# Zinc Borates: Human health tier II assessment

#### 30 June 2017

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## Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Boric acid, zinc salt	1332-07-6
Boric acid (H3BO3), zinc salt (2:3)	10192-46-8
Boron zinc oxide (B6Zn2O11), hydrate	12447-61-9
Boron zinc oxide (B6Zn2O11)	12767-90-7
Boron zinc hydroxide oxide	138265-88-0
Zinc borate oxide	149749-62-2

# Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.



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This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:www.nicnas.gov.au

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ACRONYMS & ABBREVIATIONS

## **Grouping Rationale**

The chemicals in this category are boron and zinc-containing compounds, commonly known as zinc borates. While various formulations (based on stoichiometry and hydration) are available, zinc borate is typically composed of 45 % zinc oxide (ZnO) and 34 % boric anhydride (B<sub>2</sub>O<sub>3</sub>), with 20 % water for hydration. Zinc borates are 'sparingly soluble salts' and hydrolysed to zinc hydroxide (via zinc oxide) and boric acid at physiological conditions and neutral and lower pH. Following ingestion, zinc borate readily breaks down at the stomach pH to zinc ions and boric acid (H<sub>3</sub>BO<sub>3</sub>). Therefore, as toxicokinetics and the toxicity of zinc borates are expected to be similar and will be driven predominantly by zinc and borate ions, they are grouped together for human health risk assessment (NRC, 2000; NSF International, 2011; REACHa).

The chemicals in this group have similar reported uses.

## Import, Manufacture and Use

## Australian

The following Australian industrial uses were reported under previous mandatory and/or voluntary calls for information.

Boric acid, zinc salt (CAS No. 1332-07-6) has reported domestic use including in flame retardants and fire-preventing agents.

Boric acid, zinc salt (CAS No. 1332-07-6) was reported during the call for information for the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume ranging 100–1000 tonnes per annum.

The National Pollutant Inventory (NPI) holds data for all sources of environmental release of boron and its compounds in Australia.

No specific Australian use, import, or manufacturing information has been identified for other members of this group.

#### International

The following international uses have been identified through:

- European Union Registration, Evaluation, Authorisation and Restriction of Chemicals (EU REACH) dossiers;
- Galleria Chemica;
- Substances and Preparations in the Nordic countries (SPIN) database;
- the European Commission Cosmetic Ingredients and Substances (CosIng) database;
- United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) dictionary;
- eChemPortal; and
- the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

Boric acid, zinc salt (CAS No. 1332-07-6) has reported cosmetic use as an antimicrobial agent.

Zinc borates (CAS Nos. 1332-07-6, 10192-46-8) have reported cosmetic uses in the United States of America (USA), but are used in very few formulations (Personal Care Products Council, 2011).

Boric acid, zinc salt (CAS No. 1332-07-6) has reported domestic uses including in:

- fillers;
- flame retardants and extinguishing agents; and
- fire and smoke inhibitors for plastics, textiles, synthetic resins, rubber, paper, adhesives, paints, pigments, wallpaper, carpet and floor leather etc.

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Boric acid, zinc salt (CAS No. 1332-07-6) has been reported to be present in a single domestic product (Watco Teak Oil Finish) in the USA without any stated concentration (Household Products Database, US Department of Health and Human Services).

The chemicals in this group have reported commercial uses including:

- in lubricants and additives; and
- as preservatives for engineered wood products, wood-plastic composites and in-can preservatives.

The following non-industrial uses have been identified for boric acid, zinc salt (CAS No. 1332-07-6), in:

- pharmaceutical preparations; and
- agricultural pesticides.

# Restrictions

## Australian

Although no known restrictions have been identified for the chemicals in this group, boric acid (excluding its salts) and borax are listed in the *Poisons Standard* (Standard for the Uniform Scheduling of Medicines and Poisons—SUSMP, 2016) in Schedule 5 (NICNASa; NICNASb).

Schedule 5 chemicals are labelled with 'Caution'. These are substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.

Zinc compounds and boron (including boric acid and borax) are also listed in Schedule 4 for non-industrial uses.

## International

The chemicals (CAS Nos. 1332-07-6, 12447-61-9, 12767-90-7) are listed on EU Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products—Annex III—List of substances which cosmetic products must not contain except subject to the restrictions laid down (Galleria Chemica).

The chemicals (CAS Nos. 138265-88-0, 149749-62-2) are listed on Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient "Hotlist") (Galleria Chemica).

Restrictions on the use of the chemicals listed above, for certain types of cosmetic products, according to the European Commission Cosmetics Directive Annex III (List of restricted substances) are:

- not to be used in products for children under three years of age; and
- not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1.5 % (as boric acid).

The Scientific Committee on Consumer Safety (SCCS) has recently concluded that all substances such as borates, tetraborates and octaborates, as well as other boric acid salts/esters reported in the CosIng database such as MEA-borate, MIPA-borate, potassium borate, trioctyldodecyl borate and zinc borate, break into boric acid due to contact with water following ingestion. Therefore, as these compounds have chemical, biological and toxicological properties similar to boric acid, the general restrictions applicable to boric acid for safe use in cosmetic products should apply to the whole group of borates (SCCS, 2013).

# **Existing Worker Health and Safety Controls**

## **Hazard Classification**

Zinc borate hydrate (CAS No. 138265-88-0) was previously classified as hazardous, with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia).

- T; R60 (Reproductive Category 2) (Reproductive toxicity); and
- T; R61 (Reproductive Category 2) (Developmental toxicity).

An equivalent GHS classification has not yet been published in the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

## **Exposure Standards**

## Australian

No specific exposure standards are available.

## International

The following exposure standards are identified (Galleria Chemica).

Boric acid, zinc salt (CAS No. 1332-07-6) and boric acid (H<sub>3</sub>BO<sub>3</sub>), zinc salt (2:3) (CAS No. 10192-46-8) have an exposure limit (inorganic borate compounds) of 2 mg/m<sup>3</sup> time weighted average (TWA) in Canada; 2 mg/m<sup>3</sup> TWA (inorganic zinc compounds) in Germany; and 1 mg/m<sup>3</sup> TWA (borates) in Malaysia. These chemicals also have a short term exposure limit (STEL) of 6 mg/m<sup>3</sup> (inorganic borate compounds) in Canada, and 1 mg/m<sup>3</sup> (inorganic zinc compounds) in Germany.

