Carbonic acid, disodium salt, compound with hydrogen peroxide (H2O2) (2:3): Human health tier II assessment

05 February 2016

CAS Number: 15630-89-4

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.

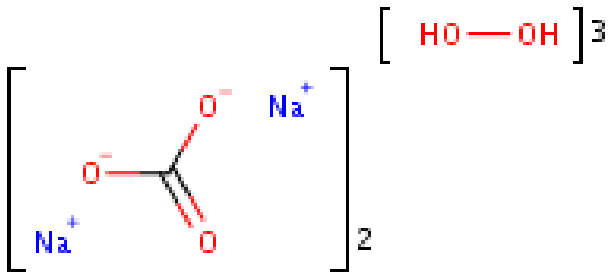
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	sodium carbonate peroxide disodium carbonate, compound with hydrogen peroxide (2:3) sodium percarbonate sodium carbonate peroxyhydrate peroxy sodium carbonate
Structural Formula	
Molecular Formula	CH2O3.3/2H2O2.2Na
Molecular Weight (g/mol)	314.02
Appearance and Odour (where available)	White crystalline powder
SMILES	C(=O)(O{-}.[Na]{+})O{-}.[Na]{+}_OO

Import, Manufacture and Use

Australian

The chemical is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume between 1000–9999 tonnes and with the following industrial uses.

The chemical has reported domestic use as a bleaching/cleaning agent.

The chemical has reported site-limited use in the manufacture of cleaning; washing agents and additives.

International

The following international uses have been identified through the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; the European Commission (EC) Cosmetic Ingredients and Substances (CosIng) database; the Organisation for Economic Co-operation and Development Screening Information Data Set Initial Assessment Report (OECD SIAR); the United States Environmental Protection Agency (US EPA) Aggregated Computational Toxicology Resource (ACToR); the US Household Products database; the Substances in Preparations in Nordic countries (SPIN) database; the US National Library of Medicine Hazardous Substances Data Bank (HSDB); Haz-Map and Galleria Chemica.

The chemical has reported cosmetic uses, including in:

- bleaching/whitening toothpastes, dental care (rinse-off) products; and
- deodorants and oxidising agents.

The chemical has reported domestic uses, including in:

- biocidal and water treatment products;
- bleaching/cleaning agents, stain removers, furnishing care products; and
- dishwashing and laundry detergents and additives.

The chemical has reported commercial uses, including in:

- adhesive and binding materials;
- anti-freezing agents;
- paints, lacquers and vanishes;
- professional cleaning products; and
- textile bleaching.

The chemical has reported site-limited use in the manufacture and formulation of mixtures containing sodium percarbonate and other chemicals.

The chemical has reported non-industrial uses, including in:

- non-agricultural and non-food pesticides;
- mild antiseptics, denture cleaners for professional use.

Restrictions

Australian

The chemical is listed in the *Poisons Standard*—the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP, 2015) in Schedules 5 and 6.

Schedule 6:

'SODIUM PERCARBONATE (CAS No. 15630-89-4) except:

(a) when included in Schedule 5; or

(b) in preparations containing 15 per cent or less of sodium percarbonate.'

Schedule 6 chemicals are labelled with 'Poison' and 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 5:

'SODIUM PERCARBONATE (CAS No. 15630-89-4) in preparations containing 35 per cent or less of sodium percarbonate except in preparations containing 15 per cent or less of sodium percarbonate.'

Schedule 5 chemicals are labelled with 'Caution' and 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.'

International

The chemical is listed in the EC Cosmetics Regulation Annex III (List of substances with restricted use in cosmetic products; CosIng): hydrogen peroxide (H_2O_2) release limits of 12 % in hair products; 4 % in skin products; 2 % in nail hardening products or products intended for eyelashes products; =0.1 % in oral hygiene products; and >0.1 % to =6 % in teeth whitening or bleaching products.

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not listed on the Hazardous Substances Information System (HSIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

The following workplace exposure standards are identified (Galleria Chemical):

- Czech Republic occupational permissible exposure limits (PEL) = 5 mg/m^3 (maximum 10 mg/m^3).
- Russia Maximum Allowed Concentration (PDK) = 2 mg/m^3.

Health Hazard Information

Limited data are available on the chemical (which will be referred to as 'sodium percarbonate' in the **Health Hazard Information** section). It rapidly decomposes to H_2O_2 and sodium carbonate in contact with body fluids (see **Toxicokinetics** section). NICNAS has previously assessed the breakdown products of sodium percarbonate under the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework (Tier II): H_2O_2 (CAS No. 7722-84-1; NICNASa) and sodium carbonate (CAS No. 497-19-8; NICNASb). Therefore, the toxicity of sodium percarbonate is assessed based on the collective information from these breakdown chemicals, particularly for those toxicological endpoints where the data are incomplete or unavailable.

