

Document supporting the non-classification of Boron

Summary

Elemental boron (CAS: 7440-42-8; EC 231-151-2) is not classified as hazardous for health, physical and environmental hazards under the UN GHS Guidelines¹ which are the basis of the classification requirements for various regulatory purposes². This statement is based on the current understanding of the available data and registered information³.

Definition

For the purposes of this document, elemental boron refers to boron powders made by chemical reduction and electrolysis. Impurities which would give rise to a classification and labelling issue are not covered by this document.

Health effects

Boron is not classified. Extensive investigations were carried out for the REACH registration dossier³, resulting in **no classification for Health hazards** of boron.

The toxicity data in the REACH registration dossier refer explicitly to elemental boron and document its negligible bioavailability and the complete lack of any human health hazard. Information in the public domain which refers to "boron", almost exclusively contains information on boric acid and borates. Due to the different hazard potential of boron compared to borates, a clear distinction needs to be made between these forms.

Thorough test packages (such as water solubility according to OECD 105, in-vitro bioaccessibility after 2 hours and 24 hours in five artificial physiological media and a 28-day oral toxicity study) were performed to assess the availability of elemental boron in the human body and to differentiate between elemental boron and borates. For further substantiation of the poor bioavailability of elemental boron, two toxico-kinetic studies (a mass balance study and a comparative toxico-kinetic study of sodium borate vs. boron) were carried out to confirm the behaviour of boron.

Acute toxicity oral:

The LD50 greater than 2000 mg/kg bw was determined according to OECD Guideline 423⁴. Thus, according to regulation (EC) 1272/2008 and subsequent amendments **elemental boron is not classified for acute oral toxicity**.

Other LD50 values⁵ were reported in secondary literature. The primary source of these data cannot be found (i.e. test methods and tested substance cannot be reviewed). Consequently these data

¹ See UNECE website for further GHS information:

http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

² Including EU CLP and REACH, International Maritime Organisation (IMSBC Code, MARPOL Convention)

³ Boron was registered under REACH in May 2013. Disseminated information is available on ECHA website: <https://echa.europa.eu/registration-dossier/-/registered-dossier/14776/>

⁴ Müller (2004), key study for acute oral toxicity is described in the REACH registration dossier (OECD 423 (2001); GLP compliant)

should not be used for the purpose of classification and labelling of elemental boron as they are not considered to be reliable.

Environmental effects

Boron is almost exclusively found in the environment in the form of boron-oxygen compounds, which are often referred to as borates.

Transformation dissolution protocols tests (TDp) of amorphous boron in accordance with OECD guideline 29 (100mg/L, 7 days at pH 6, and 1 mg/L, 28 days at pH 6 and 8) demonstrated extremely low solubility levels compared to ecotoxicity reference values identified for the soluble boron (lowest acute ecotoxicity reference value of 52.4 mg B/L for *Pseudokirchneriella subcapitata* and a long term ecotoxicity reference value of 3.5 mg/L for *Ictalurus punctatus*).

TDp test results also confirm the possibility to read across on the soluble inorganic B-salts aquatic database.

TDp testing of amorphous boron powder is conclusive for derivation of a **no classification for the environment (acute and chronic)** under DSD, CLP and GHS.

Physicochemical properties

Based on available information and physico-chemical tests reported in the REACH dossier, boron powder is **not classified for physical hazards**.

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⁵ LD50 (mouse): 550 mg/kg bw, LD50 (rat): 650 mg/kg bw, Lewis RJ, Sax's Dangerous properties of hazardous materials

LD50 (mouse): 2000 mg/kg bw, LD50 (mammal – unspecified): 300 mg/kg bw, Von Burg, 1992. Boron, boric acid, borates and boron oxide. J Appl. Toxicol. 12(2): 149-152