Salts of chloric acid: Human health tier II assessment

03 July 2015

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Chloric acid, potassium salt	3811-04-9
Chloric acid, sodium salt	7775-09-9
Chloric acid, ammonium salt	10192-29-7
Chloric acid, magnesium salt	10326-21-3
Chloric acid, barium salt	13477-00-4

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

The chemicals in this group are collectively known as the salts of chloric acid or inorganic chlorates. These chemicals are powerful oxidising agents used in several industrial, agricultural and pharmaceutical purposes. Chlorates are oxyhalogen compounds that are a combination of a metal or hydrogen cation and the ClO_3^- monovalent anion. These chemicals are not explosive themselves (apart from the ammonium salt), but form flammable or explosive mixtures with organic matter, powdered metals and ammonium compounds. Apart from barium, the cations in these compounds are of low hazard.

The toxic properties in all cases are expected to be mostly due to the chlorate ion and so very similar hazard profiles for human health are expected.

Import, Manufacture and Use

Australian

The following Australian industrial uses were reported under previous mandatory and/or voluntary calls for information.

Potassium chlorate (CAS No. 3811-04-9) and sodium chlorate (CAS No. 7775-09-9) have reported domestic use as bleaching agents.

These chemicals have reported commercial or site-limited uses as oxidising agents.

Ammonium chlorate (CAS No. 10192-29-7), magnesium chlorate (CAS No. 10326-21-3), and barium chlorate (CAS No. 13477-00-4) were not reported under previous mandatory and/or voluntary calls for information (NICNAS, 2013).

International

The following international uses have been identified through Galleria Chemica; the Substances and Preparations in Nordic countries (SPIN) database; the European Union (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) dossiers; 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 US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR); the US Environmental Protection Agency (EPA) Reregistration Eligibility Decision; the US National Library of Medicine's Hazardous Substances Data Bank (HSDB) and various assessments including Cosmetic Ingredient Review (CIR, 1995) and the Bureau of Naval Weapons Publication (Navord, 1960).

Potassium chlorate and sodium chlorate have reported cosmetic uses, including:

- in manufacturing toothpaste;
- in mouthwash;
- as an oxidising agent; and
- in deodorants.

Sodium chlorate has reported domestic use as an ingredient in household bleach.

The chemicals have reported commercial uses, including:

- for bleaching in the paper pulp industry;
- in manufacturing signal and parachute flares;
- as an oxidising agent in propellants;
- as primers;
- in fireworks; and
- in manufacturing matches.

The chemicals have reported site-limited uses, including:

- as oxygen source additives;
- in pyrotechnics including smoke grenades, bullets, gunpowder and pull-wire igniters;
- as corrosion inhibitors;
- in metal phosphating preparations;
- as bleaching agents;
- as oxidising agents for dyes and other organic compounds; and
- as rocket propellants.

The chemicals have reported non-industrial uses as:

- herbicides;
- defoliants;

- antiseptic agents; and
- weed killers.

Restrictions

Australian

The chemicals, potassium, sodium and magnesium chlorates are listed in the *Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) in Schedule 5 (SUSMP, 2015) with an exemption in preparations containing 10 % or less of these chemicals.

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).

Barium chlorate, as a barium salt, is listed in the *Poisons Standard* in Schedule 6 (SUSMP, 2015).

Schedule 6:

'Barium salts except:

(a) when included in Schedule 5;

(b) barium sulfate; or

(c) in paints or tinters containing 5 percent or less of barium calculated on the non-volatile content of the paint or tinter.'

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

Potassium and sodium chlorate are listed on the following (Galleria Chemica):

- EU Cosmetics Regulation 1223/2009 Annex III—List of substances prohibited in cosmetic products except subject to the restrictions laid down—these chemicals may be used in (a) toothpastes and (b) other products at a maximum concentration of (a) 5 % and (b) 3 % (CosIng);
- New Zealand Cosmetic Products Group Standard—Schedule 5: Components cosmetic products must not contain except subject to the restrictions and conditions laid down—these chemicals may be used in (a) toothpastes and (b) other products at a maximum concentration of (a) 5 % and (b) 3 %;
- Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient ‘Hotlist’); and
- Association of Southeast 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—these chemicals may be used in (a) toothpastes and (b) other products at a maximum concentration of (a) 5 % and (b) 3 %.

Magnesium chlorate is listed on Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient 'Hotlist').

Existing Worker Health and Safety Controls

Hazard Classification

Potassium chlorate and barium chlorate are classified as hazardous, with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

- Xn; R20/22 (acute toxicity)

Sodium chlorate is classified as hazardous, with the following risk phrase on HSIS:

- Xn; R22 (acute toxicity)

Ammonium and magnesium chlorates are not listed on HSIS.

Exposure Standards

Australian

Barium chlorate has an exposure standard of 0.5 mg/m^3 time weighted average (TWA).

