

**Cellulose / paper wool insulation  
– aspects in relation to regulatory  
requirements and risk assessment**

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## Cellulose / paper wool insulation – aspects in relation to regulatory requirements and risk assessment

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## 1 Introduction

In several European countries there have been productions of cellulose/ paper wool insulation (in the following the term - cellulose wool insulation- will be used as a generic term) since the late 70-ties. The products are marketed as being a green and more a safe alternative compared to other kinds of insulation materials (By og Byg 2003). When introducing alternative materials, which may achieve a widespread use, it is important to make an overall assessment of these products. This report looks at the regulatory framework as well as well as aspects concerning risk assessment and safe use or the potential risk in connection with the use of cellulose wool insulation.

First this document gathers information on cellulose wool and on the basis of the composition evaluates how the chemical regulation applies to the product. Focus is especially directed towards the content of boric acid and borax, which are substances known as additives to cellulose wool insulation and as flame retardants and have rather recently been classified as reprotoxic (Repr 1B) and may impair fertility and cause developmental effects. Because of this classification the substances have been defined as substances of very high concern (SVHC-substances) under the REACH regulation and as such been included on candidate list of REACH - a list that covers substances that may be further subjected to the authorization process. Furthermore, boric acid and borax are often claimed to be used because of their biocidal properties. The implication of the use of these substances as biocides in cellulose wool is discussed in the context of the biocide regulation.

The present description of the regulatory aspects will focus on exposure and safety issues in relation to occupational use whereas use by the private consumer will be dealt with to a lesser extent. A preliminary and up-dated risk assessment will be performed in order to make a preliminary conclusion with respect to whether there is a potential risk in connection with the use of the product. Treatment as waste will be covered as well.

In connection with this work four Danish suppliers of cellulose wool (Papirisolering Danmark Aps (Thermofloc), Papiruld Danmark, Isodan Danmark A/S, and CBI Danmark) has been contacted by telephone and e-mail to collect relevant information regarding their products and data on risk assessment/safe use.

## 2 Content in cellulose wool insulation, classification

Cellulose wool insulation is produced from recycled newspapers that are milled to a fine porous paper mass. To this mass, metallic oxides such as aluminium hydroxide and boric acid/ borax are added to obtain flame retardant properties and also as conservation of the product.

Data from marketing information , contact to Danish suppliers of cellulose wool and data from previous Danish reports gives a rather similar picture of the composition of cellulose wool insulation as it is described as containing recycled paper (usually from newspapers) mixed with boric acid / borax and possible further addition of aluminium hydroxide, see table 1a+b.

Borax salts are covered by various CAS numbers and can be described as disodium tetra borate in various hydrated forms:  $\text{Na}_2\text{B}_4\text{O}_7 \cdot x\text{H}_2\text{O}$  where  $x = 0-10$ , see also table 2.

Table 1a Overview regarding composition of cellulose wool insulation (from reports)

Data source	Content
<b>COWI/DTC (2000)</b>	
Product A	Recycled paper; 9% aluminium hydroxide; 3 % boric acid; 3% borax
Product B	Recycled paper; 9 % boric acid; 9% borax
<b>Schneider (1999)</b>	
Product A	Recycled paper; 6 % salts of boric acid
Product B	Recycled paper; 16 % salts of boric acid
Product C	Recycled paper; 25 % salts of boric acid
<b>Chemtox (1995)</b>	Recycled paper; % of boric acid/ borax not given

Table 1 b Overview regarding composition of cellulose wool insulation (company information)

Data source	Content
<b>Ekofiber (2012)***</b>	
<b>Ekofiber Vægg</b>	Recycled paper; 5%, 12% or 25% of boric acid + borax depending on type of product.
<b>Ekofiber Vind</b>	
<b>Ekofiber Brand</b>	
<b>Ekofiber lösull</b>	Recycled paper; 6% ammonium polyphosphat
<b>Isodan Danmark (2012)*</b>	Recycled paper: 1.5% boric acid; 1.5% borax; 9% aluminium hydroxide
<b>Papiruld*</b>	Recycled paper; < 5 % boric acid; < 1% borax decahydrate; <10% aluminium hydroxide
<b>Danmark (2012)</b>	
<b>Papirisolering Danmark (2012a+b)*</b>	Recycled paper; 10% salts of boric acid
(Thermofloc)	
<b>CBI (2010) Isocell</b>	Recycled paper: 8% boric acid; 6% borax decahydrate
	Changed to
<b>CBI (2012)* Isocell</b>	Recycled paper; 3% boric acid; ?%FR-Master** (flame retardant)

\* Currently stated to be on the Danish market

\*\* Flame retardant, composition not given

\*\*\* Swedish product. No longer imported to DK.

## Recovered paper

Recovered paper mainly consists of cellulose pulp. EINECS identifies cellulose pulp as follows: *"The fibrous substances obtained from the treatment of lignocellulosic substances (wood or other agricultural fiber sources) with one or more aqueous solutions of pulping and/or bleaching chemicals. Composed of cellulose, hemi-cellulose, lignin, and other minor components. The relative*

amounts of these components depend on the extent of the pulping and bleaching processes." (EINECS number 265-995-8).

Cellulose pulp is not classified according to (EC) No 1272/2008 Annex VI.

### Aluminium hydroxide

There is no EU-harmonized classification on aluminium hydroxide (CAS 21645-51-2).

However more than 300 companies/ notifiers have notified self-classifications of the substance to the European Chemical Agency, see <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>.

The vast majority of the companies (214 notifiers) have classified aluminium hydroxide as a skin irritant in category 2; for eye irritation in category 2, and for respiratory irritation as STOT SE.

