicate, IFG/TFG and Ceramics respectively.

Sediment:
Generic approach: $PEC_{sediment}$= 33 µg/L; 35 µg/L and 43 µg/L, and *site specific approach*: PEC_{STP} =115 µg/L 42 µg/L and 70 µg/L for borosilicate, IFG/TFG and Ceramics respectively.

5.4 Environmental impact

The risk is expressed by the calculation of a risk characterisation ratio (RCR):

RCR = PEC/PNEC,

Where a RCR below 1 indicates no risk to the compartment and a RCR above 1 indicates that risk is to be expected.

Based on the EUSES estimates for the predicted environmental concentration and the PNEC values derived in the HERA report a RCR has been calculated for the use of liquid detergents (Table 4, Appendix 2). As indicated below all the calculated RCR values are below 1 indicating no risk due to the use of boron in liquid detergents.

Furthermore, in the ECHA, Annex XV Transitional Report (2009) the RCR has been calculated for the use of boron within different industry sectors and for different life cycle stages (Tables 5 and 6, Appendix 3).
These calculations show a high concentration in the water compartment compared to sediment and STP. Also as expected, the industry sectors resulting in the highest PEC values (borosilicate, IFG/TFG and ceramics) also result in the highest risks (RCR).

In the report an added approach is applied for the risk assessment. In essence this approach assumes that species are fully adapted to the natural background concentration, and therefore that only the anthropogenic added (add.) fraction should be regulated or controlled. In contrast the total risk assessment assumes that "exposure" and "effects" should be compared based on the combined exposure from the natural background in addition to the added anthropogenic concentrations. The Predicted No Effect Concentration (PNEC) and Predicted Environmental Concentration (PEC) is therefore reported as $PNEC_{add}$ and PEC_{add}.
As preliminary conclusions it is indicated that for sewage treatment plants (STP), surface water and sediment, nearly all RCR ratios are above 1, indicating a risk. This risk also includes the use of boron in detergents and cleaners (ECHA, Annex XV Transitional Report, 2009).
The report concludes that this preliminary assessment has to be refined by industry in the REACH registrations reports.

5.5 Summary and conclusions

Several studies on the toxicity of boron towards aquatic and terrestrial organisms are available. Data do not indicate a high toxicity.

Boric acid is an inorganic compound and not degradable, i.e. not subject to hydrolysis, photodegradation or biodegradation. Boron and its inorganic compounds are subject to chemical transformation processes (adsorption, complexation, precipitation, and fixation) once released to the environment.

The criteria for persistency cannot be assessed with the traditional endpoints as they are not relevant for inorganic substances. Boron should be considered as fulfilling the criteria for Toxicity (Boron is classified as Repr. 1B), but not for Bioaccumulation. Therefore boron is not a PBT or a vPvB substance.

Ambient concentrations of boron are highly variable and significantly influenced by geological sources. Furthermore, concentrations are reported higher for urban areas influenced by anthropogenic sources.

According to the HERA (2005) report no risk can be identified towards environmental compartments from the use of liquid detergents. However, in the Annex XV Transitional Report risk was indicated in scenarios with sewage treatment plants (STP), and in water and sediment in individual local scenarios with industrial uses of boron, including detergents and cleaners. This assessment reflects generic “reasonable worst-cases” and need be refined, e.g. in the REACH registration report based more detailed data.

6. Human health hazard

Below in Section 6.1, the hazardous properties of borates are described. The description is mainly based on the following reports:

ECHA/transitional annex XV report (2009a). Boric acid (Boric acid crude natural) CAS No: 11113-50-1 (10043-35-3) EINECS No: 234-343-4 (233-139-2) ANNEX XV TRANSITIONAL REPORT

ECHA/transitional annex XV report (2009b). Disodium tetraborate anhydrous CAS No: 1330-43-4 EINECS No: 215-540-4 ANNEX XV TRANSITIONAL REPORT.

ECHA/RAC opinion (2010b). Annex 1 to the opinion on new scientific evidence on the use of boric acid and borates in photographic applications by consumers. Background Document.

EFSA (2013). Opinion of the Scientific Panel on the re-evaluation of boric acid (E 284) and sodium tetraborate (borax) (E 285) as food additive. The EFSA Journal (2013) 11(10): 3407, 1-52

EFSA (2004). Opinion of the Scientific Panel on Dietic Products, Nutrition and Allergies on a request from the Commission related to the tolerable upper intake level of Boron (Sodium Boprate and Boric acid). The EFSA Journal (2004) 80, 1-22

SCCS (2010a). Opinion on boron compounds. Scientific Committee on Consumer Safety. 22 June, 2012. SCCS /1249/09. 1-28.

Directive 98/8/EC (2009). Concerning the placing biocidal products on the market. Assessment report, Disodium tetraborate, Product-type 8 (Wood preservative). 20 February, 2009. Annex I – the Netherlands.

The information reported in this section is also based on the information registered under REACH (Reach Registration data, 2013). There might be more recent studies conducted since publication of the above mentioned reports.

6.1 Hazards

As described in section 2.1.1, boric acid and sodium borates are harmonised classified as Repr. 1B; H360FD (May damage fertility. May damage the unborn child).

6.1.1 Absorption, Distribution, Metabolism and Excretion

Available toxicokinetic data show that boron compounds (boric acid, boron oxide and sodium borates) behave similarly in rats and humans with respect to absorption, distribution, and metabolism. Difference between rats and humans is seen in terms of elimination, the difference relates to renal clearance, with the renal clearance in rats being approximately 3-4 times faster than in humans.

Absorption
Data from experimental animal studies (rat, rabbit, sheep and cattle) and human volunteer studies show that boron compounds are readily absorbed orally (approximately 100%) as seen from the levels of boron found in urine, blood and tissue. In humans, boron compounds are absorbed from the gut.

In animal studies, inhaled boron oxide aerosols were readily absorbed, as seen from the increased levels of boron excreted in the urine following inhalation exposure. In humans, studies on occupational dust exposure to borates (borax) have shown that boron can be found in blood and urine. As a worst-case assumption, inhalational absorption of 100% is used as default in risk assessment (ECHA/transitional annex XV report (2009a)) (ECHA/ RAC opinion (2010b)).

Dermal absorption of boron compounds is considered very low (< 0.5%) except through mucus membranes and severely damaged skin (ECHA/transitional annex XV report (2009a)) (ECHA/ RAC opinion (2010b)). SCCS states in their latest opinion on boron compounds that in terms of safety evaluation, absorption of 0.5% is to be used for boron compounds (SCCS, 2010a).

Distribution
In animals and humans, absorbed boron compounds rapidly distribute in the body and appear in the blood (mostly in plasma), body tissues (liver, muscle, colon, testis, epididymis, seminal vesicles, prostate, adrenals) and other organs (EFSA, 2013). Studies have shown that boron compounds can cross human placenta and can be present in breast milk (EFSA, 2013).

Metabolism
Boron compounds are not metabolised and exist mainly as boric acid in whole blood under physiological conditions.

Excretion
Regardless of the exposure route, boron compounds are excreted exclusively in the urine. Renal clearance is different in animals and humans based on a body weight comparison, and in rats the clearance is 3-4 times faster compared to humans. In humans, clearance is slightly faster in pregnant women. Excretion of boron compounds is relatively fast with a half-life of elimination of < 24 hours.

Overall, the toxicokinetic profile for animals and humans in terms of absorption, distribution, and metabolism is very similar. A difference in renal clearance is the major determinant in the differences between animals and humans, with the renal clearance in rats approximately 3-4 times faster than in humans. Absorption of borates via the oral route is nearly 100%. For the inhalation route also 100% absorption is assumed as worst case scenario. Dermal absorption through intact skin is very low. For risk assessment of borates a dermal absorption of 0.5% is used as a realistic worst case approach. In the blood, boric acid is the main species present. Boric acid is not further metabolised. Borates are distributed rapidly and evenly through the body, with concentrations in bone 2 – 3 times higher than in other tissues. Boric acid is mainly excreted in the urine. Boron is excreted rapidly, with elimination half-lives < 24 hours in humans.

6.1.2 Acute toxicity
In general, the boron compounds are of low acute toxicity after oral, dermal and inhalational administration in experimental animals.

For the boron compounds (boric acid and sodium borates), the following experimental data can be concluded (ECHA/transitional annex XV report (2009a)):
LD50 oral rat > 2000 mg/kg (489-659 mg B/kg)
LD50 dermal rat >2000 mg/kg (226-350 mg B/kg)

LC50 inhalation rat > 2 mg/l (300-371 mg B)/m3)

In humans, acute poisoning can occur after oral and inhalation exposure as well as after dermal exposure via damaged skin. A human oral lethal dose is quoted to be 2-3 g boric acid for infants, 5-6 g boric acid for children, and 15-30 g boric acid for adults (ECHA/RAC opinion (2010b).
This may be the reason that some of the sodium borates have been classified as Acute Tox4; H302 in the company notifications to ECHA.

6.1.3 Irritation

Skin: studies in rabbits using a dose level of 0.5 g showed that boric acid, sodium tetraborate decahydrate and sodium tetraborate pentahydrate do not cause skin irritation when applied to the intact or abraded skin. Hence, boric compounds (boric acid and borates) are not skin irritants (ECHA/ transitional annex XV report (2009a)).

Eye: data from experimental animal studies (rabbit) show that boric acid induced conjunctivae redness and chemosis and minor effects on the iris of the eye. The effects were reversible within 7 days. Therefore, no classification is indicated. Results from tests carried out with disodium tetraborate pentahydrate and decahydrate fulfil the criteria for classification as eye irritant (Eye Irr. 2; H319 or Eye Dam 1; H318). Based on read across from disodium tetraborate pentahydrate and disodium tetraborate decahydrate, disodium tetraborate anhydrous should also be classified as eye irritant (Eye Irr. 2; H319 or Eye Dam 1; H318) as used in several notifications.
In humans, acute irritant effects on the eye are well documented in human workers exposed to borates (ECHA/transitional annex XV report (2009a)).

Respiratory tract: In acute experimental animal studies (rat) with disodium tetraborate (pentahydrate & decahydrate) and boric acid, the effects observed were ocular and nasal discharge, hunched posture and hypoactivity. In mice, a 20% reduction of the respiratory rate was observed from inhalation of boric acid (300 mg/m3) and it was based on this response concluded that boric acid acts as sensory irritant.

In humans, acute irritant effects are well documented in surveys of human workers exposed to boric acid and borates; symptoms include nasal and eye irritation, throat irritation, cough, and breathlessness. However, only one company notification to ECHA uses a classification with STOT SE3; H335.

Based on occupational data from boron mining and processing plants, a NOEC value of 0.4 mg B/m^3 for acute irritant was established leading to a final NOEC of 0.8 mg B/m^3 (The value has to be corrected by a factor 2 as the methods used for exposure measurements underestimated air concentrations). At higher levels, dose-related effects such as nose, eye and throat irritation, sneezing, nose bleeds, coughing and breathlessness, phlegm production and broncho-constriction were observed (ECHA/transitional annex XV report (2009a)).

Using the NOEC of 0.8 mg B/m^3, an acute inhalational DNEL can be derived without using assessment factors (human data, NOEC value, worker) (ECHA/transitional annex XV report (2009a+b):

DNEL worker, acute, inhalational, local= 0.8 mg B/m^3

Overall, boric acid and borates are eye and respiratory tract irritants. In humans, borates act as respiratory sensory irritants, and a NOEC of 0.8 mg B/m^3 has been established leading to a DNEL for acute inhalational worker exposure of 0.8 mg B/m^3.

6.1.4 Sensitisation

Concerning the skin sensitisation potential of boron compounds (boric acid and sodium borates), data from experimental animal studies using the Buehler test (OECD 406) show no indication of sensitisation.

In humans, no evidence of skin sensitisation in humans exposed occupationally to boron compounds (boric acid and sodium borates) has been reported.

Thus, boron compounds (boric acid and sodium borates) are to be considered neither skin nor respiratory sensitisers.

6.1.5 Repeated dose toxicity

Several repeated dose toxicity studies are available for boron compounds (boric acid and borates) where animals are exposed via the oral route (diet or drinking water). The available subchronic and chronic studies were carried out in rats, mice and dogs. The adverse effects of boron seem to be related to haematological effects and testis lesions indicating that the main target organ of boron toxicity is the testis. The key studies are summarised below.