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit of 5 mg/m^3 occupational exposure limit (OEL) for potassium, sodium and magnesium chlorates was reported in Latvia.

Temporary Emergency Exposure Limits (TEELs) defined by the US Department of Energy (DOE) for potassium chlorate are reported as:

- TEEL-1 = 2.3 mg/m^3;
- TEEL-2 = 25 mg/m^3; and
- TEEL-3 = 900 mg/m^3.

TEELs for sodium chlorate are reported as:

- TEEL-1 = 0.11 mg/m^3;
- TEEL-2 = 1.2 mg/m^3; and
- TEEL-3 = 32 mg/m^3.

An exposure limit of 0.4–0.5 mg/m^3 TWA and 0.5–4 mg/m^3 short-term exposure limit (STEL)/MAK/OEL in different countries such as Argentina, the USA (Alaska, Hawaii), Canada, Chile, Germany, Latvia, Egypt, Colombia and Switzerland.

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a threshold limit value (TLV) of 0.5 mg/m^3 for barium chlorate.

Health Hazard Information

Toxicokinetics

Chlorates are easily absorbed from the gastrointestinal tract in animals and in rats; 13 % of the administered dose is excreted in urine as chlorate, about 4 % as chlorite and 20 % as chloride (WHO, 2005; EPA, 2006).

In a toxicokinetics study in Sprague Dawley (SD) rats, two groups of male rats (four animals/group) were orally administered 5 mg/L of ^{36}Cl-potassium chlorate. For the first group, blood samples were collected by retro-orbital bleeding for up to 48 hours after dosing and the animals were euthanized after 72 hours. For the second group, the animals were placed in metabolism cages after dosing and samples of expired air, faeces and urine were measured for up to 72 hours following dosing. Peak blood concentration level for ^{36}Cl-potassium chlorate in the first group was reached 30 minutes after ingestion. The radiolabelled chlorate was eliminated from the blood in two phases, the rapid phase with a half-life of six hours and the slower phase with a half-life of 36.5 hours. The highest concentration of measured radioactivity following administration was in the plasma (approximately 2.0 ng/g) and the least radioactivity was in the bone marrow (less than 0.5 ng/g) (CIR, 1995; EPA, 2006; REACHb).

Acute Toxicity

Oral

Potassium chlorate, sodium chlorate, and barium chlorate are classified as hazardous with the risk phrase ‘Harmful if swallowed’ (Xn; R22) in the HSIS (Safe Work Australia). The data available support the classification for potassium chlorate and sodium chlorate. There is insufficient data to remove classification for barium chlorate. Ammonium chlorate and magnesium chlorate should be similarly classified for acute oral toxicity.

Based on the available data for potassium chlorate, the median lethal dose (LD50) for rats was reported to be 1870 mg/kg bw and the lowest oral lethal dose (LDLo) was reported to be 7000 mg/kg bw in rats, 2000 mg/kg bw in rabbits and 1200 mg/kg bw in dogs. The chemical has also been reported to produce renal tubular necrosis in animals following acute oral exposure (CIR, 1995; HSDB; REACHb).

In an acute toxicity study in dogs, a sodium chlorate dose of 1000 mg/kg bw resulted in severe methaemoglobinaemia and death of one animal that had pre-existing chronic interstitial nephritis. Reported clinical signs in euthanized animals included marked splenic congestion and moderately severe chronic interstitial nephritis. Results from another study included peak blood methaemoglobin levels, with intravenous injection of 0.5 mg/kg bw of sodium chlorate, that occurred one hour after the injection (EPA, 2006; HSDB; REACHa).

In another acute oral toxicity study in dogs, mortalities were reported at all doses of sodium chlorate tested, with the lowest dose being 600 mg/kg bw (WHO, 2005).

Dermal

Potassium chlorate and sodium chlorate have low acute toxicity based on results from animal tests following dermal exposure. The dermal LD50 in rabbits was >2000 mg/kg (HSDB).

Inhalation

Based on the available information, the chemicals have moderate acute inhalation toxicity warranting hazard classification.

Potassium chlorate and barium chlorate are classified as hazardous with the risk phrase ‘Harmful by inhalation’ (Xn; R20) in the HSIS (Safe Work Australia). The available data for sodium chlorate (median lethal concentration—LC50—5.59 mg/L) support this classification (EPA, 2006; HSDB). No further details were provided.

Observation in humans

Based on the available information from various reports, incidental acute exposure to

sodium chlorate in humans caused gastritis, haemolysis, methaemoglobinaemia, haemoglobinuria, late toxic nephritis and acute renal failure (EPA, 2006; HSDB).

There are various case reports on chlorate poisoning in humans. Based on the available data, the oral lethal dose of sodium chlorate in an adult human is estimated to be 230 mg of chlorate per kilogram of body weight (WHO, 2005; EPA, 2006; REACHa) and for potassium chlorates is estimated to be 5–30 g (CIR, 1995; HSDB; REACHb).