### Boric acid / borax

Boric acid and the borax substances are according to regulation (EC) No 1272/2008 Annex VI classified as reproductive toxicants in category 1B, see table 2:

Table 2 Boric acid and borax substances on Annex VI, EU regulation 1272/2008

Substance	CAS#	EC#	Chemical formula	Classification	Specific concentration limit	Conversion factor for equivalent boron content
Boric Acid	10043-35-3	233-139-2	H <sub>3</sub> BO <sub>3</sub>	Repr. 1B; H360FD	≥5.5 %	0.175
Disodium tetraborate decahydrate	1303-96-4	215-540-4	Na <sub>2</sub> B <sub>4</sub> O <sub>7</sub> · 10H <sub>2</sub> O	Repr. 1B; H360FD	≥8.5 %	0.113
Disodium tetraborate pentahydrate	12179-04-3	215-540-4	Na <sub>2</sub> B <sub>4</sub> O <sub>7</sub> · 5H <sub>2</sub> O	Repr. 1B; H360FD	≥6.5 %	0.148
Disodium tetraborate anhydrous	1330-43-4	215-540-4	Na <sub>2</sub> B <sub>4</sub> O <sub>7</sub>	Repr. 1B; H360FD	≥4.5 %	0.215
Tetraboron disodium heptaoxide, hydrate	12267-73-1	235-541-3	Na <sub>2</sub> B <sub>4</sub> O <sub>7</sub> · x H <sub>2</sub> O	Repr. 1B; H360FD	≥4.5 %	0.215 (for x = 1)

H360FD: May damage fertility or the unborn child.

The specific concentration limits are adjusted according to the molecular weight of the substances where the basis was the specific concentration limit of 5.5% for boric acid. Expressed as boron content the specific concentration limit would be 1% B for all substances. In case of use of several of the boron containing substances the contribution for each of the substances can be calculated by the use of the conversion factor and respecting the overall specific concentration limit of boron at 1%.



The Danish EPA has played a key role in classification of boric acid and the borax substances because of the concern for the adverse effects regarding fertility and developmental toxicity of the substances. Since year 2000 boric acid and the borax substances have been placed on the Danish EPA list of “undesired substances” due to the concern for adverse effects in relation to fertility and developmental toxicity. In 2007 the EU-harmonized classification of the substances was adopted in EU based on classification proposals from Denmark and France and in 2010 the substances were identified as Substances of Very High Concern and included on the REACH candidate list also due to a Danish proposal (see later). (It should be noted, however, that the Polish authorities have put boric acid and borax on ECHAs list of Registry of Intention with a proposal to reclassify the substances as Repr. 2).

The overall aim of the classification of a substance is to warn against the hazardous properties and give information to professional and private users on how to handle the substance and to take precautionary measures in order to avoid any adverse effect from the use of the substance. Thus when chemicals are classified for severe effects such as reprotoxic effects it is important to continuously follow the use of the substances and to make sure that in the present use they do not constitute a risk during handling and use.

### 3 Cellulose wool insulation - an article or a chemical mixture?

In a regulatory context it may be discussed whether cellulose wool should be defined as a chemical mixture of chemical substances (as each of the components of the cellulose wool can be defined as specific chemical substances as indicated in section 2) or as an article (see below).

Cellulose wool shall, when considered *as a chemical mixture*, follow the rules in Regulation (EC) No 1271/2008 on ‘classification, labelling and packaging of substances and mixtures’ (the CLP-regulation). From this follows that cellulose wool containing higher concentrations of boric acid/borates that indicated above (i.e. more than 4.5-8.5% depending of the substance used) should be classified as Repr. 1B; H360FD.

If, however, cellulose wool insulation was to be regarded as an article no requirements for classification and labelling of the material would apply.

The definition of an article is described in article 2(9)f in the CLP-Regulation (EC) No 1271/2008 and article 3(3) in the REACH- regulation as:

‘...an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition’.

Furthermore the ECHA (2011) in REACH ‘Guidance on requirements for substances in articles’ gives guidance and provides examples in relation how to decide whether at material/object is to be considered as an article or a chemical mixture. Unfortunately the document does not include - among the examples given - a discussion with respect to cellulose wool insulation or a comparable material.

On the basis of the guidance decision tree and proposed questions attached to this, it is in case of cellulose wool insulation not quite straight forward to conclude whether the shape or form of cellulose wool should be considered more important than the chemical composition or *vice versa*.

However, when it comes to a regulatory decision it is in the end up to authorities that have to make the final conclusion. From direct contact made to the Danish EPA it has been clarified that cellulose wool insulation as granulate is considered as a chemical mixture and not as an article, whereas cellulose wool compressed in slaps would be considered as articles. Thus cellulose wool insulation in its porous and granular form shall follow the classification and labelling rules for chemical mixtures, whereas slaps of cellulose wool do not have to apply to these rules.

Considering the specific data achieved for four types of granular cellulose wool insulation available on the Danish market it appears that a content of 10% of boric acid and borates as given for the product Thermofloc would result in a classification of the insulation material as Repr. 1B; H360FD.

## 4 REACH, regulatory tools

### 4.1 REACH Registration

#### *Recycled paper/ cellulose pulp*

According to the REACH guidance on waste and recovered substances the following description is given in relation to recycled (recovered) paper.

Cellulose pulp is listed in Annex IV to REACH according to article 7(a) as a substance of which sufficient information is known to consider the substance to cause minimum risk because of its intrinsic properties. As a result of inclusion in Annex IV cellulose pulp is exempted from registration, downstream user and evaluation obligations. Recovered paper may contain other constituents such as pigments, inks, glues, fillers etc. Regarding the recovery and recycling process, constituents that have no specific function in the material (cellulose pulp), can therefore be considered as impurities. Cellulose pulp from recovered paper consisting exclusively of cellulose with impurities without specific function in the material will therefore be exempt from registration, downstream user and evaluation obligations (ECHA 2010).

