Annex XV dossier

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

Substance Name(s): **Diboron trioxide**

EC Number(s): **215-125-8**

CAS Number(s): **1303-86-2**

Submitted by: **Federal Institute for Occupational Safety and Health (BAuA)**
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PUBLIC VERSION: This report does not include the confidential annexe referred to in the document.

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Substance Name(s): Diboron trioxide

EC Number(s): 215-125-8

CAS number(s): 1303-86-2

- The substance is proposed to be identified as substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction category 1B[1] which corresponds to classification as toxic for reproduction category 2[2].

Summary of how the substance meets the CMR (Cat 1A or 1B) criteria

Diboron trioxide is listed by Index number 005-008-00-8 of Regulation (EC) No 1272/2008 as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009, as of 1 December 2010, and classified in Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1B (H360FD: “May damage fertility. May damage the unborn child.”). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is toxic for reproduction, Repr. Cat. 2 (R60: ”May impair fertility.” R61: “May cause harm to the unborn child”).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance? Yes

1 Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances.

2 Classification in accordance with Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.2 List of harmonised classification and labelling of hazardous substances (from Annex I to Council Directive 67/548/EEC).

PART I

JUSTIFICATION

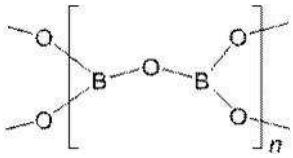
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	215-125-8
EC name:	diboron trioxide
CAS number (in the EC inventory):	1303-86-2
CAS number:	1303-86-2
CAS name:	Boron oxide (B_2O_3)
IUPAC name:	diboron trioxide
Index number in Annex VI of the CLP Regulation	005-008-00-8
Molecular formula:	B_2O_3
Molecular weight range:	≥ 69.62 g/mol
Synonyms:	*Boric oxide*

Structural formula:



1.2 Composition of the substance

Name: Diboron trioxide

Description: mono-constituent substance

Degree of purity: > 97 % w/w[3]

Further details on the composition of the substance are confidential and can be found in the technical dossier or the "confidential annex".

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
Diboron trioxide	> 97 % w/w[3]		

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
confidential			

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks
confidential			

1.3 Physico-chemical properties

The physico-chemical properties were taken from the lead registration dossier for boric oxide and are considered acceptable by DE-CA.

[3] Based on the minimum typical content indicated in the registration dossiers (downloaded on 13/10/2011)

Table 5: Overview of physicochemical properties[4]

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	*white odourless crystalline solid*	
Melting/freezing point	*> 633 K*	*Decomposition occurred*
Boiling point	*Not determined since melting point is above 300 °C*	
Vapour pressure	*Not determined since melting point is above 300 °C*	
Water solubility	*Technically not feasible*	*Boric oxide reacts quickly with water to form boric acid.* *$B_2O_3(s) + 3H_2O(l) \rightarrow 2H_3BO_3(aq)$* *The EU Annex V definition of solubility is the saturation mass concentration of the substance in water at a given temperature. Given that boric oxide reacts with water it would be technically impossible to determine the saturation mass concentration of boric oxide. Any attempt to determine the solubility would in effect be measuring the solubility of boric acid. In saturated aqueous boric acid, boric oxide will immediately react with water and crystallise out as solid boric acid. In conclusion, it is therefore technically impossible to determine the solubility of boric oxide as a discrete species.*
Partition coefficient n-octanol/water (log value)	*Not determined since a partition coefficient is not required if the substance is inorganic*	
Dissociation constant	*The dissociation constant for boric oxide as such cannot be determined because boric oxide is*	

[4] *The references of the values reported in Table 5 will be available in the technical dossier. In case references need to be included an additional column could be added manually to Table 5.*

	converted into boric acid/borate upon dissolution in water	
Flash point	*According to Annex VII, section 7.9, column 2 of Regulation No. 1907/2006, flash-point is not required if the substance is inorganic. Diboron trioxide is an inorganic substance, therefore the test is not required.*	
Flammability Flammability upon ignition (solids,gases): Flammability in contact with water: Pyrophoric properties:	*A study performed according to EU Method A.10 (Flammability (Solids)), the United Nations Document, Recommendations of the Transport of Dangerous Goods, Manual of Tests and Criteria (Test N.1.) and HSE Code of Physio-Chemical Properties 1982, it was determined that the test substance should be classified as "not a highly flammable solid".* *Testing can be waived in accordance with REACH Column 2 of Annex VII, section 7.10: The study does not need to be conducted because Boron oxide reacts quickly with water to form boric acid.* *It has been determined that the test substance was not classified as a pyrophoric solid according to UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and*	

