Peroxides of divalent cations: Human health tier II assessment

13 February 2015

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Calcium peroxide (Ca(O2))	1305-79-9
Strontium peroxide (Sr(O2))	1314-18-7
Zinc peroxide (Zn(O2))	1314-22-3
Magnesium peroxide (Mg(O2))	14452-57-4

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

Grouping Rationale

This group of chemicals consists of peroxides of divalent cations. Chemicals in this group may also be referred to as hydrogen peroxide releasing substances (CosIng). The chemicals in this group are expected to have similar toxicity given that the health effects of exposure are driven by the oxidising nature of these chemicals to a greater extent than the metal ion, which, in each case, is of relatively low toxicity.

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified.

International

The following international uses have been identified through 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; the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) and eChemPortal: the US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR), and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

All the chemicals in this group have reported cosmetic uses as bleaching and oxidising agents.

Calcium peroxide (CAS No. 1305-79-9) and zinc peroxide (CAS No. 1314-22-3) have reported commercial uses including:

- as intermediates in polysulphide-based sealants;
- as water conditioning agents; and
- in adhesives and sealant production.

The chemicals calcium peroxide (CAS No. 1305-79-9), zinc peroxide (CAS No. 1314-22-3) and magnesium peroxide (CAS No. 14452-57-4) have reported site-limited uses including as:

- process regulators and softeners; and
- vulcanising agents.

The following non-industrial uses have been identified internationally:

- in the agricultural industry; and
- in the pharmaceutical industry.

Restrictions

Australian

The chemical zinc peroxide (CAS No. 1314-22-3), to the extent it is used internally, is covered in the *Poisons Standard* (*Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP)) in Schedule 4 with the entry (SUSMP, 2014):

'ZINC COMPOUNDS for human internal use except:

(a) in preparations with a recommended daily dose of 25 mg or less of zinc; or

(b) in preparations with a recommended daily dose of more than 25 mg but not more than 50 mg of zinc when compliant with requirements of the *Required Advisory Statements for Medicine Labels*.'

'Schedule 4 chemicals are labelled with Prescription Only Medicine, or Prescription Animal Remedy. These are substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription' (SUSMP, 2014).

Given that the chemicals in the group release hydrogen peroxide the following is also relevant:

Hydrogen peroxide is listed in the *Poisons Standard* in Schedule 5 with the following entry:

'HYDROGEN PEROXIDE (excluding its salts and derivatives):

(a) in hair dye preparations containing 12 per cent or less of hydrogen peroxide except in hair dyes containing 6 per cent or less of hydrogen peroxide; or

(b) in other preparations containing 6 per cent (20 volume) or less of hydrogen peroxide except in preparations containing 3 per cent (10 volume) or less of hydrogen peroxide'.

Hydrogen peroxide is also included in Schedule 6 with the following entry:

'HYDROGEN PEROXIDE (excluding its salts and derivatives) except:

(a) when included in Schedule 5;

(b) in hair dye preparations containing 6 per cent (20 volume) or less of hydrogen peroxide; or

(c) in other preparations containing 3 per cent (10 volume) or less of hydrogen peroxide'.

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, 2014).

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, 2014).

International

The majority of the chemicals in this group have the following restrictions (Galleria Chemica):

- Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient "Hotlist") under the entry 'Peroxides and peroxide-generating compounds';
- EU Cosmetic Regulation 1223/2009 Annex III Part 1: List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down;
- New Zealand Cosmetic Products Group Standard—Schedule 5: Components cosmetic products must not contain except subject to restrictions and conditions laid down;

- Association of South East Asian Nations (ASEAN) Cosmetic Directive Annex III - Part 1: List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down;
- Canada Natural Health Products Ingredients Database (NHPID) under the entry 'Non-medicinal purposes: Oxidising Agent Restrictions: General Route of Administration: Dental Reference' (NHPID); and
- Council of Europe Resolution ResAP (2008)1 on requirements and criteria for the safety of tattoos and permanent make-up Table 3: Maximum allowed concentrations of impurities in products for tattoos and permanent make-up.

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals in this group are not listed on the Hazardous Substances Information System (HSIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards are identified for some of the chemicals in this group (Galleria Chemica):

- A time weighted average (TWA) of 2 mg/m^3 and a short-term exposure limit (STEL) for strontium and its compounds of 1 mg/m^3 in countries such as Bulgaria, Estonia, Hungary and Iceland.
- STEL of 0.5–1 mg/mg^3 in Estonia for magnesium and its organic compounds in total dust form.
- Maximum concentrations in the workplace air (MAK values) of 0.1 mg/mg^3 in Germany for zinc and its inorganic compounds.