#### **Boric acid/ borax**

The ECHA list of registered substances under REACH (June 2012) shows that boric acid and borax have been registered under CAS no. 10043-35-3 and CAS no. 1330-43-4, respectively as high production volume substances at an annual tonnage level of 100,000- 1,000,000 tonnes. REACH requires if the substance is classified as hazardous and the annual tonnage level is above 10 tons that the registration dossier and its chemical safety report contain exposure assessment and a risk characterization for the specific uses of the substance (irrespective whether the use is in relation to a chemical formulation/ mixture or in an article) and it should be described by exposure scenarios how safe use can be obtained by describing the specific conditions and risk management measures of the exposure scenario.

As boric acid / borax are classified substances the supplier shall according to article 31 in REACH provide the recipient with a Safety Data Sheet giving information concerning the hazardous properties of the substance and furthermore describe the conditions and measures to be taken in order to obtain safe use in the exposure scenarios which has been developed in the chemical safety assessment included in the CSR –report.

However the CSR reports and the exposure scenarios that have been included in the registration dossier by the registrant are not assessable in the public version of the ECHA registration inventory, so it is not from the public ECHA inventory clear whether the use of boric acid and borax in connection with cellulose wool insulation actually is included in some of the REACH registrations of the substances.

Furthermore, the use of boric acid/ borax in cellulose wool is not to be covered in the REACH registration if the use of the substances is due to the biocidal properties as this use then requires approval according to the requirements in EU Biocides directive, see chapter 5.

#### **Aluminium hydroxide**

Aluminium hydroxide (CAS 21645-51-2) has been registered under REACH at an annual tonnage level of 1,000,000 - 10,000,000 tonnes. As the registration dossier does not indicate classification for any hazardous end-point the chemical safety assessment does not need to contain exposure assessment and describe exposure scenarios for the specific uses.

## 4.2 REACH Candidate List and possible authorization

The placing of a substance on the REACH Candidate List is the first step towards the authorisation process for a substance. Among the substances on the Candidate List ECHA may choose substances and make proposal to the Commission to further include the substances on the Authorisation List on annex XIV. At present there is no information whether boric acid or borax would be prioritized by ECHA for the inclusion on the authorization list.

In June 2010 boric acid and the borax substances (the substances in table 2) were included on the Candidate List. 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  $\geq 0.1\%$  (w/w).

Suppliers of articles which contain 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 totalling over one tonne per producer or importer per year and if the substance is present above a concentration of  $0.1\%$  (w/w).

## 4.3 REACH Annex XVII restriction on manufacture, marketing and use

EU-national competent authorities can make proposals for inclusions of restrictions on annex XVII for specific uses or for general use of a substance. The proposal has to demonstrate that the risk at the present level of regulation is not adequately controlled and that the use in question poses a risk to human health or environment. The proposal shall be forwarded to ECHA and shall conform to the requirements to an Annex XV dossier.

The ECHA document 'Guidance for the preparation of the Annex XV dossier for restrictions' describe in detail the relevant elements to address in an Annex XV restriction proposal (ECHA 2007) according to the requirements given in REACH, Annex XV.

An annex XV proposal for restriction shall contain a risk assessment documenting that risk for human health or environment is not adequately controlled. Thus in relation to human health assessment the hazardous properties should be described and Derived No Effect Levels (DNEL-values) should be identified for the relevant routes of exposure. Further exposure assessment should be performed for the specific exposure scenarios and in the risk characterization phase it is evaluated whether the estimated exposure exceeds the relevant DNEL value as this would then document that risk is not adequately controlled and that the proposed restriction is needed.

Furthermore possible alternative substances or technologies should be presented and the risk associated with the alternatives should be addressed as far as possible based on the existing knowledge.

Another key part of the document is the socio-economic analysis which shall contain a socio-economic cost-benefit analysis of the implementation of the proposed restriction and shall also address the effectiveness and practicability of the restriction.

As this DHI-report focuses on the risk related issues with respect to regulatory requirements in relation to cellulose wool insulation the following section will describe the current knowledge concerning the potential risk associated to the use of cellulose wool insulation with special focus on the content of boric acid/ borax.

### 4.3.1 Risk assessment related issues

To our knowledge no up-to-date and *in depth* risk assessment of the use of cellulose wool for insulation has been performed according to the requirements of an annex XV restriction proposal. Thus it is not possible to conclude to which extent the exposure in connection with the use of cellulose wool insulation would constitute a risk for the professional or private user.

#### *Previous assessments*

Chemtox (1995) made a short report on risk assessment of boric acid/borax in cellulose wool insulation. The starting point for the assessment was a calculated accepted daily intake, ADI for boric acid/ borax of 0.30 mg / kg bw/d corresponding to an *ADI for boron equivalents of 0.05 mg B/kg bw/d*. The ADI was calculated from a NOAEL of boric acid /borax with respect to effects on reproduction of 30 mg/kg bw/d and by the use of a safety factor of 100. With respect to occupational exposure a measured dust level of 0.86 mg/m<sup>3</sup> measured as boron oxide was used for the risk characterisation. Based on this level and a respiration air volume of 4.5 m<sup>3</sup>/person/day and an assumed dust level of 0.86 mg/m<sup>3</sup> a daily inhalational dose of *0.017 mg B/kg bow/d* was calculated. This exposure level was found to be a *factor 3 below the ADI value*, and thus it was concluded that under normal occupational handling of cellulose wool the boron exposure does not constitute a risk to the worker. It should be noted that the reporting in this document is very poor and no references to the toxicological information is given.

Schneider (1999) conducted indoor measurements of boron in 4 houses where cellulose wool insulation have been used in order to evaluate whether the use of cellulose wool with a content of boric acid/ borax would result in significant exposure to the inhabitants. The level of boron (measured as boric acid) in indoor air was below the detection limits used (0.007 mg/m<sup>3</sup> for the particle phase and 0.004 mg/m<sup>3</sup> for the vapour phase). In indoor dust boric acid levels up to 0.039 mg /g dust was found. Further, a surface load on the floor of up to 0.0026 mg boric acid/ m<sup>2</sup> was found. Overall, it was concluded that these levels were far below levels of concern even for small children ingesting high amount of dust.

