Hypochlorous acid, calcium salt: Human health tier II assessment

03 July 2015

CAS Number: 7778-54-3

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.

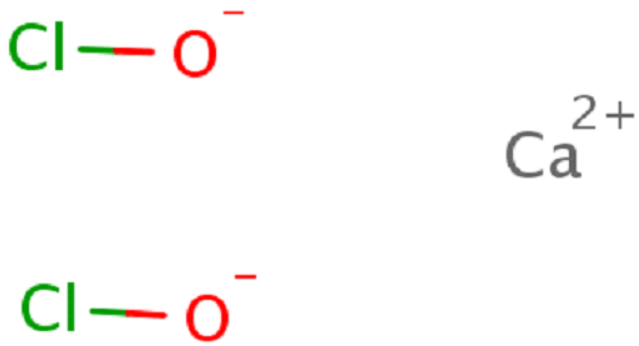
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	calcium hypochlorite chlorinated lime calcium chlorohydrochlorite calcium oxychloride caporit
Structural Formula	
Molecular Formula	Ca.2ClHO
Molecular Weight (g/mol)	142.98
Appearance and Odour (where available)	white or grayish-white powder with a strong chlorine odour.
SMILES	O{-}(Cl).[Ca]{2+}.O{-}Cl

Import, Manufacture and Use

Australian

The chemical was reported under previous mandatory and/or voluntary calls for information. The specific use of the chemical was not identified but had been reported to be used within the domestic/cleaning industry.

The chemical is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume between 1,000 and 9,999 tonnes.

International

The following international uses have been identified through:

- the European Union (EU) Registration, Evaluation and Authorization of Chemicals (REACH) dossiers;
- Galleria Chemica;
- the European Commission Cosmetic Ingredients and Substances (CosIng) database;
- the United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary;
- the Substances and Preparations in the Nordic countries (SPIN) database;
- the Organisation for Economic Co-operation and Development (OECD) Screening Information Dataset Initial Assessment Report (SIAR);
- the US National Library of Medicine's Hazardous Substances Data Bank (HSDB); and

the US Department of Health and Human Services, Household Products Database (HPD).

The chemical has reported cosmetic uses including in:

- sterilisers;
- deodorants; and
- anti-microbial agents.

The chemical has reported domestic uses including:

- as a disinfectant in water purification;
- in cleaning/washing agents (at concentrations of 21–24 % in a granule domestic cleaning product);
- as a household sanitiser; and
- as a household and commercial bleaching agent (at unspecified concentrations in liquid home-maintenance products).

The chemical has reported commercial uses including:

- as an oxidising agent, e.g. in calico printing; and
- in the refining of sugar.

The chemical has reported site-limited uses including as a laboratory chemical.

The chemical has reported non-industrial uses including:

- in non-agricultural pesticides (algaecides, fungicides and bactericides);
- as a drug preservative; and

- as a disinfectant in drugs and in swimming pools (at concentrations of 40–90 % in granule, powder and tablet landscape and yard products).

Restrictions

Australian

This chemical, calcium hypochlorite, is listed in the *Poisons Standard*—the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) in Schedules 5 and 6 (SUSMP, 2015), under '*Chlorinating compounds*'.

'Schedule 5

'CHLORINATING COMPOUNDS containing 20 per cent or less of available chlorine, **except**:

(a) when separately specified in these Schedules;

(b) sodium hypochlorite preparations with a pH of less than 11.5;

(c) liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statements:

WARNING – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products;

(d) liquid preparations containing less than 2 per cent of available chlorine; or

(e) other preparations containing 4 per cent or less of available chlorine.'

'Schedule 6

'CHLORINATING COMPOUNDS **except**:

(a) when included in Schedule 5;

(b) when separately specified in these Schedules;

(c) sodium hypochlorite preparations with a pH of less than 11.5;

(d) in liquid preparations containing not less than 2 per cent but not more than 4 per cent of available chlorine when labelled with the statements:

WARNING – Ensure adequate ventilation when using. Vapour may be harmful. May give off dangerous gas if mixed with other products;

(e) in liquid preparations containing less than 2 per cent of available chlorine; or

(f) in other preparations containing 4 per cent or less of available chlorine.'

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, 2015).

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, 2015).