Inhalation

No experimental animal studies available.

Few human inhalation studies exist evaluating the effects from repeated boron exposure. Effects from exposure to borax dust occupationally relate to alopecia, insomnia, headache, erythema and desquamation with verification of boron in the urine.

Oral

The available repeated dose toxicity studies in rats, mice and dogs (30 days to two years studies) on boric acid or disodium tetraborate decahydrate in the diet or via drinking water are of varying quality, but most studies support that boron can cause adverse hematological effects and that the main target organ of boron toxicity is the testis. Treatment with boric acid and disodium tetraborate decahydrate has shown to disrupt spermiation, induce degeneration of testicular tubules and to cause testicular atrophy. In relation to effects on the blood system: extramedullary haematopoiesis, reduced red cell volume and hemoglobin values, and deposition of haemosiderin in spleen, liver and proximal tubules of the kidney have been described (ECHA/transitional annex XV report (2009a)).

The key studies identify NOAEL values from 90-day toxicity studies in the range of 71- 98 mg B/kg bw/day in mice in relation to degeneration and atrophy of the seminiferous tubules and extra medullary haematopoiesis of the spleen. In rats a NOAEL of 8.8 mg B/kg bw/day was found in a 90-day study in relation to body weight reduction, clinical signs of toxicity, and testicular atrophy. In 2 year studies in rats the NOAEL was 17.5 B/kg bw/day in relation to body weight reduction, clinical signs of toxicity; testicular atrophy, reductions in red cell volume and haemoglobin.

Using disodium tetraborate decahydrate (drinking water), a LOAEL of 25 mg B/kg bw/day was identified from 30-60 days repeated dose toxicity studies in rats, in relation to reductions in testes and liver weights, significant reduction in epididymal weight and significant loss of germinal elements and testicular atrophy. In 2 year studies in rats (diet) the NOAEL was 17.5 B/kg bw/day in relation to body weight reduction, clinical signs of toxicity; testicular atrophy, reductions in red cell volume and haemoglobin.

The key study identified is the 2 year study in rats using boric acid and disodium tetraborate decahydrate in the diet. The details for this study are summarised below.

Weanling Sprague-Dawley rats (dose groups: 35 males/females, control group 70 males/females) received boric acid and disodium tetraborate decahydrate (0, 117, 350, or 1170 ppm, equivalent to 0, 5.9, 17.5, or 58.5 mg B/kg bw/day) in the feed. Decreased red cell volume and haemoglobin were observed in boric acid and disodium tetraborate decahydrate treated rats, mainly at the high dose levels. At the highest dose level with both boric acid and disodium tetraborate decahydrate, testicular atrophy and seminiferous tubule degeneration were observed at 6, 12 and 24 months. Microscopic examination of the tissue revealed atrophied seminiferous epithelium and decreased tubular size in the testes. No effects were observed in the control and low dose groups.
A NOAEL of 17.5 mg B/kg bw/day was derived based on the effects of boron seen, i.e. the clinical and hematological effects and the testicular atrophy observed at the highest doses tested (58.5 mg B/kg bw/day).

Repeated oral exposure of humans to boric acid and borax results in various symptoms, which may appear singly or together, and include dermatitis, desquamation of the skin, alopecia, loss of appetite, nausea, vomiting, diarrhea, menstruation disorders, anemia and focal or generalized central nervous system irritation or convulsions. The most common effect seen from human poisoning cases is anemia, generally seen at relatively high concentrations.

Dermal
No experimental animal studies available

Effects in humans from repeated dermal application have been described from several poisoning cases after treatment of burned or abraded skin. No data on the exact doses for the dermal application were found, but described effects are nausea, emesis, diarrhea, erythema, exfoliation of the skin, and convulsions. In many cases of diaper dermatitis and severe burns, treatment with boric acid and borax resulted in respiratory depression, cyanosis and death of the patients.

Overall, several repeated dose toxicity studies performed in rats, mice and dogs are available for boron compounds (boric acid and borates) where animals are exposed via the oral route (diet or drinking water). The adverse effects of boron seem to be related to haematological effects and testis lesions indicating that the main target organ of boron toxicity is the testis. A NOAEL of 17.5 mg B/kg bw/day was derived based on the effects of boron seen (clinical and hematological effects and testicular atrophy were observed at 58.5 mg B/kg bw/day).

6.1.6 Mutagenicity

Overall, none of the references used for this review indicate concern in relation to boric acid and borates for any genotoxic potential *in vitro* and *in vivo* (gene mutation, chromosomal aberrations, micronuclei, sister chromatide exchanges, and unscheduled DNA synthesis.

6.1.7 Carcinogenicity

Boron compounds (boric acid and sodium borates) have been tested with respect to carcinogenicity in long-term studies in mice, rats and dogs.

In a 2-year key study (50 animals per sex per group), B6C3F1 mice were fed a diet containing 0, 2500, 5000 ppm boric acid equivalent to dose levels of 0, 446 (75 mg B) and 1150 mg boric acid (200 mg B)/kg bw/d. No evidence of carcinogenicity was found (ECHA/ transitional annex XV report (2009a)).

In rats, no carcinogenic effects were observed in 2-year feeding studies on boric acid and disodium tetraborate decahydrate. Also in Beagle dogs, no carcinogenic effects were observed in a chronic study (only 1-2 animals/sex/dose/time were examined).

All these studies were, however, not carried out according to modern standards (number of animals examined) or to GLP (ECHA/ transitional annex XV report (2009a)) (EFSA, 2013).

Based on the studies described above, SCCS (2010a) in their expert evaluation were not able to evaluate the carcinogenic potential, whereas ECHA/RAC (2010) concluded that there was no indication of carcinogenic concern for humans. This was in line with the evaluation by EFSA (2013) concluding that no evidence of carcinogenicity was seen from oral exposure of rats and mice to boron compounds (EFSA, 2013).

Overall, there seems to be no concern for a carcinogenic potential for boric acid and sodium borates.

6.1.8 Reproduction and Developmental toxicity

The reproductive effects of boron (boric acid and borates) have been examined thoroughly in experimental animal studies (rat, mice and dog) using oral dosing. Effects on fertility were seen across species in terms of testicular lesions, more pronounced in rat and mice as studies in dogs were questionable due to insufficient dose levels and animal numbers. Overall, effects on the testis have been observed in both subchronic and chronic studies in three species: rats, mice and dogs. Further, a three generation study in rats and a continuous breeding study in mice showed effects on male and female fertility. The key studies are summarised in Table 6.1 below.

TABLE 6.1: KEY REPRODUCTIVE TOXICITY STUDIES WITH BORIC ACID AND BORATES (BORAX) (ECHA/ TRANSITIONAL ANNEX XV REPORT (2009A))

Route of exposure	Species	Exposure period	Doses (mg B/kg bw/day)	Critical effect	NOAEL Parent animals	NOAEL 1.genration litter	NOAEL 2.genration litter
Oral in diet	Rat	14 weeks pretreatment then through three generations (3 generation study)	0, 5.9, 17.5 and 58.5 mg B/kg bw/day (Boric and Borates)	Top dose level caused testes atrophy prior to first mating so no litters produced. Infertility in males and females of the high dose when mated with untreated animals. No adverse effects in mid and low dose groups in any generation.	17.5 mg B/kg bw/day	17.5 mg B/kg bw/day	17.5 mg B/kg bw/day
Oral in diet	Mice	1 week premating (continuous breeding study)	0, 26.6, 111.3, 220.9 mg B/kg bw/day (Boric acid)	Reduced sperm motility (F0) Increased uterine weight and kidney/adrenal weight, shortened oestrus cycle and 25% reduction in sperm concentration (F1) Reduced adjusted bodyweight of pups (F2)	26.6 mg B/kg bw/day (LOAEL)	26.6 mg B/kg bw/day (LOAEL)	26.6 mg B/kg bw/day (LOAEL)

In terms of human data, numerous epidemiological studies are available on the effects of boric acid and boron exposure coming from occupational exposure, and mainly through inhalation. Overall, data from epidemiological studies in humans are not conclusive in terms of absence or presence of fertility effects of boron compounds. Several epidemiological studies have investigated fertility effects in workers and populations living in areas with high environmental levels of boron, including Chinese studies in mine workers working with boron. The data are not conclusive due to questionable study design i.e. sample size, sensitivity, relevant effect parameters and description of exposure ((ECHA/transitional annex XV report (2009a)), (SCCS 2010a), (ECHA/RAC opinion (2010b)). Recently RAC confirmed the classification of boric acid as Repr.1B; H360FD, although a submitted classification proposal proposed a down classification to Repr. 2; H361d based on lack of evidence from the human data (ECHA/RAC opinion 2014).

Based on the identified NOAEL for reproductive toxicity (17.5 mg B/kg bw/day), a DNEL for consumers using an assessment factor of 100 (Interspecies 10, Intraspecies 10) was derived (ECHA/RAC opinion (2010b)):

$DNEL_{consumers}$= 0.175 mg B/kg bw/day

The developmental effects of boron (boric acid) have been examined in experimental animal studies (rat, mice and rabbit) using oral dosing. Developmental effects in terms of visceral and skeletal malformations were observed in a dose and species dependent manner in rats, mice and rabbits; rats being more sensitive than mice and rabbits. The key studies are summarised in Table 6.2 below.

TABLE 6.2: KEY DEVELOPMENTAL STUDIES WITH BORIC ACID (ECHA/ TRANSITIONAL ANNEX XV REPORT (2009A))

Route of exposure	Species	Exposure period	Doses (mg B/kg bw/day)	Critical effect -foetuses	NOAEL (maternal)	NOAEL teratogenicity, embryotoxicity
Oral in diet	Rat	Day 0-20 of gestation	Phase 1: (gd 0-20) 0; 3.3; 6.3; 9.6; 13.3; 25.0 Phase 2: (pnd 0-21) 0; 3.3; 6.3; 9.8; 12.9; 25.4	Phase 1: Reduction of foetal body weight on gd 20 in 13.3 and 25 mg/kg bw/day, malformations: incidence of short rib XIII or wavy ribs increased. Phase 2: No decreased foetal body weights effect. Short rib XIII, but no wavy rib or extra rib on lumbar I (pnd 21)	No maternal toxicity observed	NOAEL for foetal skeletal effects is 9.6 mg B/kg bw/day
Oral in diet	Rat	Day 0-20 of gestation	0; 13.7; 28.5; 57.8; 94.3;	Reduction of foetal body weight, malformations: Incidence of short rib XIII	13.7 mg B/kg bw/day	< 13.7 mg B/kg bw/day, foetal body weight decrease

Route of exposure	Species	Exposure period	Doses (mg B/kg bw/day)	Critical effect -foetuses	NOAEL (maternal)	NOAEL teratogenicity, embryotoxicity
Oral in diet	Mice	Day 0-17 of gestation	0, 43, 79, 175	Reduced bodyweight; skeletal malformations including short rib XIII.	Not identified	43 mg B /kg bw/day
Oral gavage in water	Rabbit	Day 6-19 of gestation	0, 10.9, 21.9 ,43.8	Prenatal mortality increased, malformations increased primarily cardiovascular defects (interventricular septal)	43.8 mg B/kg bw/day	21.9 mg B/kg bw/day

No human data exist with regard to developmental toxicity. From the available experimental animal data, it is concluded that prenatal exposure to boron can cause developmental toxicity. The lowest NOAEL for developmental toxicity is 9.6 mg B/kg bw/day corresponding to 55 mg boric acid/kg bw/day.

Based upon the identified NOAEL for developmental toxicity (9.6 mg B/kg bw/day corresponding to 55 mg boric acid/kg bw/day), a DNEL for consumers using an assessment factor of 100 (Interspecies 10, Intraspecies 10) was derived (ECHA/ RAC opinion (2010b)):

$DNEL_{consumer}$ = 0.096 mg B/kg bw/day

In their latest re-evaluation of boric acid and sodium borates, EFSA (2013) identified a group ADI of 0.16 mg B/kg bw/day based upon the same NOAEL value of 9.6 mg B/kg bw/day for developmental toxicity. EFSA used an uncertainty factor of 60 instead of 100 due to adjustment in the default toxicokinetic uncertainty factor for human variability.
In the REACH registration for boric acid and sodium borate a $DNEL_{consumer}$ of 0.17 mg B/kg bw/d has been derived (based on a BMDL 05 (lower 95 percentile bench mark dose level for the 5% effect level) and use of an assessment factor of 60).