COWI/DTC (2002) performed a more thorough risk assessment of cellulose wool containing boric acid /borax. Based on the evaluation of IPCS/WHO (1998) a TDI of 0.4 mg B/kg bw/d was used. This value was derived from a NOAL for reproductive toxicity in rats of 9.6 mg B/ kg bw/d and using an overall safety factor of 25. Worst case exposure for total dust when handling cellulose wool (with a content of 6% of boric acid + borax) was based on literature data 23 mg dust/m<sup>3</sup> as an 8 hours average value. With a daily occupational inhalation volume of 7.3 m<sup>3</sup> a daily exposure of 7.4 mg boric acid + borax was calculated (corresponding to 1.07 mg B/d). If a body weight of 80 kg for a worker was assumed this dose would then only account for 3.4 % of the TDI value.

Breum et al. (2002) conducted measurements and a detailed analysis of occupational exposure in relation to a test set-up for insulation work with various insulation materials. Cellulose wool insulation was handled and blown according to the described procedures by skilled persons. In general the use of granular insulation materials resulted in higher airborne exposure levels compared to use of slaps. For a worker making roof insulation with cellulose wool average dust levels of 40 -516 mg/m<sup>3</sup> dust was measured during the spraying operation (approximately 20 minutes). In addition to this Breum et al. (2002) reported other data from the literature which indicated an 8 h average dust level of 21-35 mg/m<sup>3</sup> for an operator performing roof insulation. Other data indicated a level of 55 mg B/m<sup>3</sup> in connection with roof insulation whereas a level of 15 mg/m<sup>3</sup> (measured as boric oxide) was found in connection with wall insulation with cellulose wool. Overall, it was concluded that the during the spraying of cellulose wool insulation it was not possible to comply with the occupation limit value for total organic dust of 3 mg/m<sup>3</sup> and the use of respirators for personal respiratory protection was considered to be necessary. However from the figures in the report it can be seen that also the occupational limit values for aluminium, fibres and boron was exceeded in connection with cellulose wool insulation.

It is not possible based on these data to make a more overall conclusion to which extent there might be a risk potential in connection with cellulose wool insulation. Thus it seems relevant to examine whether new information regarding hazard assessment of boric acid/ borax or further

assumptions regarding the exposure estimation would provide a better basis for a risk assessment.

Another aspect of cellulose wool insulation which has not been fully clarified is the biodurability, the possible accumulation and the toxicity of cellulose insulation fibres in the lung after chronic exposure. Muhle et al. (1997) found a half-life for clearance of 564 days of cellulose fibers from the rat lung after one single dose of 2 mg insulation fibers instilled intertracheally. Based on this they suggested that further chronic toxicity inhalation studies should be conducted.

### 4.3.2 Update of risk assessment

The following section is not intended to describe an in depth risk assessment with detailed descriptions of various exposure scenarios with respect to inhalational exposure and dermal exposure to boric acid and borax. Rather it should be seen as a first attempt to make some rough and conservative assumptions regarding worst case exposure and to evaluate whether these scenarios would point towards an exposure that exceeds the tolerable intake (in REACH termed the DNEL value) as this then could call for further and more elaborated exposure scenarios and risk assessment.

In the section below the exposures are often given in *mg boric acid* or *mg borax*. In order to make comparison to the DNEL values expressed in *mg B* the following conversion factors have to be used (from RAC 2010b):

1 mg disodium tetra borate (anhydrous) = 0.215 mg B.

1 mg boric acid = 0.175 mg B.

In the scenarios it is further assumed that the boric acid + borax is added 1:1 at a total level of 5% to the recycled paper as this level would represent an upper level that would not require classification.

#### ***Exposure, air***

- 1) A short term (15 min) realistic worst case level for an operator of 516 mg dust/m<sup>3</sup> is assumed. This maximum dust level was measured by Breum et al. (2002).

Assuming a 5% content of boric acid/borax this would lead to a level of boric acid/borax of 25.8 mg/m<sup>3</sup>.

The conversion factor from boric acid to boron is 0.175, and for anhydrous disodium tetra borate 0.215. Assuming a fifty-fifty distribution of the substances and an average conversion factor of 0.195 the exposure level can be converted to 5 mg B/m<sup>3</sup> as a realistic short term exposure.

Assuming an inhalation volume of air of 10 m<sup>3</sup>/ 8 h then inhalation for 15 minutes can be calculated to 0.31 m<sup>3</sup>.

Thus a worker with a body weight of 70 kg would be exposed to 0.022 mg B/kg bw/event.

It can be discussed whether a worker will be subjected at a dust level of 516 mg dust/m<sup>3</sup> without wearing respiratory protection as this is a very high exposure level for dust. Thus it seems during a whole day reasonable to estimate a maximum of 15 minutes at this high level.

- 2) An average 8 h value of 23 mg/m<sup>3</sup> for total dust is assumed based on the data from COWI/DTC (2002) and Breum et al. (2002). Assuming that 5% of the dust is boric acid/borates and by use of the conversion factor of 0.195 an average 8h exposure for boron of 0.22 B mg/m<sup>3</sup> can be calculated.

Assuming an inhalation volume of  $10\text{m}^3/\text{d}$  and a body weight of 70 kg this would lead to a daily exposure of  $0.032\text{ mg B/kg bw/d}$ .