Boron zinc oxide (B<sub>6</sub>Zn<sub>2</sub>O<sub>11</sub>), hydrate (CAS No. 12447-61-9) and boron zinc oxide (B<sub>6</sub>Zn<sub>2</sub>O<sub>11</sub>) (CAS No. 12767-90-7) have an exposure limit of 2 mg/m<sup>3</sup> TWA (inorganic zinc compounds) in Germany and 1–5 mg/m<sup>3</sup> TWA (borates) in Malaysia.

## **Health Hazard Information**

The chemicals in this group contain both borate anions and zinc cations. As zinc borates readily break down in the stomach to zinc ions and boric acid (H<sub>3</sub>BO<sub>3</sub>) following ingestion, the family of zinc borates share the same toxicological properties and the toxicity is driven predominantly by zinc and borate ions. Limited information is available in the literature to assess the toxicity of zinc borates. Therefore, the data obtained from studies on zinc (soluble zinc) and boron-containing compounds have been read across for this assessment. Dissolution of zinc compounds leads to the formation of Zn<sup>2+</sup> cations, which is considered to be the moiety responsible for systemic toxicity. The borate counterions within this group of chemicals do not significantly contribute to the toxicity for the majority of end points, although the reproductive toxicity of borates is much higher than that of zinc ions. Undissociated boric acid is the main species present in the blood of mammals following exposure to inorganic borates, including boric acid or borax (NRC, 2000; NSF International, 2011; HSDB; NICNASa-c; REACH).

Boron has been postulated to be an essential nutrient and an acceptable daily intake (ADI) of 0.32 mg/kg bw/day has been assigned to the chemical. This ADI would amount to 22.4 mg boron/day for a 70 kg adult human (Australian Government Department of Health, 2008). Zinc is also an essential trace element for humans and animals and the recommended dietary allowance (RDA) is 11 mg/day for men and 8 mg/day for women. Intoxication by excessive zinc exposure is rare; zinc deficiency caused by malnutrition, ageing, disease or deregulated homeostasis is a far more common risk to human health (NICNASc).

## **Toxicokinetics**

Zinc ions and boric acid are the main species present in the blood of mammals following ingestion of zinc borate. This was demonstrated in rats following a single oral dose of zinc borate (1000 mg/kg bw), as dissociation of zinc borate in the gastrointestinal tract led to subsequent systemic absorption of zinc and borate. The maximum concentrations of zinc and boron in the plasma were noted to occur 5–6 hours following administration and decreased to background levels by 72 hours. The half-life of zinc and boron ranged from five to 7.7 hours, respectively. While the primary route of elimination for zinc was via the gastrointestinal tract, urinary excretion via the kidneys was the primary elimination route for boron. Zinc and boron recovery in the excreta was approximately 70 % and 63 % of intake, respectively. The highest level of zinc was found in the pancreatic tissue, followed by liver and femur tissue; the kidneys had the highest level of boron followed by femur tissue (REACHa).

In addition to the above study on zinc borate, other information has also indicated that boric acid is the main species present in the blood of mammals following ingestion of simple inorganic borates. Boric acid is readily and completely absorbed in humans and animals following oral administration; inhalation absorption is also assumed to be 100 % (worst case scenario). Dermal absorption through intact skin is very low in all species and a dermal absorption rate of 0.5 % is assumed. There is no evidence of boric acid accumulation in humans or animals. Boric acid is excreted rapidly with a half-life of <24 hours in humans and animals, and is mainly excreted in the urine (>90 %), regardless of the route of administration (NICNASa, NICNASb).

Oral absorption of soluble zinc has been observed to vary from 8–80 % in humans; zinc deficiencies tend to increase absorption while absorption is lower in people with excessive zinc. Inhalation absorption for soluble zinc citrate and zinc nitrate is reported to be up to 40 %. Human studies have shown dermal absorption through damaged or burned skin, but no statistically significant absorption through intact skin has been reported. Zinc does not undergo metabolism and is normally found in the body as a divalent cation complexed to albumin and metallothionein proteins. Faecal elimination is the primary route of excretion after oral exposure (70–80 %), followed by elimination in urine (10–25 %), sweat and saliva (NICNASc).

## **Acute Toxicity**

Oral

Zinc borates (unspecified CAS number) have low acute toxicity in animal tests following oral exposure. The median lethal dose (LD50) in rats is >2000 mg/kg bw. Observed sub-lethal effects included mucoid diarrhoea, faecal stains, urine stains, depression, unkempt fur, and serosanguinous discharge around the nose or mouth (US EPA, 1991; NRC, 2000; CEFIC-EFRA, 2006; NSF International 2011; REACHa).

### Dermal

Zinc borates (unspecified CAS number) have low acute toxicity in animal tests following dermal exposure. The LD50 in rats is >2000 mg/kg bw. Observed sublethal effects included diarrhoea and soiling of the anogenital area. It is also noted that dermal absorption through intact skin is very low and a dermal absorption rate of 0.5 % is assumed (see **Toxicokinetics**) (US EPA, 1991; NRC, 2000; NSF International 2011; REACHa).

#### Inhalation

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Zinc borates (unspecified CAS number) have low acute toxicity in animal tests following inhalation exposure. The median lethal concentration (LC50) in rats is >4.95 mg/L. Observed sub-lethal effects included wet fur, hunched posture, piloerection, ptosis and laboured respiration (US EPA, 1991; NRC, 2000; NSF International 2011; REACHa).

## Observation in humans

There are reports of accidental or intentional poisoning incidents in humans from boric acid and zinc separately. No reports exist of such incidents occurring with zinc borate compounds.

There is a large database of accidental or intentional poisoning incidents with borates in humans. A review of more than 700 cases of acute boric acid exposures in adults and children found 88.3 % of cases were without symptoms. Although the report provided only limited information on dose response, dose ranges of 0.1–55 g and 0.01–89 g of boric acid were reported for symptomatic and asymptomatic cases, respectively (Litovitz et al., 1988).

There are case reports of lethal oral exposures to humans involving accidental or intentional ingestion of high doses of boric acid. While oral lethal doses for boric acid have been quoted as 2–3 g for infants, 5–6 g for children, and 15–30 g for adults, the data are largely unsubstantiated. Further difficulty in making an appropriate quantitative judgment about a lethal dose was also noted due to medical intervention in most cases. Following ingestion of a formula accidentally prepared with a 2.5 % aqueous solution of boric acid, five infants became lethargic, developed vomiting and diarrhoea, and died within three days of exposure (estimated dose of 4.5–14 g boric acid). Deaths have also occurred in a 77-year-old man following ingestion of 30 g of boric acid and in a 45-year-old man following ingestion of approximately 280 g of boric acid. In both instances, clinical signs were similar: vomiting, diarrhoea, erythema, cyanotic extremities, acute renal failure, cardiopulmonary hypertension and death from heart failure (NICNASa).