Overall, there is consensus among the EU scientific committees (SCCS, EFSA and RAC) that boric acid and boron compounds are toxic to fertility and development. This has recently been confirmed by RAC that concluded classifications of boric acid and disodium octaborate tetrahydrate with Repr. 1B, H360FD (May damage fertility and the unborn child) (RCHA/RAC-opinion 2014a+b)

6.1.9 Overall conclusions for boric acid and borates

Available toxicokinetic data indicate for boron compounds (boric acid and borates) that absorption, distribution, and metabolism are very similar in animal and humans. A difference in renal clearance is the major determinant in the differences between animals and humans, with the renal clearance in rats approximately 3-4 times faster than in humans. Absorption by the oral, inhalational and dermal routes is 100%, 100% and 0.5% (worst case approach), respectively. When absorbed, boric acid is the main species present in the blood. Borates are distributed rapidly and evenly through the body. Boric acid is not further metabolized and excreted mainly in the urine, elimination half-lives < 24 hours in humans. In general, under physiological conditions, boron compounds are transformed in boric acid; hence results can be transformed to other boron compounds.

In humans, the critical effects following inhalation of dust containing boron are considered to be nasal and eye irritation, throat irritations, cough, and breathlessness. Data from experimental animal studies and human studies show that boron is a respiratory irritant, and a NOEC of 0.8 mg B/m^3 has been established leading to an acute inhalational DNEL of 0.8 mg B/m^3. In terms of skin sensitisation, data from animal studies and human data show that boron compounds (boric acid and sodium borates) are not skin sensitisers.

In humans, acute irritant effects on the eye are well documented in human workers exposed to borates. In animal studies, boric acid shows irritant effects but not indicative of a classification, hence no classification applies. Borates are eye irritants and should therefore be classified accordingly as eye irritant (Eye Irr. 2; H319 or Eye Dam. 1; H318).

The acute toxicity of boron compounds (boric acid and sodium borates) is low, the following experimental animal data can be concluded:
LD50 oral rat > 2000 mg/kg (489-659 mg B/kg)
LD50 dermal rat >2000 mg/kg (226-350 mg B/kg)
LC50 inhalation rat > 2 mg/l (300-371 mg B)/m^3)

In humans, acute poisoning can occur after oral and inhalation exposure as well as after dermal exposure via damaged skin. A human oral lethal dose is quoted to be 2-3 g boric acid for infants, 5-6 g boric acid for children and 15-30 g boric acid for adults.

Data from several oral repeated dose toxicity studies (rat, mice and dog) on boron compounds (boric acid and borates) identify the testis as one of the main targets of boron toxicity, although haematological effects are also seen. A NOAEL of 17.5 mg B/kg bw/day was derived from a 2 year study in rats using boric acid and disodium tetraborate decahydrate in the diet (identified as the key study) based on the effects of boron seen, i.e. the clinical and hematological effects and the testicular atrophy observed at the highest doses tested (58.5 mg B/kg bw/day).

For reproductive and developmental toxicity, male (and female) fertility comprised as testicular lesions in different species (rat, mice and dogs) and foetal development comprised as reduced foetal body weight as well as skeletal and visceral malformations in different species (rat, mice and rabbit) are main targets of boron toxicity. For reproductive toxicity, a NOAEL of 17.5 mg B/kg bw/day was derived from a three generation reproduction study in rats using boric acid or sodium borate (borax) (identified as the key study). Based on the identified NOAEL value, a $DNEL_{consumer}$= 0.175 mg B/kg bw/day could be established using an assessment factor of 100. In terms of human data, numerous epidemiological studies are available on the effects of boric acid and boron exposure coming from occupational exposure, mainly through inhalation, but these are not conclusive in terms of absence or presence of fertility effects of boron compounds. Data from animal studies are considered to be conclusive for fertility effects in humans.

In terms of developmental toxicity, developmental effects of boron (boric acid) have been examined in experimental animal studies (rat, mice and rabbit) using oral dosing. Developmental effects in terms of visceral and skeletal malformations were observed in a dose and species dependent manner in rats, mice and rabbits, rats being more sensitive than mice and rabbits. A NOAEL of 9.6 mg B/kg bw/day for developmental effects was established in a prenatal rat study using boric acid (identified as the key study). Based on the identified NOAEL value, a $DNEL_{consumer}$ = 0.096 mg B/kg bw/day could be established using an assessment factor of 100. No human data exist with regard to developmental toxicity.
The effects of boric acid and boron compounds on reproduction and development indicate that a classification with Repr. 1B, H360FD (May damage fertility and the unborn child) should be applied for boric acid. This was recently confirmed by RAC in their opinion on proposed harmonised classification and labelling of boric acid (ECHA/RAC opinion (2014)).

6.2 Human exposure

6.2.1 Direct exposure

6.2.1.1 Consumers

Boron is a naturally occurring element. Boric acid and sodium salts of boron (primarily borax, or disodium tetraborate decahydrate) are used in a number of applications from which human exposure may be possible in various degrees. The number of applications includes: manufacture of glass, fibre glass, insulation, porcelain enamel, ceramic glazes, and metal alloys. The compounds are also used in cellulose insulation (as fire retardants), antifreeze agents, paints, wood preservatives, cosmetics, detergents, laundry additives, fertilizers (SCCS, 2010a).

Below, some data regarding potential consumer exposure from various products have been gathered:

Cosmetics

Humans may be directly exposed from different types of cosmetic products. According to the Cosmetics Directive no1223/2009, boric acid/ borax may be used in:

Talc 5%
Bath products 18%
Hair products 8%
Products for oral hygiene 0.1%
Other products 3%
(All concentrations expressed as boric acid %)

Based on the evaluation from SCCS (2010a), the total daily systemic exposure dose (SED) of boron from these cosmetic products is estimated to be 1.23 mg B per day corresponding to 0.02 mg B/kg bw/day using a body weight of 60 kg (SCCS 2010a).
In a Danish product survey from 2005 eye cosmetics (so called kohl products) on the Danish market were analysed and up to 3.2% boron was found in the products. These products are applied around the eyes using a brush or hard or soft pencil (Danish EPA 2005).

Photographic applications

An estimation of the exposure to boron (boric acid and borates) from working with photochemical products has been established for the inhalational and dermal exposure routes (ECHA/RAC opinion (2010b). Various exposure scenarios (including combined exposure scenarios) were generated (i.e. using film developer, fixer, different formulations (powder/liquid) of the products).

The estimated internal exposure from the combined dermal and inhalation exposure for the different product types and for the various scenarios ranged from 0,0008 mg – 0,0072 B/kg bw/day for typical exposure levels and 0,0130 mg – 0,0753 B/kg bw/day for realistic worst case scenarios.

Paper wool insulation

Consumer exposure may occur if insulation of a house is done as do-it-yourself work, see also Section 2.1.2. For an operator blowing paper wool insulation dust, some measurement data indicate that short term peaks of 5 mg B/m3 could be obtained. Further, an 8 hour average of 0.22 mg B/m3 was estimated (Larsen 2012). These estimations were based on measurement of dust levels and an anticipated content of boric acid/borax of 5% in the dust. Further, a dermal load of 4.13 mg B/kg bw/d was estimated.
From these data a combined internal exposure of 0.077 mg B/kg bw/d was calculated.

Furniture
A Danish EPA consumer survey in 2004 found that furniture made of rubber wood (Hevea brasiliensis) may contain very high levels of fungicides based on boron. As rubber wood degrades very fast, this wood species is always treated with fungicide, and in the survey a concentration of 801 mg B/kg wood was found from samples from a table surface (Danish EPA 2014).

Toys
In 2000 the Danish EPA in a letter to the Danish toy sales organisation and toy importers warned against the use of boric acid in playing dough as levels up to 0.9% boric acid have been found in such dough (Danish EPA 2000).

A Danish EPA consumer survey on slimy toys detected boron in 3 products, at a maximum of 0.84% of the products. For a child an absorbed dose in connection with dermal exposure was calculated to 0.097 µg B/kg bw/d (dermal absorption of 23%), whereas an oral dose was calculated to 4.4 µg B/kg bw/d (oral absorption of 100%) (Danish EPA 2006).

Fertilisers
RPA (2008) indicates that fertilisers may contain 10% boron and considers that inadvertent ingestion by the user is unlikely to exceed 100 mg fertiliser per day or 10 mg B/day (corresponding to 0.14 mg B/kg/d).
According to the Fertilizers Association the majority of fertilizers for soil application for consumers are below the specific concentration limit of 0.96% related to the boron ion.

Detergents
Although boric acid/borax are used as stabilisers in liquid fabric detergents, the main exposure to borates from detergents may stem from the use of sodium perborate as bleach in laundry detergents.
Perborates are oxidants used as bleaching agents in detergents. Perborates are transformed to boric acid/borat,e and thus the use of perborates is a source of boric acid/borate exposure as well. Modern bleaching detergents typically contain 15% sodium perborate. The EU risk assessment of perborates (EU RAR, 2007) and RPA (2008) evaluated that washing hands with detergents may result in the highest dermal exposure to perborates resulting in 61.4 mg sodium perborate per day (or 4.3 mg B/day). Assuming a dermal uptake of 1%, this would lead to a systemic exposure of 0.04 mg B/d (or 0.0006 mgB/kg bw/d).

Glass/Ceramics
RPA (2008) consider consumer exposure to borates from glass and ceramics to be zero as the borates are transformed and chemically bound into the glass and ceramics.

Other chemical products
Further products such as antifreeze products for engine cooling, brake fluids, lubricants, metalworking fluids, water treatment chemicals and fuel additives may contain boric acid and borates. Overall RPA (2008) considers the exposure potential from these uses to be far below 10 mg B/d (or 0.14 mg B/kg bw/d).

6.2.1.2 Occupational exposure
In Denmark, the following occupational limit values apply for boric acid/borax (Ministry of Employment (2011):
Disodium tetra borate, anhydrous: 1 mg/m^3
Disodium tetra borate, pentahydrate: 1 mg/m^3
Disodium tetra borate, decahydrate: 2 mg/m^3
Boron oxide: 10 mg/m^3

In the ECHA/transitional Annex XV report (2009a+b) exposure estimates have been performed for 10 different occupational scenarios with the use of boric acid and borates. EASE calculations showed typical average 8-hours exposures in the range of 0.01 – 5.9 mg B/m^3 and realistic worst case exposures in the range of 0.01-10.8 mg B/m^3.
A scenario for discharging borates from big bags indicated typical and realistic worst case exposure of 5.9 and 10.8 mg B/m^3 for inhalation exposure and 113.5 and 206.4 mg B/day for dermal exposure corresponding to dermal loads of 0.12 and 0.22 mg B/cm^2 on the exposed skin areas (960 cm^2).

For an operator blowing paper wool insulation, dust measurements indicate that short term peaks of 5 mg B/m^3 could be obtained. Further, an 8 hour average of 0.22 mg B/m^3 was estimated (Larsen 2012). These estimations were based on measurement of dust levels and an anticipated content of boric acid/borax of 5% in the dust. A dermal load of 4.13 mg B/kg bw/d was estimated.

In Denmark, the Sectorial Working Environment Council on Building and Construction has published a guidance document on how to work with insulation in general that also covers work with cellulose wool insulation. The guidance describes how it is possible to avoid or reduce occupational exposure to dust during the work. For cellulose wool, it is recommended to use protective clothing (coveralls) and respirators (P2 filter). Protective gloves are recommended if the insulation material contains boron (Branchearbejdsmiljørådet, 2011).
In a safety data sheet from a Danish manufacturer of cellulose wool insulation, respiratory protection with P2 filter, gloves, eye goggles and dust repellant clothing is recommended during dusty work (Papiruld Danmark, 2011).
No Danish measurement data on levels of boric acid, sodium borates in the occupational environment have been found.

6.2.2 Indirect exposure

6.2.2.1 Air

Overall, boron does not appear to be present in ambient air at significant levels. An estimated mean boron concentration in air has been reported to be 20 ng B/m^3 (<0.5 to 80 ng/m^3) (ECHA/ transitional annex XV report (2009a). Therefore, assuming a respiration volume of 20 m^3 per day, a respiratory exposure of 400 ng B/day (~0.4 µg B/day) can be calculated, hence this is assumed as negligible in comparison with exposure from other boron sources.