- 3) If it is anticipated that an operator has one short term exposure per day and the rest of the day is subjected to the average exposure level then a total exposure of  $0.056\text{ mg B/kg bw/d}$  can be assumed. This scenario may be considered as a realistic worst case scenario to be used further for the risk characterisation.
- 4) If it is assumed that dust levels are controlled down to the occupational exposure limit for organic dust of  $3\text{ mg/m}^3$  then the daily boron exposure could be reduced to  $0.029\text{ mg B/m}^3$ . Thus under these controlled conditions a rather low exposure of  $0.004\text{ mg B/kg bw/d}$  can be estimated. However, this scenario is not considered realistic for a worst case scenario and will not be used further.

### ***Exposure, dermal load***

In addition to inhalational exposure dermal exposure should be considered as well as dust containing boric acid/ borax may be deposited on the bare skin and thus potential skin absorption may occur (see later).

As a first tier conservative estimate it is assumed that both hands and forearms are subject to dust exposure (total surface area of  $840\text{ cm}^2 + 1140\text{ cm}^2 = 1980\text{ cm}^2$ . (Surface areas from ECHA (2010) guidance on consumer exposure estimation).

Hughson & Cherrie (2005) in their assessment of dermal exposure to zinc dust compared measured data with estimates from the EASE model and concluded that EASE is a very conservative first tier assumption. EASE assumes a dermal load of  $5\text{-}15\text{ mg/cm}^2/\text{d}$  in the category "wide dispersive use with extensive direct handling" which seems to be an appropriate category to anticipate in connection with the handling of cellulose wool.

Thus a daily dust load of  $1980\text{ cm}^2 \times 15\text{ mg/cm}^2 / 70\text{ kg} = 424\text{ mg dust/kg bw/d}$  can be calculated.

Anticipating that 5% of the dust is boric acid/ borax and using the conversion factor 0.195 for calculating the boron equivalent the dermal load can be calculated to  $4.13\text{ mg B/kg bw/d}$ .

### ***Background exposure***

In a recent risk assessment on boric acid and borates from RAC (2010b) the background exposure to borates from food and drinking water is further included in an overall exposure estimate of boron. Typical background exposure levels and realistic worst case background exposure levels are estimated to  $0.038\text{-}0.046\text{ mg B/kg bw/d}$  and  $0.058 - 0.066\text{ mg B/kg bw/d}$ , respectively.

### ***Hazard characterization, DNEL***

The most relevant starting point for hazard characterisation of boric acid and borax would be the recent opinion made by the Risk Assessment Committee at the ECHA. The RAC opinion and its background documentation (RAC 2010a+b) are related to the use of boric acid and borates as constituents in photographic applications (developers and fixing agents) for consumers developing their own film and paper photos.

In this assessment a derived no effect level DNEL (comparable to a TDI) of  $0.096\text{ mg B/kg bw/d}$  was concluded for consumers. This value was derived from a NOAEL of  $9.6\text{ mg/kg bw/d}$  in rats in an oral developmental toxicity study where effects (reduced foetal body weight and increased

incidence of short ribs) were seen at a LOAEL of 13.3 mg B/kg bw/d. To this NAOEL value an interspecies assessment factor of 10 and an intraspecies assessment factor of 10 was applied in order to achieve the DNEL value of 0.09 mg B/kg bw /d for consumers. (In this opinion an oral absorption rate of 100% is assumed and the DNEL value is then considered as a metric for the internal systemic exposure as well).

In the REACH guidance document R8 for risk characterization it is generally recommended to use an intraspecies assessment factor of 5 when a DNEL for workers is derived (ECHA 2010 c). Thus the corresponding DNEL value for workers would then be 0.19 mg B/kg bw/d.

Boric acid and disodium tetra borate have also recently been evaluated in connection with the inclusion procedure for an active substance in Annex I or Ia to the Biocides Directive 98/8/EC (AR-Biocides (2009a+b)). In these reports an acceptable exposure level of 0.1 mg B/kg bw/d as a rounded figure was used (based on the same data as used later by RAC also). In these assessments the same acceptable exposure value is used for professional operators as well as for non-professional users and the general public.

In the following preliminary risk characterisation a tolerable occupational exposure level (a DNEL value for workers) of 0.19 mg B/kg bw/d will be used as this is considered most relevant in connection with a risk assessment performed in the context of REACH.

### **Risk Characterization Ratios, RCR**

In REACH a risk characterisation is performed by calculating the Risk Characterisation Ratio according to the expression:

$$\text{RCR} = \text{DNEL} / \text{exposure}$$

Thus a RCR value above 1 indicates that the exposure is above the tolerable level and that risk is not adequately controlled.

#### ***RCR inhalational exposure***

For the inhalation exposure route an absorption rate of 100% is assumed.

For scenario 3 (the most conservative scenario) the calculated boron exposure can be directly compared to the DNEL value and a RCR can be calculated:

$$\text{RCR} = \text{Exposure} / \text{DNEL} = 0.056 \text{ mg B /kg bw/d} / 0.19 \text{ mg B /kg bw/d} = \mathbf{0.29}.$$

#### ***RCR dermal exposure***

Before calculating a RCR the dermal boron load has to be transferred to internal systemic dose taking account of the dermal absorption rate of boric acid/ borax. In the RAC-documentation and the Biocides evaluations a dermal absorption rate of 0.5% has been used in relation to dermal exposure to particles/dust of boric acid/ borax or to solutions that dry out on the skin.

Thus the dermal load of 4.13 mg B/ kg bw/d can be converted to an *internal dose* of 0.021 mg B/ kg bw/d.

From this a RCR can be calculated:

$$\text{RCR} = \text{Exposure} / \text{DNEL} = 0.021 \text{ mg B /kg bw/d} / 0.19 \text{ mg B /kg bw/d} = \mathbf{0.11}.$$



### ***RCR background exposure***

A RCR for the realistic worst case background exposure of 0.066 mg B/kg bw/d can be calculated:

$$\text{RCR} = \text{Exposure} / \text{DNEL} = 0.066 \text{ mg B /kg bw/d} / 0.19 \text{ mg B /kg bw/d} = \mathbf{0.35}.$$

### ***RCR for aggregated exposure***

An overall or aggregated RCR for the realistic worst case scenarios can be calculated by adding the RCRs for inhalational, dermal and background exposure:

$$\text{RCR aggr.} = 0.29 + 0.11 + 0.35 = \mathbf{0.75}.$$

Thus a risk in relation to the additional boron exposure from cellulose wool insulation cannot be demonstrated for these assumed worst case occupational exposure scenarios.

