# Borate minerals: Human health tier II assessment

**30 June 2017**



## Chemicals in this assessment

| Chemical Name in the Inventory | CAS Number |
|---|---|
| **Colemanite (CaH(BO2)3.2H2O)** | 1318-33-8 |
| **Ulexite** | 1319-33-1 |
| **Tincalconite** | 12045-88-4 |

## 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.

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 colemanite (CAS No. 1318-33-8), ulexite (CAS No. 1319-33-1) and tincalconite (CAS No. 12045-88-4) are borate minerals. As salts of boric acid, they possess similar chemical properties and also have similar industrial uses.

## Import, Manufacture and Use

### Australian

No specific Australian use, import, or manufacturing information has been identified for colemanite and tincalconite.

Although the National Pollutant Inventory (NPI) holds data for all sources of boron and compounds emissions in Australia, the data are not specific to these chemicals.

The total volume of ulexite introduced into Australia, reported under previous mandatory and/or voluntary calls for information, was between 100 and 1000 tonnes.

### International

The following international uses of ulexite have been identified through Galleria Chemica (Galleria Chemica).

The chemical has reported commercial use, including in fibreglass manufacturing.

The chemical has reported site-limited use including:

- as an intermediate; and
- in metallurgical applications.

## Restrictions

### Australian

No known restrictions have been identified.

### International

Tincalconite (CAS No. 12045-88-4) is listed on the following (Galleria Chemica):

- Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient 'Hotlist');
- EU Cosmetic Directive 76/768/EEC Annex III Part 1: List of Substances which cosmetic products must not contain except subject to the restrictions and conditions laid down (English); and
- New Zealand Cosmetic Products Group Standard - Schedule 5 - Table 1: Components Cosmetic Products Must Not Contain Except Subject to the Restrictions and Conditions Laid Down.

No known restrictions have been identified for the other chemicals in this assessment.

## Existing Worker Health and Safety Controls

### Hazard Classification

The chemicals are not listed on the Hazardous Substances Information System (HCIS) (Safe Work Australia).

### Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

## Health Hazard Information

Colemanite (CAS No. 1318-33-8) is known as a secondary mineral with the formula $CaB_3O_4(OH)_3 \cdot H_2O$, and is formed by the alteration of borax and ulexite.

Ulexite ore (CAS No. 1319-33-1) is a sodium-calcium-hydroborate and, like other borates, is a structurally complex mineral. It is composed of hydrogen (3.98 %), sodium (5.67 %), calcium (9.89 %), boron (13.34 %), and oxygen (67.12 %), alternatively expressed as $Na_2O$ (7.65 %), CaO (13.84 %), $H_2O$ (35.57 %), and $B_2O_3$ (42.95 %) (Gulensoy & Kocakerim, 1977; Webmineral).

Tincalconite (CAS No. 12045-88-4) is also a secondary mineral that forms as a dehydration product of borax. It is a hydrous sodium borate mineral with the formula $Na_2B_4O_7 \cdot 5H_2O$ or $Na_2[B_4O_5(OH)_4] \cdot 3H_2O$.

There is a lack of data available in the literature to directly assess the toxicity of these chemicals. The major component of the chemicals is a borate ion, which is likely to be the driver of any human health hazards associated with them. The other constituents are considered to be of low concern to human health (NICNAS, 2013). As the chemicals readily break down in the gastric environment to boric acid ($H_3BO_3$) and their other constituents, the toxicokinetics and toxicity of the chemical will be based on the borate ion.

Undissociated boric acid is the main species present in the blood of mammals following exposure to borates. Therefore, the data obtained from studies on borates have been read across for this assessment.

### Reproductive and Developmental Toxicity

No data are available regarding reproductive or developmental effects of the chemicals in this group in animals and humans. Information on borates is presented below. Boric acid (CAS No. 10043-35-3) is classified as hazardous for reproductive and developmental toxicity—Category 1B; H360FD (May damage fertility. May damage the unborn child) in the HCIS (Safe Work Australia) (NICNAS). As the chemicals contain borate as the major component and borate is also likely to be associated with human health hazards of the chemical, reproductive and developmental human health hazards could be expected following exposure (NICNAS). Further information on this endpoint, including an analysis of human epidemiological data for boron-containing compounds has been presented previously in an IMAP Tier II group assessment for boric acid, available at **https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=1330** (NICNAS).

Reproductive and developmental endpoints were reported to be the most sensitive effects in animals following exposure to boron (boric acid); the testes and the developing foetus being the most sensitive targets of boron toxicity in animal studies. A no observed adverse effect (NOAEL) for fertility of 100 mg/kg bw/day of boric acid (equivalent to 17.5 mg boron/kg bw/day) has been determined (based on testicular effects) from two-year and three-generation studies in rats. The critical endpoint NOAEL for developmental effects has been established at 55 mg/kg bw/day of boric acid (equivalent to 9.6 mg boron/kg bw/day) in rats (NICNAS).

## Risk Characterisation

### Critical Health Effects

The critical health effects for risk characterisation include reproductive and developmental toxicity.

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. The available human data are not sufficient to invalidate the animal data. This information has previously been reported in an IMAP Tier II group assessment for boric acid, available at **https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=1330** (NICNAS).