Toxicokinetics

Sodium percarbonate, when in contact with body fluids, is dissociated into H_2O_2, carbonate ions and sodium ions; all are naturally present in the human body (OECD, 2005). The substance H_2O_2 is a normal metabolite in aerobic cells and largely degraded by endogenous catalase and glutathione peroxidase enzymes, releasing oxygen and water as end products. Carbonate ions are neutralised by the gastric acid in the stomach after oral uptake, resulting in a formation of bicarbonate and carbon dioxide (CO_2). Following absorption, concentrations of H_2O_2, bicarbonate, carbonate (as part of the pH physiological buffer system), and sodium ions are expected to be well controlled and regulated in biological systems. Thus, it is unlikely that the breakdown chemicals are systemically available to a toxic level after exposure to sodium percarbonate (refer to NICNASa; b; OECD, 2005).

Due to its hydrophilic and ionic characteristics, sodium percarbonate is expected to have low dermal absorption (OECD, 2005).

As H_2O_2 is a strong oxidising agent and the carbonate ion is a strong base, sodium percarbonate has a potential to cause local adverse effects from all routes of exposure.

Acute Toxicity

Oral

The available data indicate that sodium percarbonate has a moderate acute oral toxicity, supporting a recommendation for hazard classification.

An oral median lethal dose (LD50) of 1034 mg/kg bw was reported in rats in a standard study. Toxic effects included decreased activity and coordination, lack of pain reflex, excessive salivation, diarrhoea, dyspnoea, facial and urogenital area staining, and stomach thickening (Glaza, 1990a; HSDB; OECD, 2005).

There were other reports of LD50 ~2000 mg/kg bw; however, these studies used sodium percarbonate at 10 % (rats) and 4 % (mice), and were not performed according to good laboratory practice (GLP) or standard test guidelines (see OECD, 2005 for details).

Dermal

The available data indicate that sodium percarbonate has a low acute dermal toxicity.

A dermal LD50 of >2000 mg/kg bw was reported in rabbits in a well conducted standard study. Although mortality or overt systemic toxicity were not reported, severe irritation was observed (Glaza, 1990b; HSDB; OECD, 2005).

Inhalation

The available data indicate that sodium percarbonate has a low to moderate acute inhalational toxicity.

The inhalation median lethal concentration (LC50) of >4.58 mg/L/1-h was reported in rats with no original study details or quality available (HSDB; OECD, 2005).

Although mice exposed to sodium percarbonate (up to 0.76 mg/L nose-only for 20 minutes) did not show full recovery in respiratory rates after 24-hour observation, there were no clinical signs or treatment-related effects at necropsy, including lung weight changes (Janssen, 2001; OECD, 2005) (see **Respiratory irritation**).

Corrosion / Irritation

Respiratory Irritation

The available data indicate that sodium percarbonate causes respiratory tract irritation, supporting a recommendation for classification.

In a non-GLP study in mice, sodium percarbonate decreased respiratory rates and minute ventilation volumes in all exposed groups (309, 330 354, 698, 764, and 805 mg/m^3 for 20 minutes). The decrease was throughout the exposure period at all doses, except for 309 mg/m^3 where this was seen only at the end of the exposure. Based on the study findings, it was concluded that the chemical is a respiratory irritant with an RD50 (concentration producing 50 % respiratory rate decrease) of ~700 mg/m^3 (Janssen, 2001; OECD, 2005).

Skin Irritation

The available data indicate that sodium percarbonate causes moderate skin irritation, supporting a recommendation for hazard classification.

In a well conducted standard study, rabbits exposed to sodium percarbonate (for four hours under semi-occluded conditions) exhibited erythema and oedema during a 7-day observation period, with the highest Draize score of 2 (Glaza, 1990c).

The dermal acute toxicity study in rabbits summarised above (Glaza, 1990b) reported dermal irritation with sodium percarbonate, including signs of severe erythema and oedema, slight to marked atonia, desquamation, coriaceousness and fissuring (OECD, 2005).

In a 12-day repeated dose study in rats, sodium percarbonate as a powder caused slight erythema and desquamation after the fourth application with no indication of increasing severity, while a 1 % aqueous solution was practically non-irritant as slight erythema and desquamation developed only during the last two applications (Chater, 1978; OECD, 2005).

Eye Irritation

The available data indicate that sodium percarbonate causes serious eye irritation, supporting a recommendation for hazard classification.

In six eye irritation studies (only two out of six not performed according to GLP or standard test guidelines), sodium percarbonate in powder form was highly irritating to the eyes of rabbits, causing irreversibly corrosive damage if not rinsed. In

one standard study, the total Draize score was up to 36 out of 110 (involving iritis, corneal peeling, and necrosis of conjunctivae) and persisted up to 96 hours post exposure (please refer to OECD, 2005; REACH for study details and summaries).