For cellulose wool insulation containing e.g. 10% of boric acid+ borax twice the RCR value would be obtained and an unacceptable risk could then be concluded in relation to the described worst case exposure scenarios.

Also, it has to be noted that *if* the acceptable exposure level of 0.1 mg B/kg bw /d for professional user in the context of the Biocides directive was to be used instead of the DNEL value of 0.19 then the RCR would be twice the values as calculated above and based on this an unacceptable risk level would be concluded.

Further, it can be seen that the RCR may be influenced to a great extent if several event of peak short term exposure would occur as each additional events (with an exposure of 0.022 mg B/kg bw/event) during a day would influence the RCR with 0.12. Thus four (or more) daily events would result in a RCR above 1. However it seems unlikely that such an exposure would be realistic.

### **Uncertainties regarding exposure**

The rough and preliminary nature of the above exposure estimation should be emphasized and further elaboration and documentation would be needed for a more detailed in-depth risk assessment for both typical and worst case exposure scenarios.

Consideration should especially be given to data gathering and further documentation on key parameters such as:

Typical and realistic worst case inhalational exposure levels during different tasks working with cellulose wool insulation.

Boron fraction in the dust (as boric acid and borax powder is added to the recycled paper the dust level of these substances may be considerable higher than the nominal concentration of the substances in the product).

Typical and realistic worst case dermal exposure (skin surface areas and dermal load).

Improved data on skin absorption of boric acid/borax.

Especially on damaged skin the absorption may be highly increased as several cases exist (even with lethal outcome) where boric acid powder og concentrated solutions has been applied on areas with damaged skin. A very extensive overview on these cases have been given by Kliegel

(1980), however, it is not possible from these data to give further indications regarding the percentage of uptake under varying skin conditions, however, especially the uptake from wounds and burned skin areas may be critical.

### ***Risk assessment consumers and the general public***

#### *Do-It-Yourself (DIY) insulation by the private consumer.*

The DNEL of 0.096 mg B/ kg bw/ d for consumers (the private user) and the general public is only ½ the value of the occupational DNEL, but in general it seems unlikely that consumers should be exposed to the same extent as professional operators, as e.g. spraying of cellulose wool is to be considered as a rather seldom event for the private user. However the possibility cannot be totally dismissed as web-instructions for DIY insulation work using spray equipment has been found (Papiruld Danmark, 2012). If such worst case exposures for consumers would occur (comparable to the exposure to professionals) the DNEL of 0.096 mg B/kg bw/d would clearly be exceeded.

#### *Indirect and incidental exposure*

The reported in-house levels of boron in air and dust by Schneider (1999) indicate very low exposure for indirect exposure in houses containing cellulose wool insulation.

However, incidental exposure to children may occur if they get access to the cellulose wool or dust/ powder from empty packaging during the period of the insulation work and oral exposure may occur either due to hand to mouth activities or due to deliberate ingestion of the white dust/ powder. Oral doses of boric acid down to 3-6 g have been reported as lethal (the reporting is however poor) and multiple doses of about 1 g and above have resulted in various symptoms including dermatitis, alopecia, loss of appetite, nausea, vomiting, diarrhoea, and focal or generalised central nervous system irritation or convulsions (AR-Biocides, 2009a). The amount of data on intoxications related to boric acid and borax is extensive and the doses that cause intoxications has been found to vary to a great extent from individual to individual (Valdes-Dapena & Arey, 1962 and Kliegel, 1980). Thus only a low margin of safety may be present if a child ingests a few grams of powder/ dust from cellulose wool insulation containing high amounts of boric acid and borax.

## **5 Boric acid/ borax under the EU Biocide legislation**

According to the suppliers of cellulose wool insulation boric acid / borax is not only added for its flame retardant properties but also for its preservation of the insulation material. The product sheets claim that boric acid / borax protects the insulation material against mold, or fungal growth, and furthermore, protects against pests e.g. mice as well as protecting wooden structures (Papirisolering Danmark (2012); Papiruld Danmark (2011).

Such use of boric acid / borax is subject to the EU Biocidal Products Directive (98/8/EC) and to the coming Biocidal Products Regulation, effective from Sept. 1, 2013. When the Directive and the Regulation are fully implemented, all biocidal products must be approved before they are put on the market in the EU.

According to the existing Directive 98/8/EC, Article 2 (1)(a) Biocidal products are "active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means". The Regulation will not change this interpretation.

There are 22 types of biocidal products, as defined in the Directive (where there originally were 23) in the Regulation. As for the active substances in each product-type, applications were submitted between 2004 and 2008 for the approval of about 360 different substances, each for specified product-types. An approved application is specific only for the applicant, or company, that submitted the dossier. With effect from Sept. 1, 2006, it was forbidden to use any other substances in any other product-type as biocides. Boric acid / borax were applied for products in product-types 8). Therefore, after Sept. 1, 2006, it was forbidden to claim a biocidal effect for boric acid / borax other than as a wood preservative.

The evaluation of applications for product-type 8 (wood preservative), as applied for by Rio Tinto Borax & Etimine S.A., was completed in 2009, and the substance was approved (Directive 2009/94/EC). All other applications for other product-types for boric acid / borax were withdrawn before their evaluation by the authority was completed. It is to be noted that now only the company Rio Tinto Borax & Etimine S.A. may market boric acid / borax as a biocide, and only as a biocide for wood preservation.