	Criteria for substances of Class 4, Division 4.2.	
Explosive properties	*According to Annex VII, section 7.11, column 2 of Regulation No. 1907/2006, explosive properties of the substance is not required if there are no chemical groups associated with explosive properties present in the molecule. Potential explosive properties are indicated by the presence of certain reactive groups in the molecule. The molecular structure of diboron trioxide indicates that such groups are not present. No reactive or unstable groups are present. The molecular structure does not indicate that these substances will explode under the conditions of the test as described in Test Guideline A.14 of EC Directive 92/69/EEC.*	
Self-ignition temperature	*It was determined that diboron trioxide should be classified as not a self-heating substance of Class 4, Division 4.2.*	*United Nations Recommendations on the Transportation of Dangerous Goods, Manual of Tests and Criteria (Test N4).*
Oxidising properties	*The material meets all criteria for exemption from testing and has a structure not al all conducive with that required to exhibit oxidising tendencies.*	

2 HARMONISED CLASSIFICATION AND LABELLING

Diboron trioxide is listed by Index number 005-008-00-8 of Regulation (EC) No 1272/2008 (as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009 as of 1 December 2010) in Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as follows:

Table 6: Classification according to Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	Classification		Labelling			Specific Conc. Limits, M-factors
		Hazard Class and Category Code	Hazard statement Code	Pictogram, Signal Word Code	Hazard statement Code	Suppl. Hazard statement Code(s)	
005-008-00-8	diboron trioxide; boric oxide	Repr. 1B	H360FD	GHS08 **Dgr**	H360FD		Repr. 1B; H360FD: C ≥ 3,1 %

Hazard statement code: H360FD: May damage fertility. May damage the unborn child.

Diboron trioxide is covered by Index number 005-008-00-8 of Regulation (EC) No 1272/2008 (as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009 as of 1 December 2010) in Annex VI, Part 3, Table 3.2 (list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) as follows:

Table 7: Classification according to Annex VI, Part 3, Table 3.2 (list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008

Index No	Chemical name	Classification	Labelling	Concentration Limits
005-008-00-8	diboron trioxide; boric oxide	Repr.Cat. 2; R60-61	T R: 60-61 S: 53-45	Repr. Cat. 2; R60-61: C ≥ 3,1 %

Risk phrases: R60-61: May impair fertility. May cause harm to the unborn child

3 ENVIRONMENTAL FATE PROPERTIES

Not relevant.

4 HUMAN HEALTH HAZARD ASSESSMENT

See section 2 on Harmonised Classification and Labelling.

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant.

6 CONCLUSIONS ON THE SVHC PROPERTIES

6.1 PBT, vPvB assessment

Not relevant.

6.2 CMR assessment

Diboron trioxide is listed by Index number 005-008-00-8 of Regulation (EC) No 1272/2008 as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009, as of 1 December 2010, and classified in Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1B (H360FD: “May damage fertility. May damage the unborn child.”). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC of Regulation (EC) No 1272/2008 is toxic for reproduction, Repr. Cat. 2 (R60: ”May impair fertility.” R61: “May cause harm to the unborn child”).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009 shows that it meets the criterion for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

6.3 Substances of equivalent level of concern assessment.

Not relevant.

PART II

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

1 INFORMATION ON MANUFACTURE, IMPORT/EXPORT AND USES – CONCLUSIONS ON EXPOSURE

1.1 Information on Manufacture, Import/Export and Uses

Several companies have registered diboron trioxide in 2010. Registration data indicate import and/or production volumes for diboron trioxide with a total volume more of 1000 tonnes per year.

No information was identified on current annual EU export volumes.

Based on the information from the ECHA dissemination website (ECHA 2012). different identified uses by workers in industrial settings, professional workers and consumers are described (Tables 8 and 9).