Health Hazard Information

Peroxides are strong oxidisers and are used as industrial bleaches. When any peroxide is combined with an acid, such as in the stomach, one of the products is hydrogen peroxide. As data available for chemicals in this group are limited, data for hydrogen peroxide (CAS No. 7722-84-1) have been used in the health hazard assessment to determine systemic toxicity for the chemicals in this group. Hydrogen peroxide has been assessed by NICNAS and it is classified for acute toxicity and corrosivity (NICNASa). Hydrogen peroxide does not cause severe toxic effects or reproductive toxicity on repeated exposure and is not considered mutagenic.

The Opinion of the Scientific Committee on Cosmetic Products and Non-food Products Intended for Consumers has considered zinc peroxide, together with hydrogen peroxide, for its use in tooth bleaching and teeth whitening products (SCCNFP, 2002). While no toxicological data have been presented, the opinion considered hydrogen peroxide and zinc peroxide to be chemical analogues for the chemicals in this group.

Given the limited data on chemicals in this group, data from sodium peroxide (CAS No. 1313-60-6) have been used to determine local toxicity according to read-across principles (OECD, 2014). Sodium peroxide is classified as hazardous with the risk phrase 'Causes severe burns' (Xi; R35) in the HSIS (Safe Work Australia). Sodium peroxide is a much stronger base than the members of this group, and forms sodium hydroxide as well as hydrogen peroxide in contact with water. The chemicals in this group are expected to be less corrosive than sodium peroxide.

The counter ions, calcium, magnesium and strontium, are expected to be of low hazard (NICNASb and NICNASc). Soluble zinc salts have been previously assessed by NICNAS and are harmful by ingestion and some cause serious eye damage (NICNASd).

The available data for hydrogen peroxide and sodium peroxide support the hazard classification for the chemicals in this group for acute toxicity and corrosivity (refer to **Recommendation section**).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic acute effects (acute toxicity from oral exposure) and local effects (irritation and corrosivity).

Public Risk Characterisation

Based on overseas experience, it is expected that the chemicals in this group are used in cosmetic products as bleaching and oxidising agents. The main route of exposure is expected to be through the skin and eyes. The main concerns are similar to those for hydrogen peroxide given the oxidising effects of the chemicals. Considering that these chemicals release hydrogen peroxide and considering that hydrogen peroxide is controlled by the *Poisons Standard* (SUSMP, 2014), provided that appropriate labelling is followed, the risk from the use in domestic and cosmetic products is not considered to be unreasonable.

Occupational Risk Characterisation

During product formulation, oral, dermal, ocular and inhalation exposure of workers to the chemicals in this group might 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 chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise oral, 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 data available support an amendment to the hazard classification in the HSIS (Safe Work Australia) (refer to **Recommendation** section.

NICNAS Recommendation

The assessment of these 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

Given that the chemicals in the group release hydrogen peroxide, the restrictions on the *Poison Standard* (SUSMP, 2014) for hydrogen peroxide also apply.

Work Health and Safety

The chemicals in this group are recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification for physical hazards and environmental hazards.

The classification proposed below is based on read across principles. It should be used as a default for all members of the group. If empirical data become available for any member of the group indicating that a lower (or higher) classification is appropriate for the specific chemical, these may be used to amend the default classification for that chemical.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Harmful if swallowed (Xn; R22)	Harmful if swallowed - Cat. 4 (H302)

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Irritation / Corrosivity	Causes burns (C; R34)	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 which 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.

References

Association of South East Asian Nations (ASEAN) Cosmetic Directive. Government of Singapore Health Sciences Authority. Health Products Regulation for Cosmetic Products. Accessed January 2015 at **http://www.hsa.gov.sg/content/dam/HSA/HPRG/Cosmetic_Products/Annexes%20of%20the%20ASEAN%20Cosmetic%20Directive.pdf**

Canada Natural Health Products Ingredients Database (NHPID), October 2013. Accessed January 2015 at **http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/online-enligne/nhpid-bipsn-eng.php**

Cosmetics Directive (CosIng). Accessed December 2014 at **http://ec.europa.eu/consumers/cosmetics/cosing/**

Council of Europe Resolution ResAp(2008)1 on requirements and criteria for the safety of tatoos and permanent make-up (superseding Resolution ResAP(2003)2 on tatoos and permanent make-up).

eChemPortal. Accessed December 2014 at **http://www.echemportal.org/echemportal/substancesearch/substancesearchlink.action**

European Chemicals Agency (ECHA). Classification and Labelling (C&L) Inventory. Accessed December 2014 at **http://echa.europa.eu/information-on-chemicals/cl-inventory**

Galleria Chemica. Accessed December 2014 at **http://jr.chemwatch.net/galleria/**.

