



Hydrates of Sodium Carbonate: Human health tier II assessment

12 December 2019

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Carbonic acid, disodium salt, monohydrate	5968-11-6
Carbonic acid, disodium salt, decahydrate	6132-02-1

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 in this group are 2 of the stable hydrates of sodium carbonate (CAS No. 497-19-8). These chemicals have local irritant properties and low systemic toxicity similar to sodium carbonate. They are corrosive based on their high pH and high alkali reserve, their similar uses and potential to cause local health effects due to the basicity of carbonates (NICNAS, 2012; NICNASa).

Import, Manufacture and Use

Australian

The following non-industrial uses have been identified in Australia:

- in veterinary medicine by the Australian Pesticides and Veterinary Medicines Authority (APVMA);
- as ingredients in pharmaceuticals by the Therapeutic Goods Administration (TGA); and
- as food additives by the Food Standards Australia New Zealand (FSANZ).

International

The following international uses have been identified through the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; the Organisation for Economic Co-operation and Development Screening information data set International Assessment Report (OECD SIAR); Galleria Chemica; the Substances and Preparations in Nordic countries (SPIN) database; the OECD High Production Volume chemical program (OECD HPV), the US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR), the US National Library of Medicine's Hazardous Substances Data Bank (HSDB); and the US Department of Health and Human Services—Household Products Database.

The chemicals have reported cosmetic uses, including as:

- buffering agents; and
- bulking agents

The chemicals have reported domestic uses, including in:

- cleaning and bleaching agents;
- dishwashing detergents;
- laundry detergents; and
- paints, lacquers and varnishes.

The chemicals have reported commercial uses, including:

- in textile bleaches;
- as fillers;
- as additives;
- as photochemical agents;
- in soap, fragrance, perfume and deodoriser manufacture; and
- as process regulators.

The chemicals have reported site-limited uses, including in:

- manufacturing sodium salts;
- manufacturing glass; and
- petroleum refining;

The chemicals have reported non-industrial uses, including:

- as food additives;
- in veterinary medicines; and
- in pharmaceuticals.

Restrictions

Australian

These chemicals are covered by the group —alkaline salts— entry in the *Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) in Schedules 5 and 6 and Appendix C (SUSMP, 2019).

Schedule 5

'Alkaline salts, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination:

(a) in solid orthodontic device cleaning preparations, the pH of which as an "in-use" aqueous solution is more than 11.5;

(b) in solid automatic dishwashing preparations, the pH of which in a 500 g/L aqueous solution or mixture is more than 11.5 but less than or equal to 12.5;

(c) in other solid preparations, the pH of which in a 10 g/L aqueous solution is more than 11.5; or

(d) in liquid or semi-solid preparations, the pH of which is more than 11.5, unless:

(i) in food additive preparations for domestic use; or

(ii) in automatic dish washing preparations for domestic use with a pH of more than 12.5, except when separately specified in these Schedules.'

Schedule 6

'Alkaline salts, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination for non-domestic use:

(a) in solid automatic dishwashing preparations, the pH of which in a 500 g/L aqueous solution or mixture is more than 12.5; or

(b) in liquid or semi-solid automatic dishwashing preparations, the pH of which is more than 12.5.'

Appendix C

'Alkaline salts, being the carbonate, silicate or phosphate salts of sodium or potassium alone or in any combination for domestic use:

(a) in liquid or semi-solid food additive preparations, the pH of which is more than 11.5;

(b) in solid automatic dishwashing preparations, the pH of which in a 500 g/L aqueous solution or mixture is more than 12.5; or

(c) in liquid or semi-solid automatic dishwashing preparations, the pH of which is more than 12.5.'

The SUSMP also recommends appropriate 'Warning Statements' and 'Safety Directions' when used in consumer products.

Schedule 6 chemicals are described as 'Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label'. Schedule 6 chemicals are labelled with 'Poison' (SUSMP, 2019).

Schedule 5 chemicals are described as '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.' Schedule 5 chemicals are labelled with 'Caution' (SUSMP, 2019).

International

No international restrictions were identified.

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals are not listed on 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 for the chemicals in this group (Galleria Chemica):

Temporary Emergency Exposure Limit (TEELs) defined by the US Department of Energy (DOE) for the chemical, sodium carbonate, monohydrate are reported as:

TEEL-1= 14 mg/m³;

TEEL-2= 150 mg/m³; and

TEEL-3= 910 mg/m³.