### Public Risk Characterisation

Given the uses identified for these chemicals, it is unlikely that the public will be exposed. Hence, the public risk from these chemicals is not considered to be unreasonable.

### Occupational Risk Characterisation

During product formulation oral, dermal, ocular and inhalation exposure may occur, particularly where manual or open processes are used. These could 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 chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure to the chemical are implemented. The chemical 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.

Colemanite has low water solubility under typical pH conditions and therefore exposure to significant amounts of free borates via routes apart from direct ingestion is unlikely.

## NICNAS Recommendation

Assessment of the chemicals 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)[a] | GHS Classification (HCIS)[b] |
|---|---|---|
| Reproductive and Developmental Toxicity | Not Applicable | May damage fertility or the unborn child - Cat. 1B (H360FD) |

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

[b] 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 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 that could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemicals from entering the breathing zone of any worker;

- health monitoring for any worker who is at risk of exposure to the chemicals, if valid techniques are available to monitor the effect on the worker's health;
- 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 chemicals.

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 help meet 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 chemicals 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.

## References

Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. Third edition [NOHSC:1008 (2004)]. Accessed at **http://www.safeworkaustralia.gov.au/sites/swa/about/publications/Documents/258/ApprovedCriteria_Classifying_Hazardous_Substances_NOHSC1008-2004_PDF.pdf**

Galleria Chemica. Accessed March 2015 at **http://jr.chemwatch.net/galeria/**

Globally Harmonised System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third edition. Accessed at **http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html**

Gulensoy, Hüseyin and Kocakerim, Mehmed Muhtar. 1977. Solubility of ulexite in CO2-containing water. Istanbul University, Faculty of Chemistry. Accessed on April 2015 at **http://www.mta.gov.tr/english/dergi/dergi_pdf/89/4.pdf**

National Industrial Chemicals Notificaion and Assessment Scheme (NICNAS). Tier 11 human health assessment for boric acid (CAS No. 10043-35-3). Australian Government Department of Health. Available at **http://www.nicnas.gov.au**

National Pollutant Inventory (NPI). Accessed March 2015 at **http://www.npi.gov.au/index.html**

NICNAS 2013. IMAP Assessments - Identification of chemicals of low concern to human health. Accessed April 2015 at **http://nicnas.gov.au/Industry/Existing_Chemicals/Chemicals_On_AICS/IMAP_Framework/Identification%20of%20Chemicals%20of%20Low%20Concern%20to%20human%20health.**

Safe Work Australia. Hazardous Chemicals Information System (HCIS). Accessed June 2017 at **http://hcis.safeworkaustralia.gov.au/HazardousChemical**

The Poisons Standard (the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) 2014. Accessed March 2015 at **http://www.comlaw.gov.au/Details/F2014L01343**

Webmineral. Ulexite Mineral Data. Accessed on April 2015 at **http://webmineral.com/data/Ulexite.shtml**

Last Update 30 June 2017

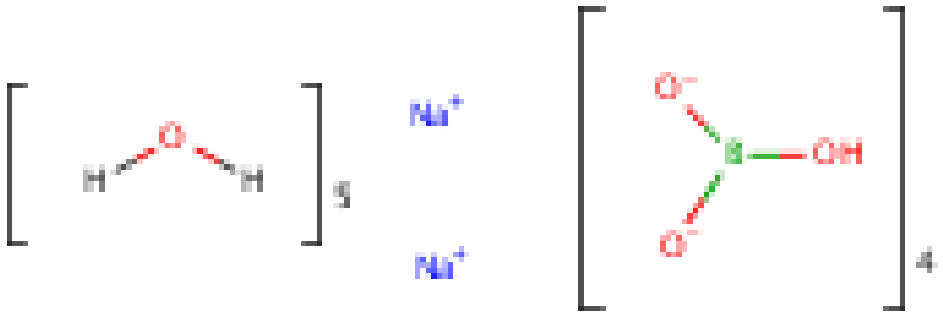
## Chemical Identities

| | |
|---|---|
| Chemical Name in the Inventory and Synonyms | **Colemanite (CaH(BO2)3.2H2O)**<br>hydrous calcium borate<br>neocolmanite |
| CAS Number | 1318-33-8 |
| Structural Formula | |

| | |
|---|---|
| |   |
| Molecular Formula | BHO2.1/3Ca.2/3H2O |
| Molecular Weight | 411.09 |

| | |
|---|---|
| Chemical Name in the Inventory and Synonyms | **Ulexite**<br>boronatrocalcite<br>sodium calcium borate<br>calcium sodium borate<br>hydrated sodium calcium borate hydroxide<br>tv rock |
| CAS Number | 1319-33-1 |
| Structural Formula |   |
| Molecular Formula | BH3O3.1/5Ca.2/5H2O.1/5Na |
| Molecular Weight | 405.23 |

| | |
|---|---|
| Chemical Name in the Inventory and Synonyms | **Tincalconite**<br>disodium tetraborate, pentahydrate |
| CAS Number | 12045-88-4 |
| Structural Formula | |

| | |
|---|---|
| |  |
| Molecular Formula | B4Na2O7.5H2O |
| Molecular Weight | 375.4 |

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