International

The chemical is listed on the Health Canada List of prohibited and restricted cosmetic ingredients (The "Hotlist") as 'chlorine' (Galleria Chemica).

Existing Work Health and Safety Controls

Hazard Classification

The chemical is classified as hazardous, with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

- Xn; R22 (Harmful if swallowed);
- Xn; R31 (Contact with acids liberates toxic gas); and
- C; R34 (Corrosivity/causes burns).

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

Hypochlorous acid, calcium salt, also commonly known as calcium hypochlorite, is a relatively stable inorganic compound which dissociates into the hypochlorite ion (ClO^-) and calcium ion (Ca^{2+}) in aqueous solution. Aqueous hypochlorite ion (ClO^-) is in a pH-dependent equilibrium with two other species of chlorine: gaseous chlorine (Cl_2) and hypochlorous acid (HClO).

The dissociation of the chemical in the body suggests that local effects such as corrosion are most likely since the hypochlorite ion is a moderately strong base, while the calcium ion is normally considered to be of low hazard (NICNAS 2013), and so the chemical may have potential to create strongly alkaline conditions at the application site (OECD, 2004) contributing to the corrosivity of the chemical. Exposure to calcium hypochlorite is also associated with short-term local effects based on the corrosive nature of the hypochlorite ion and chlorine gas.

In the absence of specific information on the chemical, data from sodium hypochlorite (CAS No. 7681-52-9) (expected to exist almost entirely as the hypochlorite ion in biological solutions), calcium ion, in the form of calcium chloride (CAS No. 10043-52-4) and chlorine gas are appropriate sources of surrogate data (NICNASa; NICNAS b) and are included in the relevant sections in the report.

Toxicokinetics

No data are available for the chemical.

The data available for sodium hypochlorite support the potential for the absorption of the hypochlorite ion by all routes. Radiolabelled (^{36}Cl) hypochlorous acid administered orally in rats was rapidly absorbed (rate constant 0.157 h^{-1}) reaching a peak blood concentration in 2–4 hours. Elimination of labelled chlorine is slow (rate constant 0.009 h^{-1}) with only 32 % recovery from urine and faeces (76 and 24 %, respectively). Binding of chlorine to proteins, amino acids and unsaturated lipids accounts for this incomplete elimination. No radioactivity was recovered in expired air (NICNASa).

Acute Toxicity

Oral

The chemical is classified as hazardous with the risk phrase 'Harmful if swallowed' (Xn; R22) in the HSIS (Safe Work Australia). The available data support this classification.

The chemical has moderate acute toxicity based on results from a non-guideline study in male Wistar rats (10 males/dose) following oral exposure. The median lethal dose (LD50) was reported to be 790 mg/kg bw. Mortalities were reported at all doses (8/10, 5/10, 9/10 and 10/10 deaths occurred at concentrations of 890, 1000, 1120, and 1260 mg/kg, respectively). Observed sub-lethal effects reported include moderate depression of the central nervous system (CNS) one hour after administration, mild to moderate persistent anorexia, and diarrhoea (OECD, 2004).

Dermal

No data are available for the chemical.

Sodium hypochlorite and calcium chloride are reported to have low acute dermal toxicity (NICNASa; NICNASb).

Inhalation

No acute inhalation toxicity data are available for the chemical. Sodium hypochlorite is reported to have low acute inhalation toxicity (NICNASa). Similarly to sodium hypochlorite, inhalation exposure of calcium hypochlorite is only possible if aerosols are formed as the chemical is not volatile (OECD, 2004).

The chemical is classified as hazardous with the risk phrase ‘Contact with acids liberates toxic gas’ (Xn; R31) in the HSIS (Safe Work Australia). The chemical is incompatible with acidic conditions, where it can react with acids to release chlorine gas.

Corrosion / Irritation

Corrosivity

The chemical is classified as hazardous with the risk phrase 'Causes burns' (Xn; R34) in the HSIS (Safe Work Australia). The available data support this classification.

The chemical is reported to be corrosive to the skin with severe effects due to the alkalinity of the hypohlorite ion (OECD, 2004). Inhalation of chlorine fumes may cause laryngeal and pulmonary irritation and exposure to bleaching powder at high concentrations of the chemical can be irritating to nose and eyes (HSDB).