Table 8: Identified uses in industrial and professional settings as reported in the REACH registration dossiers for diboron trioxide

Identified use
Glass Production (Borosilicate and crystal glass)
Glass fibre production
Frits production
Refractories
Use of Borates in Metallurgy
Flame retardents
Nuclear applications
catalysts
Use of Borates polymer production
intermediate use in the production of non oxide ceramic powders
Use of Borates in detergents and cleaners
Use of Borates in Industrial Fluids
INKS/PAINTS
Production of monocrystalline gallium arsenide wafers
Reagent chemicals
Agriculture
Construction materials
Adhesives
Crystal growth
Use of substance for production

Table 9: Diboron trioxide in consumer applications (based on the information from the ECHA dissemination website ECHA 2012)

Identified use	Product category	Subsequent service life	Article category
Uses of Borates in detergents and cleaners	PC 1: Adhesives, sealants PC 3: Air care products PC 31: Polishes and wax blends PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids PC 35: Washing and cleaning products (including solvent based products)	Yes	
Use of Borates in Industrial fluids	PC 4: Anti-freeze and de-icing products PC 16: Heat transfer fluids PC 24: Lubricants, greases, release products PC 25: Metal working fluids PC 37: Water treatment chemicals	Yes	
Adhesives	PC 1: Adhesives, sealants PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids	Yes	
Agriculture	PC 12: Fertilisers	Yes	
Construction materials	PC 9b: Fillers, putties, plasters, modelling clay PC 21: Laboratory chemicals	Yes	AC 4: Stone, plaster, cement, glass and ceramic articles AC 11: Wood articles
Reagent chemicals	PC 19: Intermediate PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents PC 21: Laboratory chemicals PC 30: Photo-chemicals PC 37: Water treatment chemicals	Yes	
Ink/Paints	PC 18: Ink and toners PC 26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids	Yes	AC 1: Vehicles AC 2: Machinery, mechanical appliances, electrical/electronic articles AC 3: Electrical batteries and accumulators AC 5: Fabrics, textiles and apparel AC 6: Leather articles AC 8: Paper articles AC 10: Rubber articles
other			

The substance has also been registered in a number of preparations listed in the SPIN (Substances in Preparations in Nordic Countries; 2011) - online database. Assigned use categories include:

- paints, lacquers and varnishes,
- glazing materials,
- welding and soldering agents,
- construction materials,
- fireproof cement,
- protective chemicals,
- photo-chemicals,
- others.

Diboron trioxide is a fire resistant additive for paints and electronics (HSDB 2010).

Preparations for soldering can contain 30-50 % of diboron trioxide. (MSDS Finoflux Lötpaste, 2008). Contents of 25-50 % diboron trioxide are reported for a flux agent suitable for alloys and/or ceramic glazings. (MSDS Alpha Flux, 2007)

1.2 Information on Occupational Exposure

Diboron trioxide is a solid at room temperature and has a negligible vapour pressure. In industry it is used as bulk material or in solutions. The main routes of occupational exposure are expected to be inhalation of dust or particles and dermal contact. Due to personal hygienic measures ingestion is not considered to be relevant.

Diboron trioxide is the anhydride form of boric acid. Because of its hygroscopic properties diboron trioxide reacts easily with water to form boric acid and hydrates (Smith 1999). In summary, the quantification of exposure to diboron trioxide is difficult.

In general, occupational exposure may occur during production of diboron trioxide, when diboron trioxide is used as reactant for the synthesis of borates or other boric compounds and in a wide variety of industrial uses including the production and use of detergents and cleaners, processing aid, metal working fluids, glass and glass fibres, ceramics, catalysts, flame retardants, biocides and insecticides (cf. Table 8). Workers in industrial and professional settings may be also exposed when using diboron trioxide containing products like soldering paste or developer and fixer solution in photographic application.

An Occupational Exposure Limit (8hr TWA) for diboron trioxide of 10 mg/m^3 was adopted in some European countries, i. e. in Belgium, Denmark, Iceland, Ireland, Norway, France, Portugal, Italy, Switzerland and Spain. The OEL (8 hr TWA) in Greece and Austria is 15 mg/m^3.