6.2.2.2 Soil

Data on boron concentrations in soils have been reported in the EU (ECHA/transitional annex XV report (2009a). For Finland and Sweden, boron concentrations in top soils ranged between 0.5 and 13 mg B/kg soil in Sweden and 1.6 and 14.2 mg B/kg soil in Finnish top soils. An EU-PEC soil concentration of 5 mg B/kg soil was derived. Using this value a theoretical scenario could be: Consumption of 20 mg soil/person per day yields an average boron intake of 0.1 µg B/day (i.e. 5 mg B/kg of soil x 0.00002 kg of soil consumed per person per day = 0.0001 mg B/person/day). For small children with an average soil ingestion rate of up to 200 mg/day the dose would be 0.001 mg B/person/day.

6.2.2.3 Drinking water

Humans are also exposed to boron through drinking water estimated to be around 0.4 mg B/L and a worst case content of 1 mg B/L (the maximum limit permitted by the EU Drinking Water Directive). Assuming a daily consumption of 2L/person/day, the typical intake from drinking water is at 0,8 mg B/person/day (0.133 mg B/kg bw/day) whereas the realistic worst case intake is 2 mg B/person/day (0.03 mg B/kg bw/day) (ECHA/ transitional annex XV report (2009a)).

6.2.2.4 Food

Humans are exposed to boron as a natural constituent in food. The richest sources of boron are fruits, vegetables, pulses, legumes and nuts. Dairy products, fish, meats and most grains are poor sources of boron (EFSA 2013).
Based on the United Kingdom National Food Survey (MAFF, 1991), the mean dietary intake of boron in the United Kingdom ranged from 0.8 to 1.9 mg/day. Increased consumption of specific foods with high boron content will increase the boron intake significantly; for example, one serving of wine or avocado provides 0.42 or 1.11 mg, respectively. Moreover, for the population obtaining their drinking water from the 10% of the public water systems that provide water containing > 0.4 mg boron/L, water used for drinking and cooking may be the major, or a significant source of boron.

Further, based on the data in *ECHA/transitional annex XV report (2009b),* the Risk Assessment Committee at ECHA used the following background exposure levels to boron form drinking water and food in their risk assessment (ECHA/ RAC opinion (2010b)). Thus the total daily boron uptake of man (60 kg) via food and drinking water was estimated to:
Typical: 2.3-2.74 mg B/person/day (0.038 – 0.046 mg B/kg bw/day)
Realistic worst case: 3.5 – 3.94 mg B/person/day (0.058 – 0.066 mg B/kg bw/day)

Boric acid and sodium borate are used as food additives, however, the only use permitted is in caviar from sturgeon.
In 2013, EFSA estimated the highest average exposure to boron across European Member States to be 0.04 mg/kg bw/day for children, 0.01 mg/kg bw/day for adolescents, 0.01 mg/kg bw/day for adults and 0.01 mg/kg bw/day for the elderly and the very elderly. The exposure to boron from the use of boric acid and sodium tetraborate as food additives at the highest 95th percentile, for consumers only, would be 0.56, 0.37, 0.13 and 0.15 mg B/kg bw/day for children, adolescents, adults and the elderly, respectively. In the same evaluation, EFSA established a group ADI for boric acid and sodium tetraborate, expressed as boron equivalents to be 0.16 mg B/kg bw/day, i.e. 10 mg from all food sources for an adult weighing 60 kg (EFSA, 2013). Considering the price of sturgeon caviar, the number of regular consumers must be assumed to be very small. The EFSA evaluation was based on fish roe (in which no boron is applied) consumption rates, not sturgeon caviar consumption data. Hence, the resulting average exposure is grossly overestimated.

Boric acid and sodium borate may be used as boron mineral sources in the manufacture of dietary supplements according to Regulation (EC) No. 1170/2009 of 30 November 2009. Multivitamin–mineral supplements for human use, listed as being for non-prescription use, may contain up to 150 µg of boron from calcium borate, magnesium borate and sodium borate, all in magnesium oxide (ECHA 2013).

Body-building supplements contain 1.5–10 mg boron per serving, with a median of 4 mg boron per serving. These supplements could result in daily exposures of 1.5–30 mg boron, as some are taken up to three times a day (ECHA 2013).

6.2.3 Summary

From the data found on exposure estimates, the dominating exposure to boric acid/borates stems from food and drinking water. The general background typical and realistic worst case (RWC) exposure in EU has been estimated to:
Typical: 2.3-2.74 mg B/person/day (0.038 – 0.046 mg B/kg bw/day)
RWC: 3.5 – 3.94 mg B/person/day (0.058 – 0.066 mg B/kg bw/day)

Especially the use of boron in dietary supplements may result in additional exposure up to 1.5-30 mg B/ day (0.02-0.4 mgB/kg bw/day).

In relation to use of boric acid/borates in cosmetics a daily dose of 1.23 mg B/day (0.02 mg B/kg bw/d) has been estimated.

Further contribution to the exposure to boric acid/borates may come from various other products, e.g. laundry detergents, fertilisers, cellulose insulation and furniture.

6.3 Human health impact

6.3.1 Workers

General scenarios
In the ECHA/transitional annex XV report (2009a+b) exposure estimates have been performed as indicated in section 6.1.1.2.
For 6 of 10 inhalation scenarios, risk was identified for local effects (irritation of eyes and respiratory tract) whereas for two scenarios (discharging borates from ships and from cleaning/sweeping) risk was identified in relation to reproductive toxicity. No risk was identified in connection with dermal exposure.

Biocides
With respect to use of boric acid/borax as a biocide an assessment report was elaborated by the Netherlands (2009a+b). In these reports an acceptable operator exposure level (AOEL) of 0.1 mg B/kg bw/d as a rounded figure from a NOAEL of 9.6 mg/kg bw/d and using an overall assessment factor of 100. It was evaluated that professionals would not be at risk when using standard personal protective equipment when using the biocides in industrial production.

Glass wool
In relation to the borate content in glass wool, Jensen (2009) made a risk assessment of the inhalational dose of boron when working with the insulation material. In connection with a glass wool content of 1 fibre/cm^3 in the inhalational air during work (the occupational limit value) a daily dose of 0.08-0.16 mg B (or 0.001-0.002 mg B/kg bw/d) was calculated based on a worst-case boron content of 3.5% in the glass wool. This dose was concluded as insignificant compared to a daily background exposure from food and drinking water of about 1.5 mg boron in adults and also compared to the EFSA (2006) TDI value of 10 mg B/d.

Cellulose wool
For an operator blowing paper wool insulation, dust measurements indicate that short term peaks of 5 mg B/m^3 could be obtained. Further, an 8 hour average of 0.22 mg B/m^3 was estimated (Larsen 2012). These estimations were based on measurement of dust levels and an anticipated content of boric acid/borax of 5% in the dust. A dermal load of 4.13 mg B/kg bw/d was estimated.
When using an absorption rate of 100% from inhalation and a dermal uptake rate of 0.5% from the dermal load, a total systemic dose of 0.077 mg B/kg bw/d was calculated. If further adding contribution from the background exposure of 0.066 mg/kg bw/d (considered as worst case), a total dose of 0.14 mg/kg bw/d was calculated. This was considered an exposure just below a DNEL value for workers of 0.19 mg B/kg bw/d (Larsen 2012). (In the report the DNEL value for workers was set to twice the DNEL value for consumers (0.096 mg B/kg bw/d derived by ECHA/RAC opinion (2010b)).

6.3.2 Consumers

Chemical products
In the ECHA/transitional annex XV reports (2009a+b) no risk assessment was made for consumer exposure due to lack of data and knowledge regarding exposure. Therefore, the EU-Commission initiated the work of RPA (2008) in order to assess the risk to consumers from borates.

Although the RPA (2008) report mostly make qualitative assessments of various types of consumer exposure, some rough exposure estimates for some consumer products are also made. However, no attempt is made by RPA (2008) to add background exposure or to add various types of consumer exposures for the risk assessment.

Food

EFSA established a group ADI for boric acid and sodium tetraborate, expressed as boron equivalents to be 0.16 mg B/kg bw/day, i.e. 10 mg from all food sources for an adult weighing 60 kg (EFSA, 2013). Based on the intake estimates on boric acid and sodium borate used as food additives in caviar, it was concluded that the worst case exposure estimates exceeded the derived ADI. It was estimated that the ADI for an adult person would be exceeded with a daily intake of 13.7 g caviar containing 4 g boric acid/kg. However, it was concluded that this type of exposure is unlikely to occur on a regular basis.

Further, EFSA (2013) concluded that exposure to boron from its natural occurrence in the diet and from other sources (dietary supplements, food contact materials, feed for food-producing animals, cosmetics, oral hygiene products, etc.) already may lead to an exposure that exceeds the ADI.

Cosmetics

SCCS (2010a) evaluated the safety of boric acid/borax in cosmetic product. Using an aggregated exposure from use of various cosmetic products, a systemic exposure of 0.02 mg/kg bw/d was calculated leading to a margin of exposure (MoE) of 480 compared to the NOAEL of 9.6 mg B/kg bw/d in relation to developmental toxicity. Thus the exposure from cosmetic products was by SCCS (2010a) considered safe also when considering the background exposure from food and drinking water.

SCCS (2010b) evaluated the safety of the boron exposure from the cosmetic use of sodium perborate and perboric acid, which are bleaching agents (hydrogen peroxide releasing substances) that during use are transformed to boric acid/borate. Using an aggregated exposure from use of various cosmetic products a systemic exposure of 0.016 mg/kg bw/d was found. Overall the SCCS (2010b) found the use of sodium perborate and perboric acid (and boric acid/borate) in cosmetic products to be safe. However, it was noted that exposure to the substances from other sources (including background exposure) was not considered in this report.

Biocides

With respect to the use of boric acid/borax as a biocide an assessment report was prepared by the Netherlands (2009a+b). In these reports an acceptable operator exposure level (AOEL) of 0.1 mg B/kg bw/d as a rounded figure from a NOAEL of 9.6 mg/kg bw/d and using an overall assessment factor of 100. This value was also used in connection with non-professional use (application by brush or spraying). It was concluded that even for unprotected non-professional users the exposure would be below the AOEL value (exposure figures not given in the report).
For indirect exposure of e.g. children playing outside on an area with boron impregnated wood, the potential exposure was considered as negligible.

Photographic applications

The Risk Assessment Committee at ECHA has derived a DNEL value of 0.09 mg B/kg bw/d. In a risk assessment of one specific exposure scenario using boric acid for photographic applications, it was concluded that the DNEL was exceeded, but only when background exposure to boron (from drinking water and food) was also taken into account.

Overall, the background exposure to borates may be very close to the DNEL value (and in some cases even above) and thus additional sources from e.g. cosmetics, dietary supplements, fertilisers, boric acid dust from cellulose insulation, etc. may for some already highly exposed people lead to exceedance of the DNEL value.

6.4 Summary and conclusions

Effects

When exposed via the oral or inhalational route, boric acid and borates are easily taken up (up to 100%) into the blood stream and distributed throughout the tissues and organs of the body. By dermal exposure an uptake of 0.5% is considered a maximum uptake. Boric acid is not further metabolised in the body, but is excreted mainly in the urine with an elimination half-life < 24 hours in humans.

In humans, the critical effects following inhalation of dust containing boron are considered to be nasal and eye irritation, throat irritation, cough, and breathlessness. Data from experimental animal studies and human studies show that boron is a respiratory irritant, and a NOEC of 0.8 mg B/m^3 has been established leading to an acute inhalational DNEL of 0.8 mg B/m^3.

In humans, acute irritant effects of the eye are well documented in human workers exposed to borates. In animal studies, boric acid show irritant effects but not indicative of a classification, hence no classification applies. Borates are eye irritants and should therefore be classified accordingly as eye irritant (Eye Irr. 2; H319 or Eye Dam. 1; H318).

In humans, acute poisoning can occur after oral and inhalation exposure as well as after dermal exposure via damaged skin. A human oral lethal dose is quoted to be 2-3 g boric acid for infants, 5-6 g boric acid for children and 15-30 g boric acid for adults.

However, the most critical effects of boric acid and borates are effects in relation to fertility (adverse effects on the testis) and development effects (malformations and prenatal mortality of the foetus).