Gastrointestinal toxicity has been reported in humans following ingestion of zinc. One fatal case was recorded after 28 g of zinc sulfate ingestion. After ingestion, the female started vomiting and developed tachycardia as well as hyperglycaemia. The female died five days later of haemorrhagic pancreatitis and renal failure (Plum et al., 2010). Various other human cases report severe diarrhoea, vomiting and abdominal pain after ingesting 2.5–112 g of zinc sulfate (NICNASc).

Following ingestion of approximately 86 mg/kg bw/day of zinc (as metallic zinc) over a two-day period to promote wound healing, a 16-year-old boy showed signs of lethargy, light-headedness, staggering and difficulty in writing clearly (NRC, 2000).

## **Corrosion / Irritation**

### **Respiratory Irritation**

Limited data concerning respiratory irritation are only available from animal studies for boric acid (CAS No. 10043-35-3).

Nasal and ocular discharge was noted in inhalation studies in rats with boric acid (CAS No. 10043-35-3) (see **Acute toxicity: Inhalation**). Ocular discharge and or nasal discharge persisted in most animals after being removed from the chamber. All animals recovered by day seven (NICNASa).

#### Skin Irritation

The available information indicates that zinc borates (unspecified CAS number) are not likely to be skin irritants.

In skin irritation studies, zinc borate did not cause skin irritation when applied to the intact skin of rabbits for four hours (US EPA, 1991; NSF International 2011; REACHa).

### Eye Irritation

Although slight eye irritant effects were reported in animal studies, effects were not sufficient to warrant a hazard classification for zinc borates (unspecified CAS number) (US EPA, 1991; NSF, 2000; CEFIC-EFRA, 2006; NSF International, 2011; REACHa).

In an eye irritation study conducted similarly to the Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 405, zinc borate (CAS No. 12767-90-7) (0.083 g) was applied to one eye of each of six New Zealand White (NZW) rabbits, which were observed up to 13 days after instillation. Corneal changes were observed only in 2/6 animals, that cleared by day seven in one animal, and by day 10 in the other animal. Iris lesions were observed only in 1/6 animals which cleared by day 10. Erythema was the main effect observed in the conjunctiva and was cleared by day 13. Maximum total irritation scores for individual animals were 8–33/100 (REACHa).

In a similar eye irritation study, zinc borate (CAS No. 149749- 62-2) (0.1 mL) was applied to one eye of each of six NZW rabbits, which were observed for up to eight days after instillation. There was no corneal opacity or iritis. Moderate conjunctival irritation that was noted in the eyes of all animals cleared by day two (REACHa).

In another eye irritation study, zinc borate hydrate (CAS No. 138265-88-0) (100 mg) was applied to one eye of each of six rabbits (strain not specified), which were observed for up to 72 hours following instillation. Irritative effects were limited to mild conjunctivitis that completely subsided in four rabbits within 72 hours or less. Maximum mean total score of 0.66 out of 110 was noted at 72 hours (REACHa).

#### Observation in humans

No adverse effects have been reported on human eyes following many years of occupational exposure to zinc borates under normal industrial use (NSF International, 2011).

#### Observation in humans

There are reports of respiratory effects in humans of boron-containing compounds.

Acute respiratory effects have been extensively documented in workers after inhaling boric acid, boron oxide, and other borates (including borax) as dusts. Effects include nasal and eye irritation, throat irritation, coughing and breathlessness. No effects on lung function were observed and the effects identified by workers were 'chemaesthetic' (caused by the activation of sensory receptors). These effects were regarded as sensory irritant effects that would typically be seen in normal populations in the absence of respiratory hypersensitivity. It was also concluded that these effects are most likely due to the physical exposure to chemical dust rather than a specific irritant effect of the chemical. As these effects were not considered a 'serious irritation to the respiratory tract' and were most likely due to a physical effect, a hazard classification as irritating to respiratory system is not warranted (NICNASa).

### Sensitisation

### Skin Sensitisation

Although limited information is available on the skin sensitisation potential of zinc borates, based on the available information, zinc borates are not likely to be skin sensitisers (US EPA, 1991; NRC, 2000; CEFIC-EFRA, 2006; NSF International, 2011; REACHa).

In a skin sensitisation study conducted according to OECD TG 406 (Buehler test) in Hartley guinea pigs, animals were exposed to zinc borate (CAS No. 138265-88-0) at a 75 % w/v formulation in distilled water for three exposures during the induction phase (six hours of exposure/once per week) on the shaved skin of the left shoulder. During the challenge phase, approximately two weeks after the last induction, animals were challenged (a single challenge) with the chemical at a 75 % w/v formulation on the shaved skin of sites that had not previously been exposed. The response (slightly patchy erythema) incidence in the test group (9/20) at 24 and 48 hours was comparable to that of the naive control group (7/10). Therefore, the chemical was not considered to be a skin sensitiser (REACHa).

In a guinea pig maximisation test conducted according to OECD TG 406 (maximisation test), Dunkin-Hartley guinea pigs were induced (intradermally) with zinc borate (unspecified CAS number) at a 1 % concentration in arachis oil followed by a topical application of the chemical at a 50 % concentration (in arachis oil) after seven days. The animals were challenged three weeks after the topical application with a 25 % concentration of zinc borate on the right flank, for 24 hours. No skin sensitisation reactions were observed following the challenge (REACHa).

#### Observation in humans

No evidence of skin or respiratory sensitisation in humans occupationally exposed to borates has been reported (NICNASa). Evidence of dermal irritation was not reported in human volunteers following application of patches containing 25 % zinc oxide (equivalent to 2.9 mg Zn<sup>2+</sup>/m<sup>3</sup>) for 48 hours (NRC, 2000).

## **Repeated Dose Toxicity**

#### Oral

Limited data are available for zinc borates. The available information on boron and zinc-containing compounds indicate that zinc borates are not likely to cause serious damage to health from repeated oral exposure. It is also noted that the main target for repeated dose oral toxicity for boron are the testes, leading to adverse reproductive and developmental effects. Although the possibility of these effects following ingestion of zinc borates cannot be ruled out, these are appropriately covered in the **Reproductive and developmental toxicity** section. Adverse haematological effects indicative of increased red blood cell destruction have also been commonly noted as signs of boron toxicity (NICNASa; NICNASb).