In addition, both the breakdown components H_2O_2 (≥8 %) and sodium carbonate (≥10 %) are currently classified with the risk phrase R41 'Risk of serious damage to eyes' in the HSIS.

Observation in humans

In a human patch (skin irritation) test, a positive reaction was observed in 1/26 volunteers with sodium percarbonate (at 4 % for 15, 30, 60 minutes through to 2, 3, and 4 hours) (York et al., 1996; OECD, 2005).

Sensitisation

Skin Sensitisation

The available data indicate that sodium percarbonate is not a skin sensitiser.

In a standard Buhler study in guinea pigs, although all animals exhibited mild reactions following the induction applications, none of the test or naive control animals showed dermal reactions at 24 or 48 hours following the challenge applications (Glaza, 1990d; OECD SIAR 2005).

Repeated Dose Toxicity

Oral

No data are available for sodium percarbonate.

According to the OECD SIAR (2005), the repeated dose toxicity of sodium percarbonate is expected to be driven mainly by H_2O_2, as for the acute toxicity of the chemical.

For H_2O_2, a no observed adverse effect level (NOAEL) of 20 mg/kg bw/d was established in rats (based on a significantly reduced plasma catalase level at higher dose levels in a 100-day gavage study), and a NOAEL of 26 mg/kg bw/d for mice (based on dose-related reductions in food and water consumption, and on the observation of duodenal mucosal hyperplasia in a 90-day drinking water study) (NICNASa).

After repeated oral exposure to sodium percarbonate, the systemic availability of carbonate ions is limited by the neutralisation of the gastric acid and the pH buffering capacity of the blood, while that of sodium ions is expected to be insignificant, compared to its normal dietary intake (see **Toxicokinetics** section; OECD SIAR 2005).

Dermal

No data are available for sodium percarbonate.

Inhalation

No data are available for sodium percarbonate.

Genotoxicity

No data are available for sodium percarbonate. Based on data for its breakdown products, sodium percarbonate is not expected to have genotoxic potential.

Hydrogen peroxide is mutagenic and genotoxic in vitro, although there is no adequate evidence to support significant mutagenic or genotoxic potential for H_2O_2 under in vivo conditions (NICNASa). Sodium carbonate has been assessed to have no genotoxic potential, based on its structure and a negative bacterial test result (NICNASb; OECD SIAR 2005).

Carcinogenicity

No data are available for sodium percarbonate. Based on the following international and NICNAS evaluation conclusions for its breakdown products, sodium percarbonate is not expected to have a carcinogenic potential.

- H_2O_2 is not classifiable as human carcinogen on the basis that 'there is inadequate evidence in humans for the carcinogenicity of H_2O_2; there is limited evidence in experimental animals for the carcinogenicity of H_2O_2 (IARC, 1999; NICNASa).
- Carbonate and sodium ions are major products of cellular metabolic activities and subject to physiological control mechanisms and homeostasis, so that they are not anticipated to be systemically available to a toxic level (NICNASb).

Reproductive and Developmental Toxicity

No data are available for sodium percarbonate. The breakdown products are not systemically available to a significant toxic level, and so sodium percarbonate is not expected to have a toxic potential for reproduction or foetus development (OECD, 2005).

Risk Characterisation

Critical Health Effects

The chemical has moderate acute oral toxicity. It is a skin and respiratory irritant, and may cause severe irritation to the eyes with lasting or irreversible effects.

Public Risk Characterisation

The chemical has reported uses mainly in domestic cleaning products and in dental care products (particularly rinse-off products). The use and supply of consumer products containing sodium percarbonate are controlled by scheduling under the *Poisons Standard*, including a number of warning statements, first aid instructions and safety directions relating to the identified hazards of the chemical. Therefore, the risk to public health of sodium percarbonate is not considered to be unreasonable and further risk management is not considered necessary for public safety (SUSMP, 2015).

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalational 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 chemical 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.

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

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

NICNAS Recommendation

Further risk management is required. Sufficient information is available to recommend that risks to work health and safety be managed through changes to classification and labelling.

Assessment of the chemical is considered to be sufficient provided that risk management recommendations are implemented and all 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 chemical should be labelled in accordance with state and territory legislation.

Work Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This assessment does not consider classification of physical and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Harmful if swallowed (Xn; R22)	Harmful if swallowed - Cat. 4 (H302)
Irritation / Corrosivity	Risk of serious eye damage (Xi; R41) Irritating to skin (Xi; R38) Irritating to respiratory system (Xi; R37)	Causes serious eye damage - Cat. 1 (H318) Causes skin irritation - Cat. 2 (H315) May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335)

[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 chemical 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, inhalation exposure to the chemical 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 chemical is 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 chemical from entering the breathing zone of any worker;
- 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 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 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 the chemical has not been undertaken as part of this assessment.

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