For reproductive toxicity, a NOAEL of 17.5 mg B/kg bw/day was derived from a three generation reproduction study in rats using boric acid or sodium borate (borax) (identified as the key study). Based on the identified NOAEL value, a $DNEL_{consumer}$= 0.175 mg B/kg bw/day could be established using an assessment factor of 100. In terms of human data, numerous epidemiological studies are available on the effects of boric acid and boron exposure coming from occupational exposure, mainly through inhalation, but these are not conclusive in terms of absence or presence of fertility effects of boron compounds. Data from animal studies are considered to be conclusive for fertility effects in humans.

For developmental toxicity a NOAEL value of 9.6 mg B/kg bw/day for developmental effects was established in a prenatal rat study using boric acid (identified as the key study). Based on the identified NOAEL value, a $DNEL_{consumer}$ = 0.096 mg B/kg bw/day could be established using an assessment factor of 100. No human data exist with regard to developmental toxicity.

The effects of boric acid and borates on reproduction and development comply with a classification as Repr. 1B, H360FD (May damage fertility and the unborn child). This was recently confirmed by RAC in their opinion on proposed harmonised classification and labelling of boric acid (ECHA/RAC opinion (2014)).

Exposure

From the data found on exposure estimates, the dominating exposure to boric acid/borates stems from food and drinking water. The general background typical and realistic worst case exposures in EU have been estimated to:

Typical: 2.3-2.74 mg B/person/day (0.038 – 0.046 mg B/kg bw/day)

RWC: 3.5 – 3.94 mg B/person/day (0.058 – 0.066 mg B/kg bw/day)

Especially the use of boron in dietary supplements may result in additional exposure up to 1.5-30 mg B/day (0.02-0.4 mg B/kg bw/day).

In relation to use of boric acid/borates in cosmetics, a daily dose of 1.2 mg B/day (0.02 mg B/kg bw/d) has been estimated.

Further contribution to the exposure to boric acid/borates may come from various other products, e.g. laundry detergents, fertilisers, biocides, cellulose insulation and furniture.

Health impact

Occupational exposure

In some situations when working with boric acid/borax, protective measures such as technical measures or personal protective equipment may be necessary in order to ensure safety. This may be relevant for industrial biocide impregnation processes, loading/unloading batches of boric acid/borax powder, blowing cellulose wool insulation into constructions, or in connection with cleaning operations).

Consumer exposure

The European Food Agency, EFSA established a group ADI for boric acid and sodium tetraborate, expressed as boron equivalents to be 0.16 mg B/kg bw/day, i.e. 10 mg from all food sources for an adult weighing 60 kg (EFSA, 2013). Further EFSA (2013) concluded that exposure to boron from its natural occurrence in the diet and from other sources (food supplements, food contact materials, feed for food-producing animals, cosmetics, oral hygiene products, etc.) already may lead to an exposures which exceed the ADI.

Thus, the background exposure from food and drinking water has to be considered when assessing additional exposure sources for boric acid/ borate exposure. As the background exposure for some individuals in the population may be quite close to the acceptable daily intake or the DNEL of 0.09 mg B/kg bw/d, additional boron exposure from dietary supplements, cosmetics, biocides, detergents, cellulose insulation, furniture, etc. may result in a total exposure exceeding the upper safe level.

One example of this has recently been identified by the Risk Assessment Committee at ECHA, who found that the extra contribution for specific uses of boron containing chemicals for photographic applications actually resulted in a total exposure (i.e. + background exposure) exceeding the DNEL value.

7. Information on alternatives

As ECHA recently (September 2014) has made a recommendation for including the boron substances from the candidate list on the authorisation list (Annex XIV), this put additional pressure on the industry in order to find alternatives for use of boric acid and sodium borate. Obviously no single substance or specific technical measure can be a one-for-all alternative to the wide range of applications and processes in which boric acid and sodium borate are used (see the list of registered uses in section 3.2.15).

However, for some specific uses, the RPA (2008) report has examined the consequences for substituting boric acid/borates. Sections 7.1 to 7.5 below are based on this report that primarily based its analysis on responses from questionnaires and information from the industry and industry organisations. The data from this report are the main source for this section as other surveys regarding alternatives and substitution of these boron substances were not found.

In connection with substitution the Danish Working Environment emphasizes that when substituting a substance or a technical process due to one specific concern it should be carefully considered and examined that the substitution does not lead to other potential risks/ concerns in the working environment.

7.1 Glass and glass fiber

Information provided by the manufacturers of glass fiber indicate that borax pentahydrate or diboron trioxide are used for the glass fiber production. The boron content is generally less than 5%; however, concentrations in some specialized applications are higher.

Borate additives lower the melting and forming temperature of SiO_2 glass, but without raising the electrical conductivity. The boron added to the glass forms covalent bonds with oxygen atoms in the silica network and the boron is an integral part of the structure. The majority of E-glass (electrical grade glass) produced in Europe contains < 5% by weight of boron as di-boron tri-oxide (B_2O_3).

A strong relationship exists between boron content of glass, fibre forming temperature, and crystallisation temperature. Therefore, the production of continuous fibre glass with low or zero boron contents requires special technology. However, such technology is not freely available on the market due to patent restrictions. In addition, the very high temperatures involved demands a special infrastructural design that most plants cannot incorporate.

In addition to the effects described above, information provided by glass manufacturers indicates that borates also:
· increases chemical resistance to water, acids and alkaline liquids;
· increases resistance to thermal shock (three times that of soda-lime glass);
· improves resistance to stress;
· improves radiation shielding properties;
· increases in strength (over twice as strong as soda-lime glass)
· lowers thermal expansion (coefficient one third that of soda-lime glass); and
· lowers electrical conductivity.

As such, the combination of properties produced through the addition of borates to glass is unique. These properties together make borosilicate glass uniquely suited to the production of e.g. laboratory equipment and cookware.

Information provided by several companies and industry associations indicates that overall borosilicate glass is used for:
· heat resistant glass cookware;
· laboratory equipment, including pharmaceutical equipment;
· pharmaceutical packaging material;
· glass fibre insulation material;
· light bulbs (and other electrical lighting);
· textile glass fibre composites (fibre glass);
· enamel frit and other enamelling products;
· glass for liquid crystal display screens (LCDs);
· radiation shielding for the nuclear industry and hospital x-ray equipment;
· solar panels;
· ophthalmic lenses, especially for high prescription eyesight correction; and
· heat resistant glass panels (e.g. in cookers).

With respect to possible non-use of borates, information provided from glass producers and their trade associations indicates that there are currently no known viable alternatives to the use of borates in the manufacture of borosilicate glass or indeed, mineral wool insulation products. Since borates are an integral component for glass fibre manufacturing, non-use of borates would mean that fibre glass products could no longer be manufactured.

Further, RPA (2008) concluded the substitution of borates in glass not to be relevant as the presence of borates in glass products is extremely unlikely to result in any significant exposure to borates of consumers using such products, since the borates are chemically bound into a crystal lattice of interconnected oxide molecules in the glass.

7.2 Fertilisers

Boron is one of the seven elements which are essential to plant growth and classified as 'micro-nutrients'. As such, boron containing fertilisers are applied to a diverse range of crops and plants (both commercially and by consumers). As an essential element there seems to be no alternatives to boron in fertilisers (RPA 2008).

7.3 Paint and coating

In paints and coatings, borates are multi-functional coating additives with flame retardant, corrosion inhibiting and buffering properties, which may be found in offset printing inks and interior wall paint.
In some applications, it is currently unclear whether borates can be substituted (e.g. in flame retardant coatings, where they serve a critical life-saving function).

(RPA 2008)

7.4 Adhesives

The precise composition of adhesives varies by application, but up to 10% of the borate may be added to starch and dextrin based adhesives.
According to the manufacturers' organisation non-use of borates in the adhesives would be more expensive and the client would have to apply a thicker adhesives films. Also the machines using the adhesives in the processes would have to run at a slower speed.
Further, starch and dextrine based adhesives would have to be replaced by non-renewing synthetic and petrol based alternatives. Thus, biodegradable casein labelling adhesives for returnable wash off applications are likely to be replaced by synthetic adhesives that are not easily biodegradable. In all systems, there would be the need for higher amounts of preservatives.

In corrugated board adhesives, the industry indicates that there is currently no alternative technology commercially available.

In tube winding adhesives, the industry also indicates that there is currently no direct alternative technology commercially available without rebuilding tube winding factories. While some mills use sodium silicates, this is only possible with adapted production equipment such as drying tunnels and they need more energy to dry the tubes. The average dry solids for a sodium silicate-based adhesive is 45% while for a dextrin based adhesive, it is 65% dry solids. Using dextrin based adhesives, a tube winding company does not have to dry the tubes. In order for a tube winding factory to use alternative adhesive technologies, the factory will have to invest in extra stock and drying oven.

For use of borates as pH buffers (stabilisers) in aminoplastic resins for wooden (medium density fibre board and chipboard) panels production, sodium acetate may be a possible alternative. It is based on the same technology and the technical performance is similar, although there is a higher substance consumption. The costs are indicated to be similar. Borates are not considered critical in this use.
(RPA 2008)

7.5 Metal working fluids

The primary functions of the borate substances in metalworking fluids are corrosion protection and pH buffering. Borate compounds offer excellent long term stability with low foam and good tolerance to hard water conditions. Borate esters possess friction reducing, anti-wear and anti-oxidant characteristics in lubricating oils.

Borate polyols and polyamines in lubricants form an extremely resilient film on metal load-bearing surfaces that improves load capacity and protects from wear and tear. Potassium borates are also used in high pressure lubricants due to their stable dispersion of microspheres.

Information provided by downstream user companies indicates that borate-based end products cannot be replaced in the lubricant industry with the same level of performance and cost efficiency. While a number of possible substitutes have been evaluated, at this stage, none have the same efficiency as borates and none are as cost effective. Furthermore, it is considered that the end-products are used in highly automated industries.

According to the European Lubricant Industry there are no simple (drop-in) alternatives to boric acid in metalworking fluids that can be used as a direct replacement. In general, products have to be reformulated with other ingredients and the physico-chemical, functional and stability properties assessed and maintained.
(RPA 2008)

7.6 Cellulose wool insulation

Insulation of building constructions may be performed as well with other fire resistant materials such as stone wool, mineral wool or glass wool insulation. Also polystyrene insulation products may be used; however this material is not in itself fire resistant.

Dollerup and Skov (2005) in a research project looked for alternative substances to replace boric acid and borates in cellulose insulation: They compared (and tested) cellulose insulation with alternative substances against cellulose insulation containing boric acid/borates with respect to fire resistance, emissions in connection with fire, properties regarding humidity, microbial properties, insulation properties, and environmental hazards. From the testing it was overall concluded that it was not possible to find an appropriate alternative without affecting the cost of manufacture due to more expensive processing using the alternative substances.

However, when looking at websites regarding cellulose insulation products, there seems to be alternative and boron free cellulose insulation products available today.

7.7 Other uses

RPA (2008) tabulated further uses of borates and the availability of alternatives, Table 7.1.

TABLE 7.1: SUMMARY OF AVAILABILITY OF ALTERNATIVES TO BORATES (RPA 2008)

Application/Product	Availability of Alternatives	Other Comments
Antifreezes (engine coolant)	Unknown	
Brake fluids	Unknown	May be a critical use
Lubricants/Metal working fluids	No	Reformulation costs could be significant
Water treatment chemicals	Yes	Costs may need to be considered
Fuel additives	Unknown	

7.8 Specific cases of substitution

The database “Subsport” contains some examples/cases of substitution of boric acid/borates that have been reported to the database by companies/institutions making the substitution, e.g.:

Jewellery

Borax has been successfully substituted in a welding processes in gold jewelry production and in gem stone protection, where a welding process was applied using liquids (flux agents) containing borax. Borax was substituted with either alterative substances (acetone and hydrogen) or a laser welding technique.

Cooling lubricants

In cooling lubricants, boric acid as a bactericidal agent has been successfully substituted using lactic acid instead.

Diagnostics
In a solution for diagnostic staining, a solution of boric acid, ethidium bromid, diethylether, and trypan blue was substituted with a solution containing acetic acid, sodium hydroxide, and acid black 2 which was considered a far less toxic alternative.