An overall no observed adverse effect level (NOAEL) of 17.5 mg boron/kg bw/day (equivalent to 100 mg boric acid/kg bw/day) has been determined, from a twoyear study of boric acid (CAS No. 10043-35-3) in rats for effects on the testes and haematology. The lowest observed adverse effect level (LOAEL) was 58.5 mg boron/kg bw/day (equivalent to 334 mg boric acid/kg bw/day) (NICNASa, b). For zinc sulfate heptahydrate (CAS No. 7446-20-0), the no observed effect levels (NOELs) available from 90-day mouse and rat studies were >100 mg/kg bw/day. Considering the NOELs and the treatment-related effects reported in various repeated dose toxicity studies, zinc sulfate heptahydrate (CAS No. 7446-20-0) was not considered to cause serious damage to health from repeated oral exposure (NICNASc).

In a repeated dose toxicity study, Sprague Dawley (SD) rats (10/sex/group) were fed boric acid (CAS No. 10043-35-3) in the diet at doses of 0, 15, 50, 149, 500 or 1490 mg/kg bw/day for 13 weeks (equivalent to 0, 2.6, 8.8, 26, 88 and 260 mg/kg bw/day or boron). Rapid respiration, hunched position, bloody nasal discharge, urine stains on the abdomen, inflamed eyes, desquamation and swollen paws and tails were observed in animals at the two highest doses. Reduced food consumption and body weight gains were also noted in these animals. All animals at the highest dose had died by week six. All the male rats at the two highest doses had atrophied testes, histologically complete atrophy of the spermatogenic epithelium, and decreased seminiferous tubule size. A 90-day NOAEL of 149 mg/kg bw/day (equivalent to 26 mg boron/kg bw/day) was established in this study based on bodyweight reduction, clinical signs of toxicity, and testicular atrophy (NICNASa).

In a repeated dose toxicity study, boric acid (CAS No. 10043-35-3) was fed to SD rats (35/sex/group) in the diet at doses of 0, 33, 100 or 334 mg/kg bw/day for two years (equivalent to 0, 5.9, 17.5 and 58.5 mg/kg bw/day of boron) (see **Reproductive and developmental toxicity**). Males of the highest dose group showed hunched positions; inflamed bleeding eyes; tail skin and pad paw desquamation; significant reduction in red cell volume and haemoglobin; shrunken scrotums; testicular atrophy and seminiferous tubule degeneration (at six, 12 and 24 months); and atrophied seminiferous epithelium and decreased tubular size in the testes at microscopic examination. A two-year NOAEL of 100 mg/kg bw/day of boric acid (equivalent to 17.5 mg/kg bw/day of boron) was determined based on clinical and haematological effects and the testicular atrophy observed at the highest doses (NICNASa).

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In a repeated dose oral toxicity study similar to OECD TG 408, zinc sulfate heptahydrate (CAS No. 7446-20-0) was fed to ICR mice (12/sex/dose) in the diet at doses of 0, 300, 3000 or 30000 ppm for 90 days. An NOEL of 3000 ppm (equivalent to 458 mg/kg bw/day in males, and 479 mg/kg bw/day in females) was determined based on increased mortality; retarded growth; reduced food and water intake; and gross and histopathological changes in the kidneys, thyroid, pancreas, gastrointestinal tract and spleen at the 30000 ppm concentration (NICNASc).

In another study in Wistar rats (12/sex/dose) administered zinc sulfate heptahydrate (CAS No. 7446-20-0), an NOEL of 3000 ppm (equivalent to 234 mg/kg bw/day in males, and 243 mg/kg bw/day in females) was determined. This NOEL was based on: dwarfism, depressed weight gain, moderate changes in haematology (reduction in leukocyte count and a slight decrease in haematocrit and haemoglobin concentrations in males), pancreatic lesions, degeneration and necrosis of acinar cells, and interstitial fibrosis at 30000 ppm (NICNASc).

#### Dermal

No data are available.

#### Inhalation

Limited data are available for zinc borates and for boron-containing compounds. The limited data available for zinc borate (CAS No. 138265-88-0) and the zinccontaining compound zinc sulfate (CAS No. 7733-02-0), do not support the criteria for hazard classification for zinc borates (NICNASa; NICNASc).

In a repeated dose inhalation toxicity study, SD rats (five animals/group/sex) were exposed (nose-only inhalation) to zinc borate (CAS No. 138265-88-0) at target exposure concentrations of 5, 10, 25, 75 or 150 mg/m<sup>3</sup> for six hours/day, five days/week for two weeks (minimum of 10 exposures). Overall, mean measured exposure concentrations were 5.1, 10.4, 24, 75, and 150 mg/m<sup>3</sup>, respectively. The no-observed-adverse-effect-concentration (NOAEC) was established as 24 mg/m<sup>3</sup>, based on lower food consumption, histopathology (mild to moderate degeneration of the olfactory epithelium in the nose, and the lung findings of moderate alveolar proteinosis (REACHa)

In a well-documented repeated dose inhalation toxicity study, Wistar Kyoto rats (12 males/dose) were exposed (nose only) to aerosolised zinc sulfate (CAS No.

7733-02-0) at doses of 10, 30 or 100 mg zinc/m<sup>3</sup> (environmentally relevant levels) for five hours/day, three days/week, for 16 weeks. Animals were euthanised 48 hours after the last exposure. Under the test conditions described, it was concluded that subchronic inhalation of zinc sulfate, at environmentally relevant levels, induced cardiac effects; changed expression levels of cardiac genes involved in cell signalling events, ion channel regulation and coagulation. However, these effects are not clear functional disturbances or morphological changes and therefore do not meet the criteria for hazard classification (NICNASc).

#### Observation in humans

In addition to numerous acute poisoning incidents with boric acid (CAS No. 10043-35-3) (see Acute toxicity: Observation in humans), some data are available on effects from repeated doses of boric acid or borax as treatments for medical conditions. Multiple oral and dermal exposures resulted in a variety of symptoms including dermatitis, alopecia, loss of appetite, nausea, vomiting, diarrhoea and focal or generalised central nervous system (CNS) effects or convulsions (NICNASa, NICNASb).

Multiple studies on increased zinc consumption due to zinc supplements have demonstrated a resulting copper deficiency manifested by decreased copper metalloenzyme activity, as well as haematological effects such as anaemia, neutropaenia, decreased cholesterol levels, immunotoxic and gastrointestinal effects (NICNASc).

