

ILMA 2017 Annual Meeting MWF Committee

Boric Acid Update

John K. Howell, Ph.D., GHS Resources Inc.

Outline

- Canada update
- Regulatory Status
 - European Union SVHC
 - US OSHA Classification
- Reproductive Toxicity
- Boric Acid Esters

Canada: Boric Acid Update

- July 23, 2016, Environment Canada published Draft Boric Acid Screening Assessment initiating 60-day comment period
 - Includes boric acid, borax, sodium tetraborate but not boric acid amides
 - “The draft screening assessment proposes to conclude that boric acid, its salts and its precursors are harmful to the environment as set out in section 64 (a) of CEPA 1999. It also proposes to conclude that boric acid, its salts and its precursors are harmful to human health as set out in section 64 (c) of CEPA 1999.”
- <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2AA865DC-1>
- Publication of responses to public comments on the draft Screening Assessment Report and Risk Management Scope: on or before July, 2017 **However...**

Canada: Boric Acid Update

- **Update April 2017:**

The Government of Canada is reviewing public comments provided in response to publication of the draft screening assessment for boric acid, its salts and its precursors, published on July 23, 2016. Taking into consideration the complexity of this assessment, the number of public comments received, as well as the inclusion of boron measurements in Cycle 5 of the Canadian Health Measures Survey, the Government of Canada will be taking additional time to review this information prior to publishing the final screening assessment.

Draft Screening Assessment and Risk Management Scope

In July 2016, the draft screening assessment was released and the related Notice was published in the [Canada Gazette, Part I: Vol. 150, No. 30 - July 23, 2016 \(PDF Version - 244 K\)](#). Fourteen substances met categorization criteria under subsection 73(1) of the Canadian Environmental Protection Act, 1999 (CEPA 1999) and were identified as priorities for action. Given that the screening assessment focuses on a common moiety of concern (boric acid), all boron-containing substances, other than polymers, were assessed for their potential to be precursors of boric acid, including those on the [Domestic Substances List \(DSL\)](#). The draft screening assessment proposes to conclude that boric acid, its salts and its precursors are harmful to the environment as set out in section 64 (a) of CEPA 1999. It also proposes to conclude that boric acid, its salts and its precursors are harmful to human health as set out in section 64 (c) of CEPA 1999. A risk management scope document was also released in conjunction with this publication. There is a 60-day public comment period associated with these publications.

Submissions Received

Information on boron-containing substances was gathered from industry and interested stakeholders through Phase 1 of the [Domestic Substances List Inventory Update](#) Notice issued under Section 71 of CEPA 1999. Information was also gathered through voluntary approaches.

Submissions Received for the Boron-Containing Substance Grouping

Type of Response	Number of Submissions
Mandatory section 71 Notice	92
Declaration of Stakeholder Interest	31
Voluntary Data Submissions (for example, studies, additional information)	29

Background

Section 71 Notice (Mandatory Survey)

In October 2009, a Notice was issued in the Canada Gazette, Part I: Vol. 143, No. 40 - October 3, 2009 ([PDF Version - 1,057 K](#)) under section 71 of CEPA 1999.

Canada: Boric Acid Update

- July 22nd, 2016: Health Canada Re-evaluation Decision RVD2016-01, Boric Acid and Its Salts (Boron) “After a re-evaluation of non-antisapstain uses of boric acids, Health Canada’s Pest Management Regulatory Agency (PMRA) is granting continued registration of most uses in Canada.” (Boric acid and its salts offer a broad range of control of insects and fungi in structures, wood and wood products.)

<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/reevaluation-decision/2016/document-boric-acid-salts-boron-rvd2016-01.html>

Boric Acid – Regulatory Status

- Boric acid and several of its sodium salts (e.g., borax, disodium tetraborate, etc.): included on list EU of Substances of Very High Concern (SVHC), 06/10/2017
 - Classification: Reproductive Toxin, Cat 1B(H360), Signal word: Danger 
 - Hazard Statements, May damage fertility. May damage the unborn child
 - Within EU, specific concentration limits (SCL) apply, e.g., a mixture needs to contain 5.5% or more boric acid (equiv. to 1% boron) before the mixture itself must be classified
 - Recently recommended for inclusion on Annex XIV, but not yet so listed
- U.S, a mixture containing 0.1% or more boric acid is classified as Cat 1 reproductive toxin: Danger, May damage fertility or the unborn child 

Boric Acid – Reproductive Toxicity

- Scialli, *et al.*, 2010: Authors did not find any clear evidence of male reproductive effects attributable to boron with exposures to Chinese miners of between 11 – 125 mg/day (equivalent to 70 – 850 mg borate/day)
 - An 8-hour exposure to 5 mg/l mist containing 0.5% borate (assuming inhalation of 10 m³ air) gives maximum exposure of 0.25 mg/day
- Ball and Harrass, 2013: Authors, using weight of evidence approach, conclude that it is improbable that boric acid will cause reproductive or developmental effects in humans:
 - Differences between gestation periods as well as mechanistic differences between laboratory animals and humans suggest the likelihood of similar effects in humans is low
 - Mechanism of boric acid is similar to aspirin, a widely used drug known to cause developmental effects in rodents, but not shown to cause developmental effects in humans in controlled studies

Scialli, A.R., *et al.*, *Repro Tox* **29**, pp 10-24, An Overview of Male Reproductive Studies of Boron with an Emphasis on Studies of Highly Exposed Chinese Workers.

Ball, R. Wayne and Harrass, Michael, Rio Tinto Minerals, Greenwood Village, CO., Society of Toxicology, 2013, Poster

Boric Acid Esters

- Compare CAS 68586-07-2, boric acid, compd. with 2-aminoethanol (1:1), which is a *salt*, with CAS 68130-12-1, boric acid, 2-aminoethyl ester.
- UKLA reports (July, 2015) that the
 - “complex reaction product of boric acid and ethanolamine is not classified for reproductive hazard today due to an absence of test data...registrants have submitted a test plan as part of their REACH registration and are committed to performing reproductive toxicity testing of this substance.”
- Published reports indicate some commercial borate esters do not hydrolyze to re-form boric acid¹

¹ – Anderson, S., Does Boric Acid Have a Future in Metalworking Fluids, Tribology & Lubrication Technology, November, 2012, pp. 40 – 42,