Health Hazard Information

Sodium carbonate (CAS No. 497-19-8) exists in 3 stable forms—anhydrous, monohydrate (CAS No. 5968-11-6) and decahydrate (CAS No. 6132-02-1) forms. Sodium carbonate monohydrate is expected to have similar intrinsic properties (corrosivity based on high pH and high alkali reserve) to the anhydrous form. Both the carbonate ion (generally as bicarbonate) and sodium ions are normal body constituents. Therefore, no systemic toxicity is expected for this group of chemicals.

In the absence of data for the chemicals in this group, the health hazard information of the previously assessed sodium carbonate was used in this assessment as a read-across. Therefore, this report should be read in conjunction with the Tier II assessment report of 'Alkaline Salts- Carbonates' (NICNASa).

The Tier II human health assessment report for the previously assessed 'Alkaline Salts-Carbonates' is available at: www.nicnas.gov.au

Acute Toxicity

Oral

The chemicals have low acute toxicity based on results from animal tests following oral exposure. The median lethal dose (LD50) for the monohydrate (20 % aqueous solution) in rats is 2800 mg/kg bw in rats.

In an acute oral non-guideline study, Wistar rats (n=10/dose/sex) were orally treated with a 20 % solution of sodium carbonate monohydrate in water at doses of 1300, 1800, 2600, 3600 or 5000 mg/kg bw and were observed for 14 days post-treatment. Mortality recorded was 0/10 at 1300 mg/kg bw; 1/10 at 1800 mg/kg bw; 4/10 at 2600 mg/kg bw; 7/10 at 3600 mg/kg bw and 10/10 at 5000 mg/kg bw. Observed clinical signs included ataxia, muscle tremors, red nasal discharge, urinary staining of the abdomen, soft stool, piloerection, prostration, lethargy, faecal staining of the abdomen and dyspnoea. Necropsy findings reported were mottled liver, mottled or pale kidneys, nasal or oral discharge, red intestines, stomach with red pyloric regions or containing red liquid and mottled red or dark lungs in all treatment groups. An LD50 of 2800 mg/kg bw was determined (OECD, 2002; REACH).

Dermal

Based on the available data, the chemicals in this group are considered to have low acute dermal toxicity. The median lethal dose (LD50) for the monohydrate (20 % aqueous solution) in rats was >2000 mg/kg bw in rats.

In an acute dermal toxicity study in New Zealand White (NZW) rabbits (n=6), 2000 mg/kg bw of sodium carbonate monohydrate was dermally administered as a 1000 mg/mL aqueous slurry on abraded and non-abraded skin with observation for 14 days. No mortality was observed. Observed effects included weight gain in 3/6 treated animals; weight loss in 3/6 treated animals; well-defined to severe erythema and slight to severe oedema in all 6 treated animals at 24 hour observations. The LD50 >2000 mg/kg bw was reported (OECD, 2002; REACH).

Inhalation

No data are available for these chemicals. However, based on the available data on sodium carbonate, these chemicals are expected to have low acute toxicity following inhalation exposure.

Corrosion / Irritation

Corrosivity

Based on the strong alkaline nature of the chemicals in this groups (pH 11.6) in aqueous solutions and the available data on sodium carbonate, the chemicals in this group are expected to be corrosive to mucous membranes at high concentrations (NICNASa; OECD, 2002; REACH).

Respiratory Irritation

These chemicals are strongly alkaline in nature and concentrated solutions can produce corrosive effects. Based on the available data for sodium carbonate, local responses including histopathological changes of the respiratory tract and lungs were considered to be due to the high alkalinity of this group of chemicals (OECD, 2002; REACH). Hazard classification is warranted.

Skin Irritation

The chemicals in this group are considered to have low skin irritation potential based on the available study data. However, both chemicals are strongly alkaline and long-term exposure to solid or concentrated aqueous solutions are likely to produce serious skin irritation or corrosive effects on intact skin depending on the concentration of the chemical and the length of contact.

In a skin irritation study, 0.5 mL of 1gm/mL of sodium carbonate monohydrate was applied to abraded skins of 6 NZW rabbits occlusively for 24 hours. No signs of dermal irritation were observed with the mean scores for erythema and oedema reported as 0 (NICNASa; OECD, 2002; REACH).

Eye Irritation

Based on the available data for sodium carbonate monohydrate and sodium carbonate, the chemicals in this group are considered to cause serious eye irritation and warrant hazard classification.