Hazardous Substances Data Bank (HSDB). National Library of Medicine. Accessed on December 2014 at **http://toxnet.nlm.nih.gov**.

Health Canada (2011). Cosmetic ingredient hotlist. Health Canada List of Prohibited and Restricted Cosmetic Ingredients, March 2011. **http://www.hc-sc.gc.ca/cps-spc/cosmet-person/indust/hot-list-critique/hotlist-liste-eng.php**

National Industrial Chemicals Notification and Assessment Scheme (NICNASa). Human health Tier II assessment for hydrogen peroxide (CAS No.7722-84-1). Australian Government Department of Health and Ageing. Accessed December 2014 at **http://www.nicnas.gov.au**

National Industrial Chemicals Notification and Assessment Scheme (NICNASb) (2012). Inventory Multi-Tiered Assessment and Prioritisation Framework: Indentificatuion of chemicals of low concern to human health.

National Industrial Chemicals Notification and Assessment Scheme (NICNASc) (1999). Full Public Report on Tersperse 2600. Accessed January 2015 at **http://www.nicnas.gov.au/__data/assets/pdf_file/0005/9527/PLC126FR.PDF**

National Industrial Chemicals Notification and Assessment Scheme (NICNASd). Tier II environment assessment for soluble zinc salts. Australian Government Department of Health. Available at **http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=1323**

New Zealand (NZ) Environmental Protection Agency (EPA) 2006. Cosmetic Products Group Standard. Accessed January 2015 at **http://www.epa.govt.nz/Publications/Cosmetic%20Products%20Group%20Standard.pdf**

Substances in Preparations in Nordic Countries (SPIN). Accessed December 2014 at **http://195.215.202.233/DotNetNuke/default.aspx**

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

The Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers (SCCNFP) 2002. Opinion on Hydrogen (carbamide, zinc) peroxide in tooth bleaching/whitening products (SCCNFP/0602/02). Accessed December 2014 at **http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out180_en.pdf**

United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) dictionary. Accessed December 2014 at **http://gov.personalcarecouncil.org/jsp/gov/GovHomePage.jsp**

US Environmental Protection Agency's Aggregated Computational Toxicology Resource (ACToR). Accessed December 2014 at **http://actor.epa.gov/actor/faces/ACToRHome.jsp**

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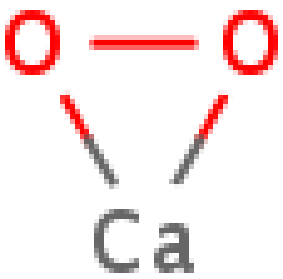
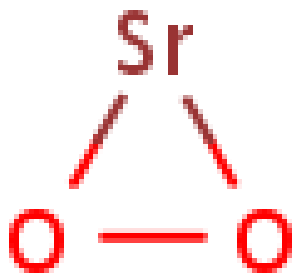
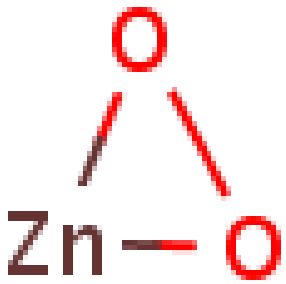
Chemical Identities

Chemical Name in the Inventory and Synonyms	**Calcium peroxide (Ca(O2))** Calper Calcium dioxide Calper G
CAS Number	1305-79-9
Structural Formula	
Molecular Formula	CaO2
Molecular Weight	72.08

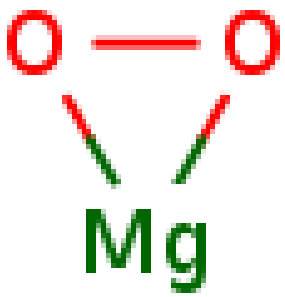
Chemical Name in the Inventory and Synonyms	**Strontium peroxide (Sr(O2))** Strontium dioxide
CAS Number	1314-18-7
Structural Formula	

	
Molecular Formula	O2Sr
Molecular Weight	119.62

Chemical Name in the Inventory and Synonyms	**Zinc peroxide (Zn(O2))** Zinc dioxide Zinc superoxide
CAS Number	1314-22-3
Structural Formula	

	
Molecular Formula	O2Zn
Molecular Weight	97.388

Chemical Name in the Inventory and Synonyms	**Magnesium peroxide (Mg(O2))** Magnesium dioxide Magnesium superoxol Peromag
CAS Number	14452-57-4
Structural Formula	

	
Molecular Formula	MgO2
Molecular Weight	56.303

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