### Genotoxicity

Although the appropriate data are limited, the available information on zinc borates and on boron- and zinc-containing compounds indicate that zinc borates are not likely to be mutagenic or genotoxic.

Zinc borate (unspecified CAS number) tested negative in several in vitro tests such as:

- bacterial reverse mutation tests (Ames tests) with Salmonella typhimurium strains; and
- In vitro mammalian cell gene mutation tests with mouse lymphoma L5178Y cells (NRC, 2000; NSF International, 2011; REACHa).

Boric acid (CAS No. 10043-35-3) was negative in several in vitro tests and also

in an in vivo mouse bone marrow micronucleus chromosome aberration test. It was concluded that boric acid (CAS No. 10043-35-3) did not have mutagenic or genotoxic potential (NICNASa).

Mixed results were observed for zinc sulfate (CAS No. 7733-02-0) and zinc acetate (CAS No. 557-34-6) in several in vitro (Ames, mitotic gene conversion) and in vivo (chromosomal aberration, dominant lethal assay, comet) tests for gene mutation and clastogenicity. As zinc is an essential trace element for humans and animals, it is not anticipated to be genotoxic. Overall, the weight of evidence indicated that zinc is not mutagenic to germ cells (NICNASc).

## Carcinogenicity

Limited animal and human data are available regarding the carcinogenicity of zinc borates. The available information on zinc and boron-containing compounds indicates that zinc borates are not likely to be carcinogenic. Zinc borates are also considered not to be mutagenic or genotoxic (see **Genotoxicity**) (NRC, 2000; NSF International, 2011; NICNASa; NICNASc).

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Boric acid (CAS No. 10043-35-3) and borax (CAS No. 1303-96-4) did not produce any evidence of carcinogenicity in SD rats and B6C3F1 mice in chronic/carcinogenicity studies. The US EPA (2005) also concluded that there is 'inadequate information to assess carcinogenic potential of zinc' due to inadequate or inconclusive studies from occupational exposure to zinc and carcinogenic animal studies (NICNASc).

In a carcinogenicity study, boric acid (CAS No. 10043-35-3) was administered to B6C3F1 mice in the diet at 0, 2500 or 5000 ppm (equivalent to 0, 446 and 1150 mg/kg bw/day for boric acid) for two years. There was no evidence of carcinogenicity in the study and the testicular effects noted related to reproductive and developmental toxicity. The NOAEL for carcinogenicity was equivalent to 1150 mg/kg bw/day for boric acid (201 mg/kg bw/day for boron), the highest tested dose (NRC, 2000; NICNASa).

In another chronic/carcinogenicity study, borax (CAS No. 1303-96-4) was fed to SD rats in their diet at doses of 0, 117, 350 or 1170 ppm boron or as 0, 52, 155 and 516 mg/kg bw/day borax (equivalent to boron at 0, 5.9, 17.5, 58.5 mg/kg bw/day) for two years in the chronic study. An NOAEL of 155 mg/kg bw/day of borax (equivalent to 17.5 mg/kg bw/day of boron) was determined, based on clinical effects and the testicular atrophy observed at the highest dose (NICNASb).

In a carcinogenicity study, male and female Chester Beatty mice were exposed to zinc sulfate (CAS No. 7733-02-0) in drinking water at doses of 4.4 g/L (1000 ppm zinc) and 22 g/L (5000 ppm zinc) for 45 weeks. Histopathology reported no difference between treated and control groups regarding the incidence of forestomach epithelial hyperplasia. There were also no differences in the incidences of hepatoma, malignant lymphoma and lung adenoma observed between treatment and control groups (NICNASc).

In another limited carcinogenicity study, female Porton mice (98–100 per group) were exposed to zinc at concentrations as high as 121.7 mg/m<sup>3</sup> (as zinc oxide/hexachloroethane smoke mixture (which produces zinc chloride)), for one hour/day, five days/week for 20 weeks. Although statistically significant increases in the incidence of alveologenic carcinoma were reported 13 months after the end of the exposure period, there was no increase in the observed incidence of tumours at the lower exposure doses of 1, 1.3 and 12.8 mg zinc/m<sup>3</sup>. Following administration of similar dose levels to guinea pigs and rats, no significant carcinogenic responses were observed. Several confounding factors, including the short duration of the exposure (20 weeks), using only females and the presence of several other compounds in the smoke with carcinogenic potential, limit the usefulness of these studies (NICNASc).

## **Reproductive and Developmental Toxicity**

Zinc borate hydrate (CAS No. 138265-88-0) was previously classified as hazardous, Category 2 substance toxic to reproduction, with the risk phrases 'May impair fertility' (T; R60) and 'May cause harm to the unborn child' (T; R61) in HSIS (Safe Work Australia). Whilst an equivalent GHS classification has not yet been published, this chemical and the others in the group warrant classification for reproductive and developmental toxicity—Category 1B; H360FD (May damage fertility. May damage the unborn child) in the HCIS (Safe Work Australia).

Limited data are available regarding reproductive or developmental effects of zinc borates in animals and humans. However, as the chemicals dissociate in solution to form boric acid, which is likely to be associated with human health hazards of the chemical, reproductive and developmental human health hazards could be expected following exposure (NICNASa).

Reproductive and developmental end points were the most sensitive effects in animals following exposure to boron (boric acid) (NICNASa). Boric acid (CAS No. 10043-35-3) is classified as a hazardous for reproductive and developmental toxicity—Category 1B; H360FD (May damage fertility. May damage the unborn child) in the HCIS (Safe Work Australia).

Studies have provided evidence that high doses of zinc in rats adversely affect spermatogenesis in males and impair fertility in females. The very high concentrations of zinc compounds (≥1000 mg/kg bw zinc sulfate heptahydrate) required to produce these adverse effects did not satisfy the criteria for classification (NRC, 2000; NSF International, 2011; NICNASc).

While the appropriate data are limited for zinc, information on boron-containing compounds (boric acid) in animals is sufficient to support classification for zinc borates (refer to **Recommendation** section) (NICNASa; NICNASb; NICNASc).