In a study, NZW rabbits (n=9) were treated with 0.1 mL of undiluted sodium carbonate monohydrate instilled in 1 eye for 4 seconds and observed for 14 days post exposure. Treated eyes of 3 animals were rinsed with 3 mL distilled water. Six treated animals with unwashed eyes had showed signs of severe irritation with corneal opacity, ulceration, pannus, iritis and conjunctival redness, which persisted for 14 days. Mean maximum Draize score in the animals with unwashed eyes was 105. Positive signs of irritation were also noted in 1/3 animals with washed eyes and the mean Draize score was 13 (OECD, 2002; REACH).

Sensitisation

Skin Sensitisation

Based on the available data, these chemicals are not considered to be skin sensitisers (NICNASa; OECD, 2002; REACH).

Repeated Dose Toxicity

Oral

No data are available for the chemicals in this group. Under normal physiological conditions, this group of chemicals are not expected to cause any systemic toxicity. Based on the available data, these chemicals are not expected to have oral repeat dose toxicity (NICNASa; OECD, 2002; REACH).

Dermal

Based on available data on related chemicals, these chemicals are not expected to cause any systemic dermal repeat dose toxicity (NICNASa; OECD, 2002; REACH).

Inhalation

Based on the available data on anhydrous sodium carbonate, these chemicals are not expected to cause any systemic inhalation repeat dose toxicity. However, due to their corrosive nature, they are expected to cause local effects on the lungs (NICNASa; OECD, 2002; REACH).

Genotoxicity

Based on the available data on structurally similar chemicals, these chemicals are not expected to be genotoxic (NICNASa; OECD, 2002; REACH).

Carcinogenicity

No data are available on the chemicals in this group. Based on available data on anhydrous sodium carbonate, these chemicals are not expected to be carcinogenic (NICNASa; OECD, 2002; REACH).

Reproductive and Developmental Toxicity

Based on the available information on anhydrous sodium carbonate, the chemicals in this group are not expected to show any specific reproductive or developmental toxicity (NICNASa; OECD, 2002; REACH).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include corrosivity and respiratory irritation because of the high basicity of the chemicals in this group. These effects are particularly relevant to domestic use of these chemicals.

Public Risk Characterisation

The general public may be exposed to the chemicals through oral, dermal, ocular and inhalation routes when using domestic products containing this group of chemicals. Possibility of ingestion of highly alkaline cleaning/washing products by children is of particular concern. When used in cosmetic products, the final pH of the product will be outside the range where irritant effects are expected.

The chemicals are currently listed on Schedules 5, 6 and Appendix C of the SUSMP. A number of warning statements, first aid instructions and safety directions relating to the alkalinity of the chemicals apply. The current controls are considered adequate to minimise the risk of public health posed by the use of cosmetic and domestic products containing these chemicals, therefore the chemicals in this groups are not considered to pose an unreasonable risk to public health.

Occupational Risk Characterisation

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

The available data support an amendment to the hazard classification in the HCIS (Safe Work Australia) (refer to **Recommendation** section).

NICNAS Recommendation

Assessment of this group of 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

Public Health

Products containing the chemicals should be labelled in accordance with state and territory legislation (SUSMP, 2019).

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
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Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
Irritation / Corrosivity	Not Applicable	May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335) Causes severe skin burns and eye damage - Cat. 1B (H314)

^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 consumers

Products containing the chemicals should be used according to the instructions 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 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;
- 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 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.

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Last Update 12 December 2019

Chemical Identities

Chemical Name in the Inventory and Synonyms	Carbonic acid, disodium salt, monohydrate sodium carbonate monohydrate thermonatrite
CAS Number	5968-11-6
Structural Formula	
Molecular Formula	CH ₂ O ₃ .H ₂ O.2Na
Molecular Weight	124.0

Chemical Name in the Inventory and Synonyms	Carbonic acid, disodium salt, decahydrate sodium carbonate, decahydrate natron sal soda washing soda
CAS Number	6132-02-1
Structural Formula	

	<p style="text-align: center;">Na^+ Na^+ H_2O H_2O</p> <p style="text-align: center;">H_2O H_2O H_2O H_2O</p> <p style="text-align: center;">H_2O H_2O H_2O H_2O</p> <p style="text-align: center;"></p>
Molecular Formula	CH2O3.10H2O.2Na
Molecular Weight	286.1

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