Playing dough
Playing dough traditionally contained boric acid/borates as preservatives. In this case the conventional playing dough was substituted by an alternative playing dough product containing flour, starch, egg powder, palm oil, maltodextrin and other food ingredients.

7.9 Summary and conclusions

ECHA has recently (September 2014) made a recommendation for including the boron substances from the candidate list on the authorisation list (Annex XIV). This of course put additional pressure on the industry in order to find alternatives for use of boric acid and sodium borate.
However, no single substance or specific technical measure can be a one-for-all alternative to the wide range of applications and processes in which boric acid and sodium borate are used.
For the use of borates in the glass industry there seems not for the majority of the applications to be a suitable alternative, as the borate incorporated in the glass provides the materials with quite unique properties such a physical resistance and resistance towards thermal chock. Further, borate is covalently bound into the glass matrix and the exposure potential to borate from glass ware may be considered as negligible.
Also in relation to use of borate in starch and dextrin adhesives no appropriate alternatives have been found as use of alternatives either may affect the production processes to a great extent and increase the costs or result in substitution to synthetic petrochemical-based adhesives.
As boron is an essential micronutrient, substitution in fertiliser is not considered possible.
In lubricating oil it may be difficult to find alternatives for borate for some applications.
However, there seems to be alternatives in other areas, e.g. surface coatings and paints, insulation materials, welding processes, pH buffer solutions, and in diagnostic applications.

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Appendices

Appendix 1: Background information to chapter 2 on legal framework

The following annex provides some background information on subjects addressed in Chapter 2. The intention is that the reader less familiar with the legal context may read this concurrently with chapter 2.

EU and Danish legislation

Chemicals are regulated via EU and national legislations, the latter often being a national transposition of EU directives.

There are four main EU legal instruments:

- Regulations (DK: Forordninger) are binding in their entirety and directly applicable in all EU Member States.
- Directives (DK: Direktiver) are binding for the EU Member States as to the results to be achieved. Directives have to be transposed (DK: gennemført) into the national legal framework within a given timeframe. Directives leave margin for manoeuvering as to the form and means of implementation. However, there are great differences in the space for manoeuvering between directives. For example, several directives regulating chemicals previously were rather specific and often transposed more or less word-by-word into national legislation. Consequently and to further strengthen a level playing field within the internal market, the new chemicals policy (REACH) and the new legislation for classification and labelling (CLP) were implemented as Regulations. In Denmark, Directives are most frequently transposed as laws (DK: love) and statutory orders (DK: bekendtgørelser).
- The European Commission has the right and the duty to suggest new legislation in the form of regulations and directives. New or recast directives and regulations often have transitional periods for the various provisions set-out in the legal text. In the following, we will generally list the latest piece of EU legal text, even if the provisions identified are not yet fully implemented. On the other hand, we will include currently valid Danish legislation, e.g. the implementation of the cosmetics directive) even if this will be replaced with the new Cosmetic Regulation.

- Decisions are fully binding on those to whom they are addressed. Decisions are EU laws relating to specific cases. They can come from the EU Council (sometimes jointly with the European Parliament) or the European Commission. In relation to EU chemicals policy, decisions are e.g. used in relation to inclusion of substances in REACH Annex XVII (restrictions). This takes place via a so-called comitology procedure involving Member State representatives. Decisions are also used under the EU ecolabelling Regulation in relation to establishing ecolabel criteria for specific product groups.
- Recommendations and opinions are non-binding, declaratory instruments.

In conformity with the transposed EU directives, Danish legislation regulate to some extent chemicals via various general or sector specific legislation, most frequently via statutory orders (DK: bekendtgørelser).

Chemicals legislation

REACH and CLP

The REACH Regulation[1] and the CLP Regulation[2] are the overarching pieces of EU chemicals legislation regulating industrial chemicals. The below will briefly summarise the REACH and CLP provisions and give an overview of 'pipeline' procedures, i.e. procedures which may (or may not) result in an eventual inclusion under one of the REACH procedures.

(Pre-)Registration

All manufacturers and importers of chemical substance > 1 tonne/year have to register their chemicals with the European Chemicals Agency (ECHA). Pre-registered chemicals benefit from tonnage and property dependent staggered dead-lines:

- 30 November 2010: Registration of substances manufactured or imported at 1000 tonnes or more per year, carcinogenic, mutagenic or toxic to reproduction substances above 1 tonne per year, and substances dangerous to aquatic organisms or the environment above 100 tonnes per year.
- 31 May 2013: Registration of substances manufactured or imported at 100-1000 tonnes per year.
- 31 May 2018: Registration of substances manufactured or imported at 1-100 tonnes per year.

Evaluation

A selected number of registrations will be evaluated by ECHA and the EU Member States. Evaluation covers assessment of the compliance of individual dossiers (dossier evaluation) and substance evaluations involving information from all registrations of a given substance to see if further EU action is needed on that substance, for example as a restriction (substance evaluation).

Authorisation

Authorisation aims at substituting or limiting the manufacturing, import and use of substances of very high concern (SVHC). For substances included in REACH annex XIV, industry has to cease use of those substance within a given deadline (sunset date) or apply for authorisation for certain specified uses within an application date.

Restriction

If the authorities assess that that there is a risks to be addressed at the EU level, limitations of the manufacturing and use of a chemical substance (or substance group) may be implemented. Restrictions are listed in REACH annex XVII, which has also taken over the restrictions from the previous legislation (Directive 76/769/EEC).

Classification and Labelling

The CLP Regulation implements the United Nations Global Harmonised System (GHS) for classification and labelling of substances and mixtures of substances into EU legislation. It further specifies rules for packaging of chemicals.

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[1] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

[2] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

Two classification and labelling provisions are:

1. **Harmonised classification and labelling** for a number of chemical substances. These classifications are agreed at the EU level and can be found in CLP Annex VI. In addition to newly agreed harmonised classifications, the annex has taken over the harmonised classifications in Annex I of the previous Dangerous Substances Directive (67/548/EEC); classifications which have been 'translated' according to the new classification rules.
2. **Classification and labelling inventory**. All manufacturers and importers of chemicals substances are obliged to classify and label their substances. If no harmonised classification is available, a self-classification shall be done based on available information according to the classification criteria in the CLP regulation. As a new requirement, these self-classifications should be notified to ECHA, which in turn publish the classification and labelling inventory based on all notifications received. There is no tonnage trigger for this obligation.

Ongoing activities - pipeline
In addition to listing substance already addressed by the provisions of REACH (pre-registrations, registrations, substances included in various annexes of REACH and CLP, etc.), the ECHA web-site also provides the opportunity for searching for substances in the pipeline in relation to certain REACH and CLP provisions. These will be briefly summarised below:

Community Rolling Action Plan (CoRAP)
The EU member states have the right and duty to conduct REACH substance evaluations. In order to coordinate this work among Member States and inform the relevant stakeholders of upcoming substance evaluations, a Community Rolling Action Plan (CoRAP) is developed and published, indicating by who and when a given substance is expected to be evaluated.

Authorisation process; candidate list, Authorisation list, Annex XIV
Before a substance is included in REACH Annex XIV and thus being subject to Authorisation, it has to go through the following steps:

1. It has to be identified as a SVHC leading to inclusion in the candidate list[3]
2. It has to be prioritised and recommended for inclusion in ANNEX XIV (These can be found as Annex XIV recommendation lists on the ECHA web-site)
3. It has to be included in REACH Annex XIV following a comitology procedure decision (substances on Annex XIV appear on the Authorisation list on the ECHA web-site).

The candidate list (substances agreed to possess SVHC properties) and the Authorisation list are published on the ECHA web-site.

Registry of intentions
When EU Member States and ECHA (when required by the European Commission) prepare a proposal for:

- a harmonised classification and labelling,
- an identification of a substance as SVHC, or
- a restriction.
-

This is done as a REACH Annex XV proposal.

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[3] It should be noted that the candidate list is also used in relation to articles imported to, produced in or distributed in the EU. Certain supply chain information is triggered if the articles contain more than 0.1% (w/w) (REACH Article 7.2 ff).

The 'registry of intentions' gives an overview of intensions in relation to Annex XV dossiers divided into:

- current intentions for submitting an Annex XV dossier,
- dossiers submitted, and
- withdrawn intentions and withdrawn submissions

for the three types of Annex XV dossiers.

International agreements

OSPAR Convention

OSPAR is the mechanism by which fifteen Governments of the western coasts and catchments of Europe, together with the European Community, cooperate to protect the marine environment of the North-East Atlantic.

Work to implement the OSPAR Convention and its strategies is taken forward through the adoption of decisions, which are legally binding on the Contracting Parties, recommendations and other agreements. Decisions and recommendations set out actions to be taken by the Contracting Parties. These measures are complemented by other agreements setting out:

- issues of importance
- agreed programmes of monitoring, information collection or other work which the Contracting Parties commit to carry out.
- guidelines or guidance setting out the way that any programme or measure should be implemented
- actions to be taken by the OSPAR Commission on behalf of the Contracting Parties.

HELCOM - Helsinki Convention

The Helsinki Commission, or HELCOM, works to protect the marine environment of the Baltic Sea from all sources of pollution through intergovernmental co-operation between Denmark, Estonia, the European Community, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden. HELCOM is the governing body of the "Convention on the Protection of the Marine Environment of the Baltic Sea Area" - more usually known as the Helsinki Convention.

In pursuing this objective and vision the countries have jointly pooled their efforts in HELCOM, which is works as:

- an environmental policy maker for the Baltic Sea area by developing common environmental objectives and actions;
- an environmental focal point providing information about (i) the state of/trends in the marine environment; (ii) the efficiency of measures to protect it and (iii) common initiatives and positions which can form the basis for decision-making in other international fora;
- a body for developing, according to the specific needs of the Baltic Sea, Recommendations of its own and Recommendations supplementary to measures imposed by other international organisations;
- a supervisory body dedicated to ensuring that HELCOM environmental standards are fully implemented by all parties throughout the Baltic Sea and its catchment area; and
- a co-ordinating body, ascertaining multilateral response in case of major maritime incidents.

Stockholm Convention on Persistent Organic Pollutants (POPs)

The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have adverse effects to human health or to the environment. The Convention is administered by the United Nations Environment Programme and is based in Geneva, Switzerland.

Rotterdam Convention
The objectives of the Rotterdam Convention are:

- to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm;
- to contribute to the environmentally sound use of those hazardous chemicals, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties.
- The Convention creates legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure. It built on the voluntary PIC procedure, initiated by UNEP and FAO in 1989 and ceased on 24 February 2006.

The Convention covers pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by Parties and which have been notified by Parties for inclusion in the PIC procedure. One notification from each of two specified regions triggers consideration of addition of a chemical to Annex III of the Convention. Severely hazardous pesticide formulations that present a risk under conditions of use in developing countries or countries with economies in transition may also be proposed for inclusion in Annex III.

Basel Convention
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal was adopted on 22 March 1989 by the Conference of Plenipotentiaries in Basel, Switzerland, in response to a public outcry following the discovery, in the 1980s, in Africa and other parts of the developing world of deposits of toxic wastes imported from abroad.

The overarching objective of the Basel Convention is to protect human health and the environment against the adverse effects of hazardous wastes. Its scope of application covers a wide range of wastes defined as “hazardous wastes” based on their origin and/or composition and their characteristics, as well as two types of wastes defined as “other wastes” - household waste and incinerator ash.

The provisions of the Convention center around the following principal aims:

- the reduction of hazardous waste generation and the promotion of environmentally sound management of hazardous wastes, wherever the place of disposal;
- the restriction of transboundary movements of hazardous wastes except where it is perceived to be in accordance with the principles of environmentally sound management; and
- a regulatory system applying to cases where transboundary movements are permissible.

Eco-labels
Eco-label schemes are voluntary schemes where industry can apply for the right to use the eco-label on their products if these fulfil the ecolabelling criteria for that type of product. An EU scheme (the flower) and various national/regional schemes exist. In this project we have focused on the three most common schemes encountered on Danish products.