The testes and the developing foetus have been identified as the most sensitive targets of boron toxicity in animal studies, with the rat being the most sensitive species. The reported testicular effects include reduced organ weight and organ to body-weight ratio; atrophy and degeneration of the spermatogenic epithelium; impaired spermatogenesis; and reduced fertility. The developmental effects that have been reported included high prenatal mortality; reduced foetal body weight; and malformations and variations of the eyes, CNS, cardiovascular system, and axial skeleton. The NOAEL for fertility of 100 mg/kg bw/day of boric acid (equivalent to 17.5 mg/kg bw/day of boron) has been determined (based on testicular effects) from two-year and three-generation studies in rats. The NOAEL for developmental effects has been established at 55 mg/kg bw/day of boric acid (equivalent to 9.6 mg/kg bw/day of boron) in rats (NICNASa; NICNASb).

Epidemiological studies of worker exposure and general populations with high environmental boron showed no reproductive or developmental effects (see below). The higher levels of zinc in the soft tissue of humans, which were over two times greater than in comparative tissues in laboratory animals (including the target organs of boric acid such as foetal tissues, epididymis and testes), have been postulated to have a protective effect against boron toxicity. The protective effect of zinc against boric acid-related effects has also been demonstrated in laboratory studies (see below). It has also been concluded that, based on epidemiological studies, the animal data are relevant to humans (see below) (SCCS, 2010; ECHA, 2014).

#### Zinc borate

The protective effect of zinc, administered as zinc chloride, has been demonstrated against boric acid-related effects on spermatogenesis using a primary culture of seminiferous tubules from rats (REACHb).

In a oral repeated dose toxicity study, zinc borate 2335 (CAS No. 138265-88-0) was administered by gavage to Wistar rats at doses of 50, 100, 200 or 375 mg/kg bw/day of zinc borate for 90 days. These doses were equivalent to 7.46, 14.92, 29.84, and 55.95 mg/kg bw/day of boron. The NOAEL was determined to be 375 mg/kg bw/day (zinc borate) in females as no adverse effects were noted at this dose. In males, administration of zinc borate at 375 mg/kg bw/day resulted in adverse effects on male reproductive organs, including effects on spermatogenic parameters with corresponding lower organ weights and gross and microscopic findings. Adverse effects on spermatogenic parameters were also noted at 200 mg/kg bw/day in males, without any corresponding microscopic findings. Therefore, the NOAEL in males was established as 100 mg/kg bw/day. The NOAEL in males was equivalent to 14.92 mg/kg bw/day for boron. Although a boric acid-only group was not included in the study, the NOAEL of 14.92 mg/kg bw/day of boron for males obtained in the present study is less when compared to an NOAEL of 17.5 mg/kg bw/day of boron for a boric acid-only group (see **Reproductive Toxicity**). Based on these results, it can be concluded that zinc had no effect in

reducing the toxicity of boron on spermatogenesis in this study (REACHc).

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In a preliminary prenatal developmental toxicity study, zinc borate (unspecified CAS number) was administered (gavage) to eight rats/group (time mated) for gestation days (GD) 6–20 at doses of 100, 200, 300, 400 or 500 mg/kg bw/day (14.92, 29.84, 44.76 and 74.6 mg/kg bw/day of boron). There was little evidence of maternal toxicity at any of the tested doses. The NOAEL for the developmental toxicity was stated as 100 mg/kg bw/day, based on lower foetal body weights at the higher doses (equivalent to 14.92 mg/kg bw/day for boron). The study concluded that a 55 % increase in the developmental NOAEL was achieved compared with the NOAEL of 9.6 mg/kg bw/day for boron (boric acid-only). While there is limited evidence of a reduction in reproductive and developmental toxicity for zinc borate compared with boric acid, the toxicity remains significant (Chemical Safety Report, 2014).

In a developmental toxicity study, zinc borate (CAS No. 138265-88-0) was administered by gavage to pregnant SD rats (25 animals/group) for GD 6–20 at doses of 100, 125 or 150 mg/kg bw/day. The NOAEL for maternal toxicity was established as 150 mg/kg bw/day (highest tested dose), as no evidence of maternal toxicity was noted at any dose level. Developmental effects were noted in the 100, 125 and 150 mg/kg bw/day groups. Mean male, female, and combined foetal weights in the 100, 125 and 150 mg/kg bw/day groups were significantly (p<0.01) lower (up to 5.5 %, 10.9 %, and 10.9 %, respectively) than the concurrent control group. In addition, skeletal developmental variations (higher mean litter proportions of reduced ossification of the 13th rib(s), sternebra(e) numbers 5 and/or 6 unossified, 7th cervical ribs, and 25 presacral vertebrae; and lower mean litter proportions of 14th rudimentary rib(s)) were noted at 100, 125, and 150 mg/kg bw/day. The NOAEL for developmental toxicity was considered to be <100 mg/kg bw/day (REACHc).

#### Observation in humans

Epidemiological studies of worker exposure and general populations with high environmental boron showed no reproductive or developmental effects. In studies of Chinese and Turkish workers and in populations living in areas with high environmental levels of boron, semen parameters were evaluated in both studies, as semen analysis is the most sensitive indicator for testicular toxicity in humans. Even though a mean boron intake of up to 125 mg/day (over 100 times greater than the average daily exposure of the general population) was determined for the highest exposed Chinese group, adverse testicular effects were not seen. Turkish workers also did not show any adverse testicular effects despite a high mean calculated daily boron exposure (14.45 ± 6.57 mg/day of boron) in the exposed group (SCCS, 2010; NICNASa).

Other epidemiological studies of exposure to workers and general populations with high environmental boron showed no reproductive or developmental effects. The higher levels of zinc in the soft tissue of humans have been postulated to have a protective effect against boron toxicity. There was limited evidence of a reduction in reproductive and developmental toxicity for zinc borate compared with boric acid in laboratory studies (SCCS, 2010; Bureau for Chemical Substances, 2013; NICNASb; NICNASb; NICNASd).

The above epidemiological studies have been considered recently as part of the opinion on harmonised classification and labelling of boric acid (CAS No. 10043-35-3), by the committee for risk assessment in the EU (ECHA, 2014). The highest occupational exposure levels of boron in the two occupational cohorts and in the environmental exposed cohorts were much lower than the animal studies; 15-135 times lower than the animal LOAEL for fertility effects and 7-66 times lower than the animal LOAEL for developmental toxicity. At those exposure levels in epidemiological studies, assuming a similar sensitivity of humans as in the four laboratory species studies, it is unlikely that any adverse effects on human male fertility would have been noted. It was also noted that effects on female fertility and prenatal development were not investigated as part of the epidemiological studies. Therefore, the stated epidemiological studies do not sufficiently address the relevance of the animal toxicity data to humans at similar dose levels as causing toxicity in experimental animals. It was concluded that human data showing no clear evidence of reproductive toxicity do not contradict the animal data (ECHA, 2014).