Sodium hypochlorite is reported to be corrosive to the skin and eyes at high concentrations and if aerosolised, sodium hypochlorite or the associated chlorine is a respiratory irritant (NICNASa). Calcium chloride is a slight skin irritant, a severe eye irritant and a potential respiratory irritant (NICNASb).

Sensitisation

Skin Sensitisation

No data are available for the chemical. Repeated insult patch tests conducted on healthy human volunteers with other hypochlorite formulations have shown no evidence of potential allergic contact dermatitis (NICNASa).

Repeated Dose Toxicity

Oral

No data are available for the chemical.

Sodium hypochlorite and calcium chloride are reported to cause no systemic adverse effects following repeated oral exposure (NICNASa; NICNASb).

Dermal

No data are available for the chemical.

Sodium hypochlorite is reported to cause no systemic adverse effects following repeated dermal exposure (NICNASa; NICNASb).

Inhalation

No data are available for the chemical.

Repeated inhalation exposure of rats and mice to chlorine gas caused increased incidence of nasal lesions (OECD, 2004). This study is not used to provide surrogate data for the calcium hypochlorite since the chemical can only release gaseous chlorine at high concentrations upon mixing with strong acids (refer to **Acute toxicity: inhalation** section).

Observation in humans

While no data are available for the chemical, based on human experience and control studies in volunteers, it was reported that exposure to chlorine gas of up to 0.5 ppm (1.5 mg/m^3) for six hours on three consecutive days did not cause adverse effects to the lungs (OECD, 2004).

Genotoxicity

Based on the limited data available, the chemical is not considered to be genotoxic.

While several in vitro studies of chlorine/hypochlorite solutions indicate mutagenic potential, the experimental design and results were limited by the corrosive properties of the solutions which may have affected the in vitro test systems (OECD, 2004).

Chlorine/hypochlorite solutions were found to have no mutagenic potential in several in vivo studies (OECD, 2004).

Sodium hypochlorite and calcium chloride are reported to have no genotoxic potential in vitro and vivo (NICNASa; NICNASb).

Carcinogenicity

No data are available for the chemical.

Sodium hypochlorite and calcium chloride are reported to have no carcinogenic potential (NICNASa; NICNASb).

The International Agency for Research on Cancer (IARC) has classified hypochlorite salts as ‘not classifiable as to their carcinogenicity in humans’ (Group 3), based on inadequate evidence for carcinogenicity in animal testing and a lack of data for carcinogenicity in human testing (IARC, 1991).

Reproductive and Developmental Toxicity

No data are available for the chemical.

Sodium hypochlorite and calcium chloride are reported to have no specific reproductive or developmental toxicity (NICNASa; NICNASb).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include local effects (corrosive effects on the skin, eyes, gastrointestinal and respiratory tracts).

Public Risk Characterisation

The chemical has uses in cosmetic and domestic products such as bleaching and anti-microbial agents within cleaning products; and as a disinfectant in water purification. However, it is expected to be present at low concentrations (refer to **Import, manufacture and use** section) in liquid products. The main route of public exposure is expected to be skin and eye contact and inhaling vapours (in contact with acids). Labelling for calcium hypochlorite formulations is controlled by the *Poisons Standard* (SUSMP, 2015). Provided that the appropriate precautions are taken to avoid skin and eye contact and inhaling vapours (in contact with acids), the risk from using domestic products is not considered to be unreasonable.

Occupational Risk Characterisation

During product formulation, oral, dermal, inhalation (in contact with acids) and ocular exposure 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 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.

Given the critical health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise oral, dermal, inhalation (in contact with acids) and ocular 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

Current risk management measures are considered adequate to protect public and workers' health and safety, provided that all requirements are met under workplace health and safety, and poisons legislation as adopted by the relevant state or territory. No further assessment is required.

Regulatory Control

Public Health

Products containing the chemical should be labelled in accordance with state and territory legislation (SUSMP, 2015).

Work Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted 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)* Contact with acids liberates toxic gas (R31)*	Harmful if swallowed - Cat. 4 (H302) Contact with acid liberates toxic gas (AUH031)
Irritation / Corrosivity	Causes burns (C; R34)*	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 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, inhalation and ocular 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 which 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;
- 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 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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