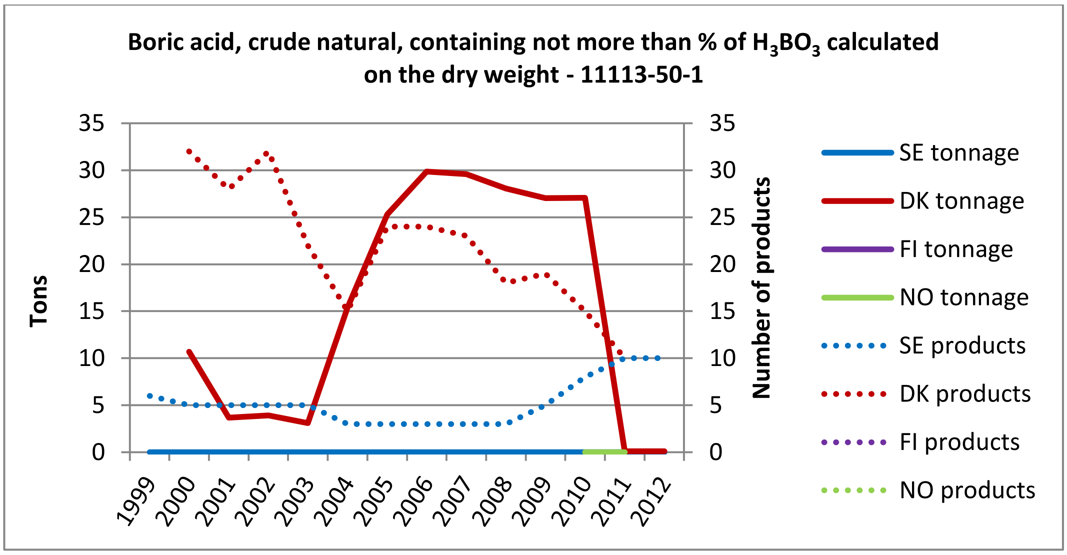
EU flower
The EU ecolabelling Regulation lays out the general rules and conditions for the EU ecolabel; the flower. Criteria for new product groups are gradually added to the scheme via 'decisions'; e.g. the Commission Decision of 21 June 2007 establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners.

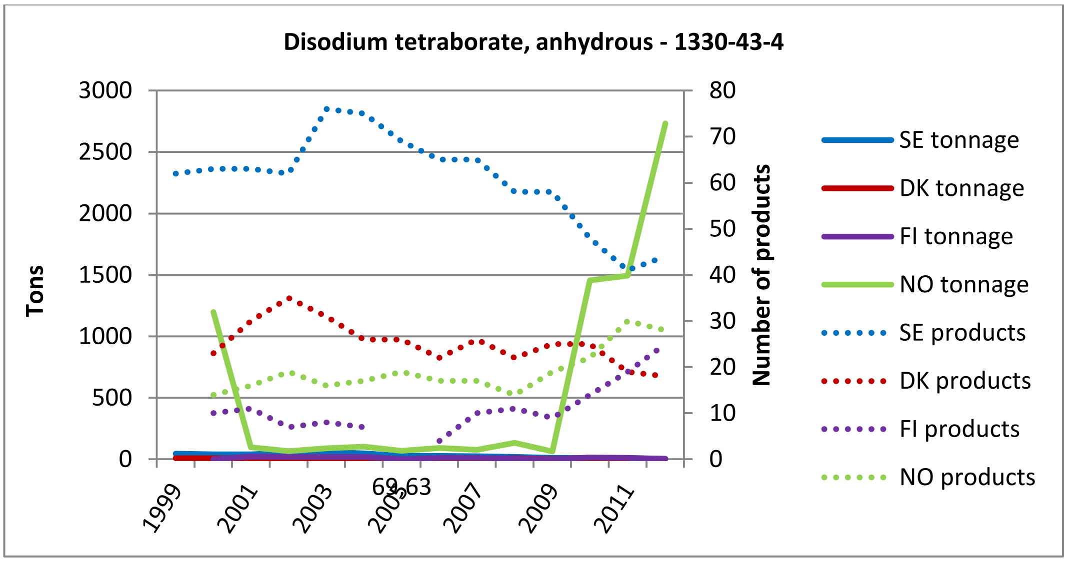
Nordic Swan
The Nordic Swan is a cooperation between Denmark, Iceland, Norway, Sweden and Finland. The Nordic Ecolabelling Board consists of members from each national Ecolabelling Board and decides on Nordic criteria requirements for products and services. In Denmark, the practical implementation of the rules, applications and approval process related to the EU flower and Nordic Swan is hosted by Ecolabelling Denmark "Miljømærkning Danmark" (http://www.ecolabel.dk/). New criteria are applicable in Denmark when they are published on the Ecolabelling Denmark's website (according to Statutory Order no. 447 of 23/04/2010).

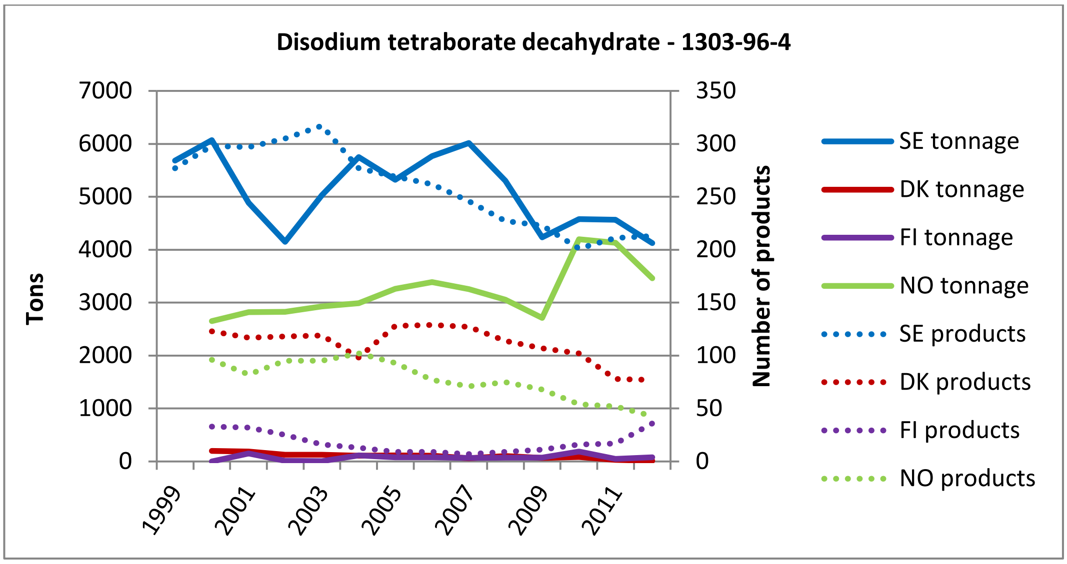
Blue Angel (Blauer Engel)
The Blue Angel is a national German eco-label. More information can be found on: http://www.blauer-engel.de/en.

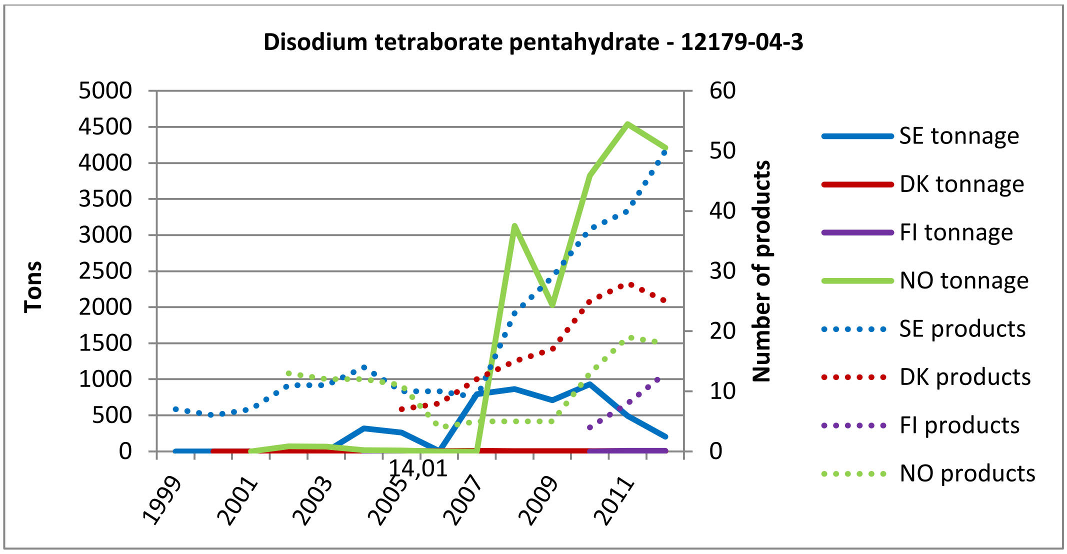
Appendix 2: Additional data on the tonnage and numbers of products containing Boric acid; Disodium tetraborate, anhydrous; Disodium tetraborate decahydrate; Disodium tetraborate pentahydrate and Diboron trioxice, boric acid (data retrieved from the Nordic Spin database)

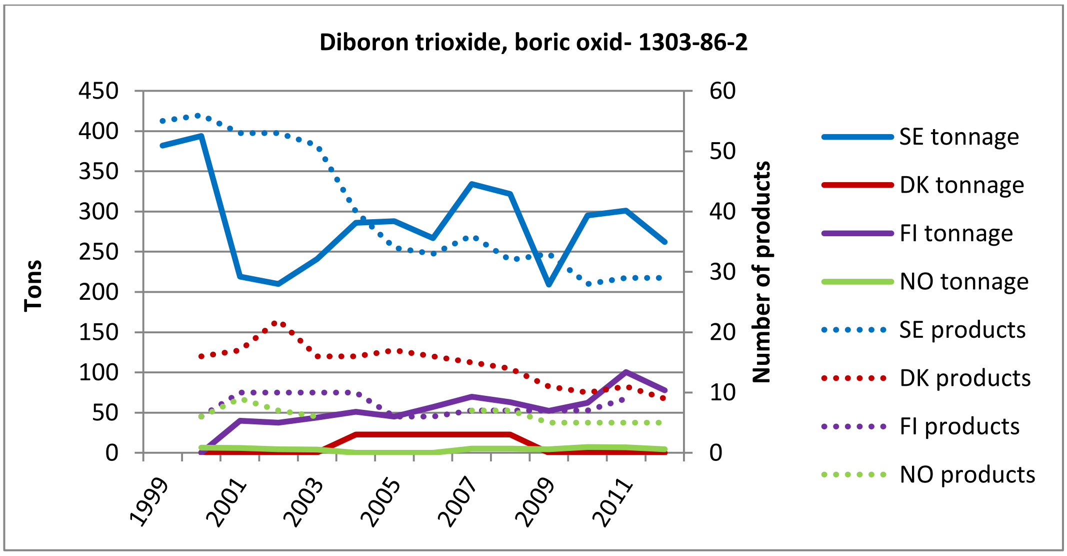
Tonnage and products reported in Nordic countries in the years 1999-2011. Data is only presented for boric substances where data are sufficient for graphic presentation.