According to the claims mentioned above for boric acid / borax in cellulose wool, this use could be covered by the following product types:

*Product-type 8: Wood preservatives.*

These are products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms. Approval of these products prior to marketing has been mandatory in Denmark for many years. In 2004 an application for boric acid/ borax for this use according to the Biocidal Products Directive was submitted by the company Rio Tinto Borax & Etimine S.A.

*Product-type 9: Fibre, leather, rubber and polymerised materials preservatives.*

These are biocidal products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration.

In Denmark this product type is not as yet subjected to an approval procedure. However, according to Commission Decision 2010/72/EU, boric acid, disodium tetra borate anhydrous and disodium octaborate tetra hydrate are not allowed to be marketed as biocidal active substances for this product type after 9 February 2011.

*Product-type 10: Masonry preservatives.*

These are biocidal products used for the preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological and algal attack. This product type is partly covered by the current Danish approval procedure. However, as for product-type 9, according to Commission Decision 2010/72/EU, boric acid, disodium tetra borate anhydrous and disodium octaborate tetra hydrate are not allowed to be marketed as biocides for this product type after 9 February 2011.

*Product-type 14: Rodenticides.*

Products used for the control of mice, rats or other rodents were covered by the original Danish approval procedure.

According to the current list of approved substances for this product type, either boric acid or any borax substances are included. See the following URL:

[http://www.mst.dk/Virksomhed\\_og\\_myndighed/Bekaempelsesmidler/biocider/Hvornår+ansøger+du/aktivstoffer+og+ansøgningsfrister/produkttype14.htm](http://www.mst.dk/Virksomhed_og_myndighed/Bekaempelsesmidler/biocider/Hvornår+ansøger+du/aktivstoffer+og+ansøgningsfrister/produkttype14.htm).

***Thus, the use of boric acid and borates in cellulose wool with the claim of biocidal function other than wood preservation is not allowed in accordance with current EU biocides legislation.***

However, it should be noted that if the supplier claims that boric acid / borax is added only for its flame-retardant properties and does not further mention or claim biocidal properties, then

the use is not subject to the requirements and approval procedure according to Danish or EU legislation.

## 6 Occupational measures

For synthetic mineral fibers a statutory order stipulates a set of requirements for the work covering the various occupational tasks where workers may be exposed during storage, handling and use of the fibers in construction and demolition work (AT 1988).

No such statutory order exists for cellulose wool insulation. However, the Sectoral 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 contain 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 avoiding clothing is recommended during dusty work. (Papiruld Danmark, 2011).

Furthermore, the following occupational limit values are relevant to observe (AT 2011):

Organic dust, total: 3 mg/m<sup>3</sup>

Disodium tetra borate, anhydrous: 1 mg/m<sup>3</sup>

Disodium tetra borate, pentahydrate: 1 mg/m<sup>3</sup>

Disodium tetra borate, decahydrate: 2 mg/m<sup>3</sup>

## 7 Waste - legislation and handling

According to the statutory order on waste (Danish MoENV, 2011) § 2 (2) and Annex 4, waste is to be considered as hazardous waste and treated as such if the content of a substance in the waste would lead to classification as hazardous according to the criteria for classification of chemical mixtures (see table 1 concerning the specific concentration limit of boric acid and the borax substances). Thus the concentration limits apply to waste in all forms including articles.

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. The use of cellulose insulation waste as compost on green areas has been described on the website by Papiruld Danmark. However, according to § 10 in the statutory order for the use of waste for agricultural purposes (Danish MoENV, 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.

## 8 Summary & conclusions

The aim of this report was to evaluate cellulose wool insulation in a regulatory and risk based context and to describe how the current legislation applies to the insulation material. The starting point for such an evaluation is of course information of the content of the material. Thus chemical content of the material can - based on information from the Danish Cellulose wool suppliers - be described as a mixture of the chemical substances: recycled paper; boric acid and

borax (disodium salts of boric acid) and additional metallic oxides/ hydroxides e.g. aluminium hydroxide. Information from four Danish Companies indicate that the content of boric acid / borax may vary from 3 to 10% and that one product had a further content of aluminium hydroxide which was indicated to be below 10%.

The addition of these metal oxides is preliminary due to their flame retardant properties. However for boric acid / borax also the biocidal properties are mentioned as it is claimed that the insulation material is protected against decay from mold, fungi and pests e.g. mice and that the insulation further protect wooden structures.

#### *CLP classification*

In relation to hazardous properties and classification only boric acid and borax have EU harmonised classifications. Boric acid and the borax substances are classified for hazardous properties in relation to fertility and adverse developmental effects as Repr. 1B H360FD (May damage fertility or the unborn child). Specific concentrations limit in the range of 4.5% to 8.5% apply to the classification depending on the level of hydration of the substances.

Company specific classification for aluminium hydroxide has been notified to ECHAs classification inventory and the substance have been notified with classification for skin irritation in category 2; for eye irritation in category 2, and for respiratory irritation as STOT SE.

No classification for cellulose paper pulp has been notified. Furthermore, cellulose pulp is exempted from registration in REACH as the substance is included in Annex IV to REACH as a substance of which sufficient information is known to consider the substance to cause minimum risk because of its intrinsic properties.

Classification and labelling requirements according to the EU CLP regulation only apply to chemical mixtures and not to materials covered by the definition of articles.

According to the REACH and CLP regulation an article is defined as '...an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition'. Based on this it is the current opinion of the Danish EPA that granular cellulose wool insulation is to be considered as a chemical mixture, whereas compressed material in a slap form is considered as an article. From this it follows that granular cellulose wool insulation should be classified and labelled Repr. 1B H360FD if the content of boricid/ borax is above the specific concentration limit in relation to the boron content. No classification/ labelling is warranted if cellulose wool insulation is marketed as compressed slaps.