To our knowledge measurements of exposure to diboron trioxide solely are not available. Garabrant et al. (1984) reported measurements on occupational exposure to dust containing boric acid and diboron trioxide at a borate/boric acid manufacturing plant. The observed concentration of total particulate matter measured during full shift in eight samples ranged from 1.2 to 8.5 mg/m^3 with a mean of 4.1 mg/m^3. No further information was provided on the fraction of diboron trioxide in the dust which leaves some uncertainties about the exposure of workers.

1.3 Information on Consumer Exposure

Diboron trioxide is used in the production of different glass types, glass fibres, ceramics and enamels. Exposure calculations for do-it-yourself installation or removal of glass wool insulation and release of glazed ceramic ware and food contact materials as well as migration studies from glass ware are cited in the Annex XV dossier for boric acid (ECHA 2010). It is thereby chemically/physically bound into the different types of glass, ceramic products and enamels, thus the liberation of diboron trioxide from these products is extremely unlikely to result in any significant exposure to consumers using such products. However, the registration dossiers for diboron trioxide point out further uses with potential relevance for consumer exposure (cf. Table 9). Some of these are also listed in the SPIN-online database (2011).

Publicly available exposure data explicitly referring to diboron trioxide are rare.

The included SPIN-exposure toolbox provides a qualitative evaluation of consumer exposure based on the data available in the register resulting in rankings of 'no, potential, probable and very probable indications'. Its characterisation of consumer exposure to diboron trioxide is "potentially" for Norwegian and Swedish data of 2008 and Swedish data of 2009, the most recent data judged.

The Risk Assessment Committee mentions the substance in its assessment of consumer risks arising from the presence of boron compounds in preparations for photographic applications. It concluded that if exposure *via* food and drinking water is considered as additional boron source, photographic applications pose a risk to consumers, for the specific scenarios based on reasonable worst case assumptions if film developer solutions are prepared from powder formulations and used for tank or tray processing on the same day (RAC 2010).

2 CURRENT KNOWLEDGE ON ALTERNATIVES

Diboron trioxide might be used as an alternative to other boron compounds and *vice versa*. Diboron trioxide could for example be used to replace other boron compounds especially boric acid as additive to TiO_2 pigments in polymers (E.I. du Pont de Nemours and Co., 1999), in catalyst production (BASF Aktiengesellschaft, 1981), and in ceramics (Matsushita Electric Industrial Co., 1999). In certain applications diboron oxide can be replaced by boron nitride (Osram Sylvania Inc., 1999). Other boron compounds are not considered to be adequate substitutes for diboron trioxide due their similar toxicity to reproduction.

3 RISK-RELATED INFORMATION

In the Chemical Safety Reports the risk for the different consumer uses of products containing boron is considered adequately controlled besides single uses for which use is advised against or concentration limits have been set as risk management measure. Therefore a restriction proposal appears not to be an adequate measure. The most important sources of exposure are food and drinking water. It has to be considered that all sources of boron exposure (like boron compounds in preparations for photographic applications or occupational exposure) contribute to the total boron exposure, and thus to the risk for consumers.

Due to the toxicological similarities of boron compounds classified as toxic to reproduction category 1B the following boron compounds have already been included in the Candidate List following their identification as substances of very high concern:

- **Boric acid** (CAS: 10043-35-3);
  covering also
  boric acid, crude natural (CAS: 11113-50-1)

- **Disodium tetraborate, anhydrous** (CAS: 1330-43-4);
  covering also
  disodium tetraborate pentahydrate (CAS: 12179-04-3),
  disodium tetraborate decahydrate (CAS: 1303-96-4) and
  tetraboron disodium heptaoxide, hydrate (CAS: 12267-73-1)

- **Tetraboron disodium heptaoxide, hydrate** (CAS: 12267-73-1);
  covering also
  disodium tetraborate, anhydrous (CAS: 1330-43-4),
  disodium tetraborate pentahydrate (CAS: 12179-04-3),
  disodium tetraborate decahydrate (CAS: 1303-96-4)

With respect to the endpoint of concern (reproductive toxicity) diboron trioxide was not considered a priority substance for substance evaluation. As an argument of high importance, it is emphasized that diboron trioxide could be used to replace other boron compounds and contributes to the overall addition of toxicologically relevant boron. In order to ensure consistency for all classified boron compounds, diboron trioxide should be treated equally.

REFERENCES

References to Part I

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