Disodium tetraborate decahydrate - 1303-96-4
Tons
Number of products
7000
6000
5000
4000
3000
2000
1000
0
350
300
250
200
150
100
50
0
1999
2001
2003
2005
2007
2009
2011
SE tonnage
DK tonnage
FI tonnage
NO tonnage
SE products
DK products
FI products
NO products


Disodium tetraborate pentahydrate - 12179-04-3
Tons
Number of products
5000
4500
4000
3500
3000
2500
2000
1500
1000
500
0
60
50
40
30
20
10
0
14,01
1999
2001
2003
2005
2007
2009
2011
SE tonnage
DK tonnage
FI tonnage
NO tonnage
SE products
DK products
FI products
NO products


Diboron trioxide, boric oxid- 1303-86-2
Tons
Number of products
450
400
350
300
250
200
150
100
50
0
60
50
40
30
20
10
0
1999
2001
2003
2005
2007
2009
2011
SE tonnage
DK tonnage
FI tonnage
NO tonnage
SE products
DK products
FI products
NO products

Appendix 3: Calculated Predicted Environmental Concentration (PEC) and corresponding Risk Characterisation Ratios (RCRs) for environmental compartments

TABLE 1
PREDICTED ENVIRONMENTAL CONCENTRATIONS BASED ON THE USE OF BORON IN DETERGENTS (EUSES CALCULATIONS) (HERA, 2005)

Environmental Concentration	Value as B	Value as Boric Acid
Regional PEC in surface water (total)	0.45 mg/L	2.6 mg/L
Continental PEC in surface water (total)	0.0013 mg/L	0.0074 mg/L
Local PEC in surface water (average annual)	0.45 mg/L	2.6 mg/L
Regional PEC in sediment	0.0080 mg/kg w. w.	0.046 mg/kg w. w.
Local PEC in fresh-water sediment	0.96 mg/kg w. w.	5.5 mg/kg w. w.
Regional PEC in agricultural soil	<0.00008 mg/kg w. w.	<0.00046 mg/kg w. w.
Continental PEC in agricultural soil	<0.00002 mg/kg w. w.	<0.00011 mg/kg w. w.
Local PEC in agricultural soil (averaged over 30 days)	0.029 mg/kg w. w.	0.17 mg/kg w. w.
Local PEC in agricultural soil (averaged over 180 days)	0.028 mg/kg w.w.	0.16 mg/kg w. w.
Local PEC in grassland (averaged over 180 days)	0.006 mg/kg w. w.	0.037 mg/kg w. w.
Local PEC in pore water of agricultural soil	0.016 mg/L	0.091 mg/L
Local PEC in STP effluent	0.044 mg/L	0.25 mg/L

TABLE 2
CALCULATED PREDICTED ENVIRONMENTAL CONCENTRATIONS (PECS) (*GENERIC ASSESSMENT*) BASED ON THE USE OF BORON WITHIN DIFFERENT INDUSTRY SECTORS AND FOR DIFFERENT LIFE CYCLE STAGES (EUSES CALCULATIONS) (ECHA/ TRANSITIONAL ANNEX XV REPORT (2009A+B)

Industry sector	Life cycle stage	$PEC_{add.\ STP}$ [µg/L]	$PEC_{add.\ water}$ [µg/L]	$PEC_{add.\ sediment}$ [mg/kg d. w.]
Producers	Production/import	22.31	2,325.4	17.3
Borosilicate	Formulation	3.75 - 5.36	470.4 - 630.4	4.2 - 5.4
IFG/TFG	Formulation	3.8 - 7.6	474.4 - 854.4	4.3 - 6.9
Ceramics	Formulation	4.88 - 6.98	582.4 - 791.4	5 - 6.5
Industrial	Formulation	4.65	558.4	4.9

Industry sector	Life cycle stage	$PEC_{add. STP}$ [µg/L]	$PEC_{add. water}$ [µg/L]	$PEC_{add. sediment}$ [mg/kg d. w.]
fluids				
Metallurgy	Formulation	4.12	506.4	4.5
Flame retardants	Formulation	7.51	845.4	6.9
Detergents	Formulation	4.71	565.4	4.9
Cleaners	Formulation	0.29	124.4	1.8
Agriculture (fertilisers)	Formulation	1.74	269.4	2.8
Various chemical effects	Formulation	3.44	438.4	4
Borosilicate	Industrial use	44.67	4,561.4	32.6
IFG/TFG	Industrial use	47.5	4,834.4	34.6
Ceramics	Industrial use	58.13	5,907.4	42.6
Industrial fluids	Industrial use	7.75	856.4	7
Metallurgy	Industrial use	3.3	425.4	3.9
Flame retardants	Industrial use	0.375	132.4	1.9
Detergents	Private use	3.06	401.4	3.8
Cleaners	Private use	0.53	147.4	2
Agriculture (fertilisers)	Industrial use	4.36	530.4	4.7
Various chemical effects	Industrial use	5.43	637.4	5.4

TABLE 3
CALCULATED PREDICTED ENVIRONMENTAL CONCENTRATIONS (PECS) (*SITE SPECIFIC ASSESSMENT*) BASED ON THE USE OF BORON WITHIN DIFFERENT INDUSTRY SECTORS AND FOR DIFFERENT LIFE CYCLE STAGES (EUSES CALCULATIONS) (ECHA/ TRANSITIONAL ANNEX XV REPORT (2009A+B).

Industry sector	Life cycle stage	$PEC_{add. STP}$ [µg/L]	$PEC_{add. water}$ [µg/L]	$PEC_{add. sediment}$ [mg/kg d. w.]
Producers	Production/import	18.38 - 31.07	1,933.4 – 3,201.4	14.5 - 23.4
Borosilicate	Formulation	2.81 - 9.7	375.4 – 1,064.4	3.6 - 8.4
IFG/TFG	Formulation	0.89 - 3.45	174.4 - 439.4	2.2 - 4
Ceramics	Formulation	1.75 - 5.82	269.4 - 677.4	2.8 - 4
Industrial fluids	Formulation	2.35 - 5.11	329.4 - 605.4	3.3 - 5.2
Metallurgy	Formulation	0.73 - 1.35	167.4 - 229.4	2.1 - 2.5
Flame retardants	Formulation	10.87	1,181.4	9.2
Detergents	Formulation	*	*	*
Cleaners	Formulation	*	*	*
Agriculture (fertilisers)	Formulation	0.52 - 1.93	146.4 - 288.4	2 - 3
Various chemical effects	Formulation	0.95 - 2.8	189.4 - 380.4	3.4
Borosilicate	Industrial use	161.67	16,262.4	114.6
IFG/TFG	Industrial use	57.44	5,834.4	41.9
Ceramics	Industrial use	97.06	9,800.4	69.7
Industrial fluids	Industrial use	5.11	605.4	5.2
Metallurgy	Industrial use	1.35	229.4	2.5
Flame retardants	Industrial use	0.38	229.4	2
Detergents	Private use	*	*	*

Industry sector	Life cycle stage	$PEC_{add. STP}$ [µg/L]	$PEC_{add. water}$ [µg/L]	$PEC_{add. sediment}$ [mg/kg d. w.]
Cleaners	Private use	*	*	*
Agriculture (fertilisers)	Industrial use	*	*	*
Various chemical effects	Industrial use	6.66	760.4	6.3

*site specific data not available

TABLE 4
CALCUALTED RISKS (RCRS) FOR THE ENVIRONMENTAL COMPARTMENTS DUE TO THE USE OF BORON IN LIQUID DETERGENTS (HERA, 2005)

Environmental compartment	PEC value as B	PNEC value as B	RCR (PEC/PNEC)
Surface Water			
Regional	0.45 mg/L	3.45 mg/L	0.13
Continental	0.0013 mg/L		<0.01
Local	0.45 mg/L		0.13
River monitoring data	0.447 mg/L		0.13
Freshwater sediment			
Regional	0.008 mg/kg	3.29 mg/kg ww.	<0.01
Continental	0.003 mg/kg		<0.01
Local	0.96 mg/kg		0.29
Agricultural soil			
Regional	<0.00008 mg/kg	0.16 mg/kg ww.	<0.01
Continental	0.00002 mg/kg		<0.01
Local 30 days	0.029 mg/kg		0.18
Local 180 days	0.028 mg/kg		0.17
Grassland soil			
Local 180 days	0.006 mg/kg	0.16 mg/kg ww.	0.04
Irrigation			

Environmental compartment	PEC value as B	PNEC value as B	RCR (PEC/PNEC)
Soil Porewater	0.016 mg/L	1 mg/L	0.02
STP effluent	0.044 mg/L		0.04
Sewage treatment plant			
Local	0.044 mg/L	112 mg/L	< 0.01

TABLE 5
CALCULATED RISK CHARACTERISATION RATIOS (RCRS) (*GENERIC ASSESSMENT*) BASED ON THE USE OF BORON WITHIN DIFFERENT INDUSTRY SECTORS AND FOR DIFFERENT LIFE CYCLE STAGES (ECHA/ TRANSITIONAL ANNEX XV REPORT (2009A+B).

Industry sector	Life cycle stage	$RCR_{add.\ STP}$	$RCR_{add.\ water}$	$RCR_{add.\ sediment}$
Producers	Production/import	12.75	12.92	9.61
Borosilicate	Formulation	2.14 -3.06	2.61 - 3.50	2.33 - 3.00
IFG/TFG	Formulation	2.17- 4.34	2.61 - 3.50	2.39 - 3.83
Ceramics	Formulation	2.79 - 3.99	3.24 - 4.40	2.78 - 3.61
Industrial fluids	Formulation	2.66	3.10	2.72
Metallurgy	Formulation	2.35	2.81	2.50
Flame retardants	Formulation	4.29	4.70	3.83
Detergents	Formulation	2.69	3.14	2.72
Cleaners	Formulation	0.17	0.69	1.00
Agriculture (fertilisers)	Formulation	0.99	1.50	1.56
Various chemical effects	Formulation	1.97	2.44	2.22
Borosilicate	Industrial use	25.53	25.34	18.11
IFG/TFG	Industrial use	27.14	26.86	19.22

Industry sector	Life cycle stage	$RCR_{add. STP}$	$RCR_{add. water}$	$RCR_{add. sediment}$
Ceramics	Industrial use	33.22	32.82	23.67
Industrial fluids	Industrial use	4.43	4.76	3.89
Metallurgy	Industrial use	1.89	2.36	2.17
Flame retardants	Industrial use	0.21	0.74	1.06
Detergents	Private use	1.75	2.23	2.11
Cleaners	Private use	0.30	0.82	1.11
Agriculture (fertilisers)	Industrial use	2.49	2.95	2.61
Various chemical effects	Industrial use	3.10	3.54	3.00

TABLE 6
CALCULATED RISK CHARACTERISATION RATIOS (RCRS) (*SITE SPECIFIC ASSESSMENT*) BASED ON THE USE OF BORON WITHIN DIFFERENT INDUSTRY SECTORS AND FOR DIFFERENT LIFE CYCLE STAGES (ECHA/ TRANSITIONAL ANNEX XV REPORT (2009A +B)

Industry sector	Life cycle stage	$RCR_{add. STP}$	$RCR_{add. water}$	$RCR_{add. sediment}$
Producers	Production/import	10.5 - 17.75	10.74 - 17.79	8.06 - 13
Borosilicate	Formulation	1.61 - 5.54	2.09 - 5.91	2.00 - 4.67
IFG/TFG	Formulation	0.51 - 1.97	0.97 - .44	1.22 - 2.22
Ceramics	Formulation	1.00 -3.33	1.50 - 3.76	1.56 - 2.22
Industrial fluids	Formulation	1.34 - 2.92	1.83 - 3.36	1.83 - 2.89
Metallurgy	Formulation	0.42 - 0.77	0.93 - 1.27	1.17 - 1.39
Flame retardants	Formulation	6.21	6.56	5.11
Detergents	Formulation	*	*	*

Industry sector	Life cycle stage	$RCR_{add. STP}$	$RCR_{add. water}$	$RCR_{add. sediment}$
Cleaners	Formulation	*	*	*
Agriculture (fertilisers)	Formulation	0.30 - 1.10	0.81 - 1.60	1.11 - 1.67
Various chemical effects	Formulation	0.54 - 1.63	1.05 - 2.11	1.28 - 1.89
Borosilicate	Industrial use	92.38	90.35	63.67
IFG/TFG	Industrial use	32.82	32.41	23.28
Ceramics	Industrial use	55.46	54.45	38.72
Industrial fluids	Industrial use	2.92	3.36	2.89
Metallurgy	Industrial use	0.77	1.27	1.39
Flame retardants	Industrial use	0.22	0.74	1.11
Detergents	Private use	*	*	*
Cleaners	Private use	*	*	*
Agriculture (fertilisers)	Industrial use	*	*	*
Various chemical effects	Industrial use	3.81	4.22	3.5

*site specific data not available RCR not calculated

Survey of Boric acid and sodium borates (borax)

This survey is part of the Danish EPA's review of the substances on the List of Undesirable Substances (LOUS). The survey concerns the substance boric acid and the salts thereof called borates. This substance was included in the LOUS list in 2009 due to its reproductive toxic effects. The report defines the substances and present information on the use and occurrence of boric acid and the borates internationally and in Denmark, information on existing regulation, on environmental and health effects, on monitoring and exposure, on waste management and on alternatives to the substances.

Denne kortlægning er et led i Miljøstyrelsens kortlægninger af stofferne på Listen Over Uønskede Stoffer (LOUS). Kortlægningen omhandler stofferne borsyre og de afledte borsalte kaldet borater. Rapporten definerer stofferne og indeholder blandt andet en beskrivelse af brugen og forekomsten af borstofferne internationalt og i Danmark, om eksisterende regulering, en beskrivelse af miljø- og sundhedseffekter af stoffet, af moniteringsdata, af affaldsbehandling samt alternativer til stofferne.

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