### **Other Health Effects**

#### Neurotoxicity

Limited data are available regarding the neurological effects of zinc borates in animals and humans. The available information indicates that zinc borates are not likely to have neurotoxic properties. It is also noted that even though CNS depression has been reported in poisoning cases in humans with boric acid at very high doses, there is no indication that boric acid has neurotoxic properties (NRC, 2000; NICNASa, NICNASc).

Boric acid (CAS No. 10043-35-3) at a single oral (gavage) dose of 2000 mg/kg bw administered to SD rats (10/sex/dose) was not neurotoxic. There were no mortalities and no clinical signs of toxicity, although a 16 % decrease in total body weight gain was noted in the treatment group, compared with the control group at the end of the study. Functional observations and motor activity evaluations did not show any evidence of neurotoxicity and neurohistopathological findings were also negative (NICNASa).

Gross or microscopic effects on the brain were not observed in rats exposed to various quantities and durations of aerosolised boron oxide: concentrations of boron oxide at 470 mg/m<sup>3</sup> (73 mg boron/m<sup>3</sup>) for 10 weeks; boron oxide 175 mg/m<sup>3</sup> (27 mg boron/m<sup>3</sup>) for 12 weeks; and boron oxide 77 mg/m<sup>3</sup> (12 mg boron/m<sup>3</sup>) for 24 weeks (NICNASa).

## **Risk Characterisation**

### **Critical Health Effects**

The critical health effects for risk characterisation include reproductive and developmental toxicity, which is driven by the borate ion.

Although the available animal data show clear evidence of reproductive and developmental toxicity, epidemiological studies of workers and general populations exposed to boron show no reproductive or developmental effects. However, there are limitations in the human studies (See **Reproductive and Developmental Toxicity Section – Observation in humans**). The available human data are not sufficient to invalidate the animal data.

## **Public Risk Characterisation**

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Although the use of chemicals in this group in cosmetic products in Australia is not known, chemicals in this group have reported limited cosmetic uses overseas (see **Import, manufacture and use**). The available American database does not give evidence for a widespread use in cosmetic products with only two reported uses (Personal Care Products Council, 2011). Considering the limited use and reported cosmetic use overseas (as an antimicrobial agent), the concentrations in final cosmetic products are not considered to be sufficiently high to cause any significant human health concerns.

Even though the chemicals in this group have reported domestic uses in Australia and overseas (see **Import, manufacture and use**), the available American database does not give evidence for a widespread use in consumer products (Household Products Database, US Department of Health and Human Services). Only one of the chemicals in this group was present in a single domestic product in the USA, without any stated concentration. Considering the limited use and reported functions of these chemicals (flame retardants and extinguishing agents), these chemicals are not expected to be present in sufficient amounts to cause any concern for human health.

Therefore, the risk to public health is not considered to be unreasonable and further risk management is not considered necessary for public safety.

## **Occupational Risk Characterisation**

During product formulation oral, dermal, ocular and inhalation exposure of workers to the chemicals in this group can occur, particularly where manual or open processes are used. These might include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemicals at lower concentrations could also occur while using formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical health effects, the chemicals in this group could pose an unreasonable risk to workers unless adequate control measures to minimise oral, dermal, ocular and inhalation exposure to the chemicals are implemented. The chemicals should be appropriately classified and labelled to ensure that a person conducting a business or undertaking at a workplace (such as an employer) has adequate information to determine appropriate controls.

The data available support an amendment to the hazard classification in HCIS (see **Regulatory control: Occupational health and safety** in the **Recommendation** section).

## **NICNAS Recommendation**

The assessment of zinc borates is considered to be sufficient, provided that the recommended amendment to the classification is adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

## **Regulatory Control**

### Work Health and Safety

The chemicals are recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental hazards.

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

Hazard	Approved Criteria (HSIS) <sup>a</sup>	GHS Classification (HCIS) <sup>b</sup>
Reproductive and Developmental Toxicity	Not Applicable	May damage fertility. May damage the unborn child - Cat. 1B (H360FD)

<sup>a</sup> Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

<sup>b</sup> Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

\* Existing Hazard Classification. No change recommended to this classification

## Advice for consumers

Products containing the chemicals in this group should be used according to the instruction on the label.

## Advice for industry

### **Control measures**

Control measures to minimise the risk from oral, dermal, ocular, and inhalation exposure to the chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemicals are used. Examples of control measures which may minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- health monitoring for any worker who is at risk of exposure to the chemical if valid techniques are available to monitor the effect on the worker's health;
- air monitoring to ensure control measures in place are working effectively and continue to do so;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the Managing risks of hazardous chemicals in the workplace—Code of practice available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

#### Obligations under workplace health and safety legislation

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation* of safety data sheets for hazardous chemicals— Code of practice and Labelling of workplace hazardous chemicals—Code of practice, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of these chemicals has not been undertaken as part of this assessment.

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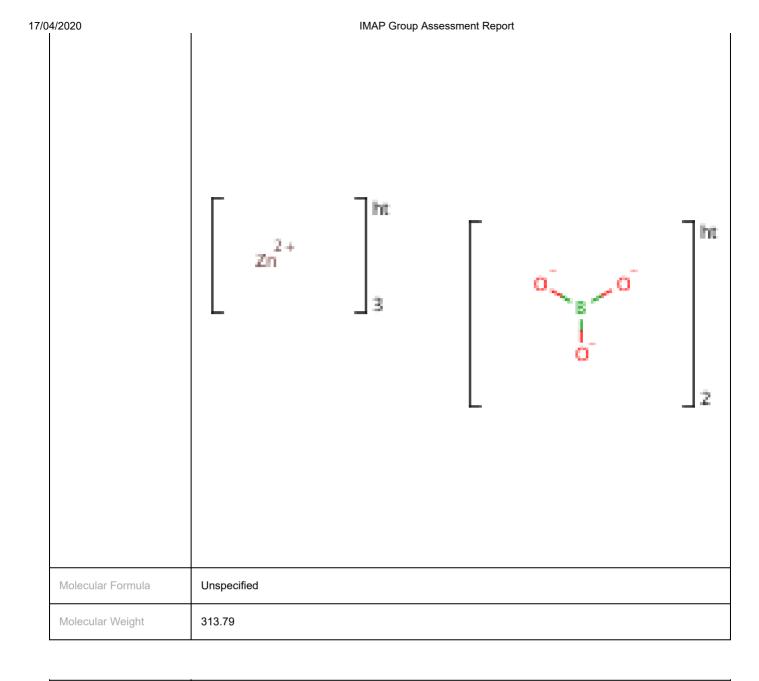
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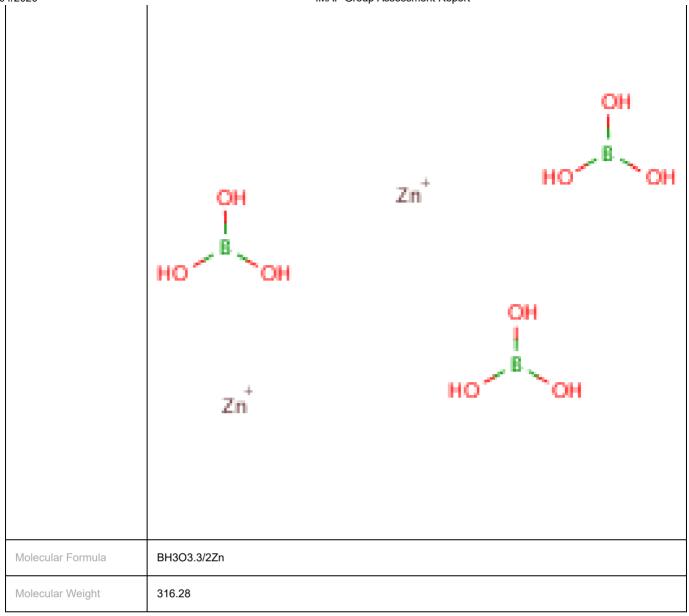
# **Chemical Identities**