#### *REACH*

With respect to the REACH legislation boric acid and borax have been identified as Substances of Very High Concern (SVHCs) and as such been included on the candidate list for authorization. If considered relevant ECHA may choose substances from the candidate list and propose the Commission to include these on Annex XIV of REACH that lists all substances that are subject to authorisation before use. Thus inclusion on the candidate list is a warning signal which indicates that more strict regulation may apply to these substances. The use of the substances that are listed on the candidate list in chemical mixtures or in articles gives further obligation regarding information from the suppliers. Suppliers of chemical mixtures shall on request deliver safety data sheets for mixtures not subject to classification but with a level of the SVHC substance above 0.1 %, while suppliers of articles on specific request from consumers shall inform if the content of a SVHC substance is above 0.1%.

In a REACH registration of a chemical substance it is further the obligation of the registrant when the substance is classified as hazardous and it is marketed at an annual tonnage level above 10 tons to make exposure assessment and risk characterization and demonstrate the safe use by describing an exposure scenario for each of intended use of the substance. As the chemical safety report is not public available from the ECHA web site covering REACH registrations it is not possible to evaluate to which extent the registration dossiers on boric acid and borax cov-

er a risk characterization and a description of exposure scenarios for the use of the substances in cellulose wool insulation.

REACH gives the opportunity to the national competent authority to propose restriction related to specific uses of a substance if it in an Annex XV dossier submitted to ECHA can be demonstrated that the risk is not adequately controlled for the current use of the substance. In order to evaluate whether there could be a basis for such a restriction proposal a preliminary attempt has been made to evaluate whether the use of cellulose wool with a certain content of boric acid/ borax would constitute a risk. The assessment is based on recent expert evaluations defining a tolerable exposure level of boron (a DNEL level) and from preliminary assumptions regarding realistic worst case exposure scenarios.

From this preliminary assessment it can be seen that if cellulose wool contain boric acid/borax levels of about 5% no unacceptable risk can be demonstrated in relation to occupational as well as consumer exposure as the calculated risk characterisation ratios are below 1. However, if a private consumer use spray application the risk characterisation ratio may be above 1 indicating an unacceptable risk level for this worst case scenario. However, for higher levels of boric acid and borax e.g. at a level of 10% or higher a risk characterisation ratio above 1 can be calculated for the occupational worst case scenarios. It has to be emphasized that this is based on rather preliminary assumptions regarding exposure and further in depth analyses of typical and worst case exposure has to be performed for further substantiating the results of the calculated risk characterization ratios.

#### *Biocides legislation*

Under the current EU Biocides legislation boric acid and borax as active biocidal substances have only been approved in connection with products for wood preservation. Thus the use of boric acid and borax in cellulose wool insulation with the claim of biocidal function other than wood preservation is not allowed.

However, if the supplier claims that boric acid / borax is added only for its flame-retardant properties and does not further mention or claim biocidal properties, then the use is not subject to the requirements and approval procedure according to Danish or EU Biocides legislation.

#### *Occupational measures*

For the work with synthetic mineral fibre a statutory order with requirements has been issued by Danish Working Environment Authority. No such statutory order exists in relation to cellulose wool insulation. However from a guidance document and a safety data sheet it can be seen that coveralls, gloves, eye goggles and respiratory protection with an P2 filter is recommended .

Also it has to be noted that Danish occupational limit values exist for organic dust and disodium tetra borate.

#### *Waste*

According to the Danish statutory order on waste the waste is to be considered as hazardous waste and treated as such if the content of a substance in the waste would lead to classification as hazardous according to the criteria for classification of chemical mixtures. Thus the specific concentration limit of the boric acid/ borax calculated as boron content should be considered for the waste.

Local instructions and approvals from the municipality regarding waste handling and re-use e.g. in agriculture or other recycling options should always be followed.

#### **Overall conclusions**

*Classification and labelling* requirements according to the EU CLP regulation only apply to chemical mixtures and not to materials covered by the definition of articles. It is the current opinion of the Danish EPA that granular cellulose wool insulation is to be considered as a chemical mix-

ture, whereas compressed material in a slab form is considered as an article. From this it follows that granular cellulose wool insulation should be classified and labelled Repr. 1B H360FD if the content of boric acid/ borax is above the specific concentration limit given for this classification. However, no classification and labelling is warranted if cellulose wool insulation is marketed as a compressed slab as this is considered as an article.

As boric acid and the borax substances have been identified as *Substances of Very High Concern (SVHCs)* and been included on the Candidate List for authorisation ECHA may in future decide to prioritise these substances for inclusion into the *authorisation process (Annex XIV in REACH)*. If the substances are included on Annex XIV an application for authorisation need be submitted to ECHA demonstrating safe use of the substances in cellulose wool insulation. If adequate control of risks can be demonstrated a permission for the further use has to be granted.

If it can be demonstrated that risk is not adequately controlled in relation to use of boric acid and borax in cellulose wool insulation, the national authorities can make a specific proposal for *restrictions in REACH (Annex XVII)*. A preliminary risk assessment for insulation workers performed in connection with this report indicates, however, that an unacceptable risk cannot be shown in relation to occupational exposure scenarios with boric acid and borax from cellulose wool insulation unless the concentration of these substances is above the specific classification limits. If private consumers are subjected to identical worst case scenarios using spray application of the insulation material this may lead to an unacceptable risk level.

When boric acid and borax are used for their *biocidal properties* this has to be in accordance with *the EU Biocides legislation*. Under the current EU Biocides legislation boric acid and borax as active biocidal substances have only been approved for the use in products for wood preservation. Thus the use of boric acid and borax in cellulose wool insulation with the claim of a biocidal function other than wood preservation is not allowed.

Finally, it can be debated whether the use of reprotoxic substances as additives in a product in concentrations of about 5% (and just below the classification limit) is to be considered as a 'green product' which often is claimed for cellulose wool insulation due to the use of recycled paper.

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