Chemical Name in the Inventory and Synonyms	Boric acid, zinc salt zinc borate
CAS Number	1332-07-6
Structural Formula	

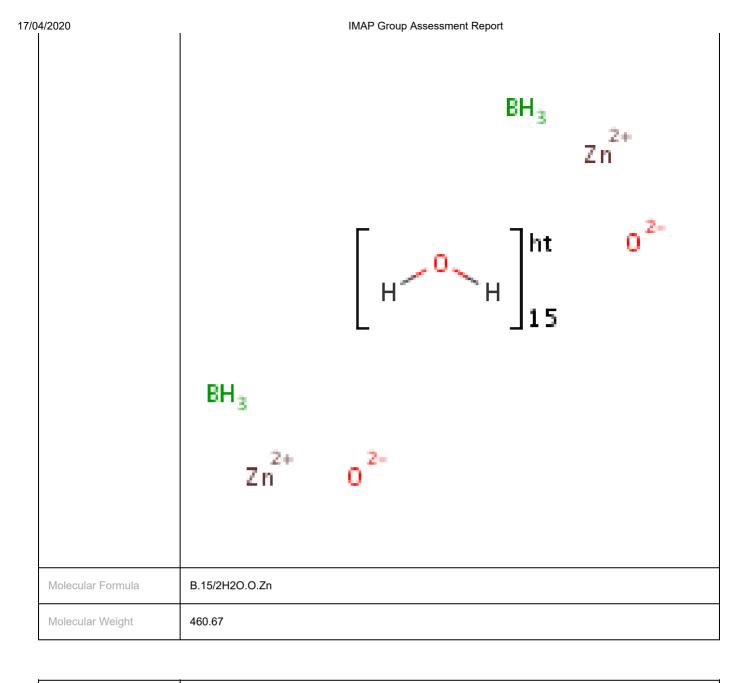


Chemical Name in the Inventory and Synonyms	Boric acid (H3BO3), zinc salt (2:3) diboron trizinc hexaoxide zinc borate zinc orthoborate zinc orthoborate zinc borate (Zn3(BO3)2)
CAS Number	10192-46-8
Structural Formula	





Chemical Name in the Inventory and Synonyms	Boron zinc oxide (B6Zn2O11), hydrate boron zinc oxide (B6Zn2O11), hydrate (2:15)
CAS Number	12447-61-9
Structural Formula	



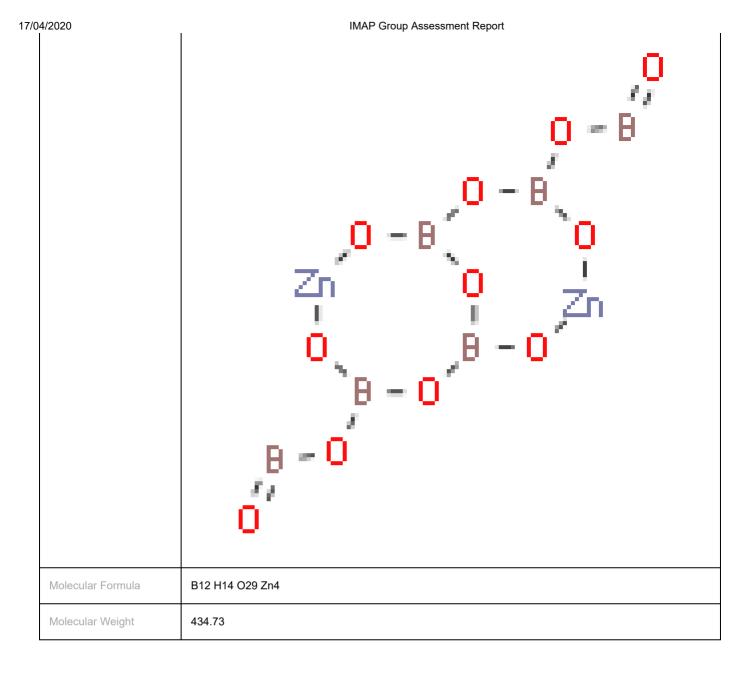
Chemical Name in the Inventory and Synonyms	Boron zinc oxide (B6Zn2O11) boric acid (H4B6O11), zinc salt (1:2) hexaboron dizinc undecaoxide zinc hexaborate zinc borate Firebrake 500
CAS Number	12767-90-7
Structural Formula	

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1	

	$BH_{3}^{2+} o^{2-}$
Molecular Formula	B.O.Zn
Molecular Weight	371.68

Chemical Name in the Inventory and Synonyms	Boron zinc hydroxide oxide zinc borate hydrate Zinc borate 2335
CAS Number	138265-88-0
Structural Formula	

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Chemical Name in the Inventory and Synonyms	Zinc borate oxide Firebrake 415
CAS Number	149749-62-2
Structural Formula	No Structural Diagram Available

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Molecular Formula	B2 O7 Zn4.H2 O
Molecular Weight	413.27

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