Corrosion / Irritation

Skin Irritation

The chemicals are reported to slightly irritate the skin in animal studies. The effects were not sufficient to warrant a hazard classification.

In a skin irritation study in rabbits, no irritation was reported with sodium chlorate (2000 mg/kg) after four-hour occlusive exposure. An occluded 24-hour contact with the chemical caused slight irritation (EPA, 2006; REACHa).

Eye Irritation

The chemicals are reported to be slightly irritating to eyes in animal studies. The effects were not sufficient to warrant a hazard classification.

Results from an acute eye irritation study showed sodium chlorate produced mild to moderate conjunctival irritation four hours after instillation into the rabbit eye. The effects were fully reversed in most of the animals 24 hours after exposure. No treatment-related effects were seen on either the cornea or iris of the animals (EPA, 2006; HSDB; REACHa).

Observation in humans

Humans exposed to solid potassium chloride in industrial settings have reported cases of dermal irritation and burns. Other reports mention inflammation and bleeding of the gums caused by potassium chlorate in toothpastes (CIR, 1995; HSDB; REACHb).

Sensitisation

Skin Sensitisation

Based on the limited available information, these chemicals were not found to induce dermal sensitisation. Sodium chlorate was reported to have no skin sensitisation potential in a test conducted in guinea pigs (EPA, 2006).

Repeated Dose Toxicity

Oral

Based on the available information from various repeated dose oral studies, these chemicals are not considered to cause serious damage to health by repeated oral exposure.

In another three-month oral gavage study in rats, SD rats (14 animals/sex/dose) were administered sodium chlorate at doses of 0, 10, 100 or 1000 mg/kg bw/day for up to three months. Clinical effects observed at the highest dose (1000 mg/kg bw/day) included anaemia with decreases in the erythrocyte count, haemoglobin concentration and haematocrit values. A no observed adverse effect level (NOAEL) of 100 mg/kg bw/day was reported (WHO, 2005; EPA, 2006; HSDB; REACHa).

In a four-month study in rats, male SD rats (four animals/dose) were administered with either 10 or 100 mg/L ClO_3^- in drinking water for 20 hours/day, seven days/week for four months. Both groups showed a significant decrease in blood glutathione concentrations after two months and decreased erythrocytic fragility. No NOAEL was reported (CIR, 1995; HSDB).

In a 90-day study in rats, SD rats (10/sex/dose) were treated with sodium chlorate at a dose of 30, 100 or 510 mg/kg bw/day for males and 42, 164 or 800 mg/kg bw/day for females in drinking water for 90 days. Effects observed included pituitary lesions (vacuolisation), thyroid gland colloid depletion, decreased body weights, organ weight changes and reduced erythrocyte counts and haemoglobin content. A NOAEL of 30 and 42 mg/kg bw/day was reported for males and females respectively. The lowest observed adverse effect level (LOAEL) was 100 mg/kg bw/day in males and 150 mg/kg bw/day in females (WHO, 2005; EPA, 2006; HSDB; REACHa).

In a three-month oral gavage study in beagle dogs (four animals/sex/dose), a slight elevation in the methaemoglobin level (within the normal limits) in the highest dose (360 mg/kg bw/day) group was observed (WHO, 2005; EPA, 2006; HSDB).

The renal effects reported in an acute toxicity study using potassium chlorate were not seen in the repeat dose toxicity (CIR, 1995; HSDB).

Dermal

Based on the physicochemical properties of the chemicals in this group, their ionic nature and their high water solubility, dermal toxicity from repeated exposure is not expected.

Inhalation

No data are available.

Observation in humans

Volunteers were administered 5 mg/L (36 µg/kg) of sodium chlorate in 0.5 litres of water per day for 12 weeks. Observations were made for eight weeks. No significant changes were reported. A NOAEL of 36 µg/kg bw/day was reported (WHO, 2005; Health Canada, 2008; REACHa).

Genotoxicity

Based on the data available, the chemicals in this group are not considered to be genotoxic.

Negative results were reported for sodium chlorate in various in vitro point mutation assays (Ames test) in *Salmonella typhimurium* strains TA97, 98, 100, 102 and 1535, with or without metabolic activation (CIR, 1995; WHO, 2005; EPA, 2006; HSDB; REACHa).

Negative results were observed for potassium chlorate and sodium chlorate in several other in vitro assays on the chemicals (CIR, 1995; WHO, 2005; EPA, 2006; HSDB):

- gene mutation in human lymphocytes and Chinese hamster lung cells;
- chromosomal aberration in Chinese hamster ovary cells;
- sister chromatid exchange in V79 Chinese hamster cells and human lymphocytes; and

- DNA damage in HeLa cells.

No in vivo data are available.

Carcinogenicity

Based on the available information, the chemicals are not carcinogenic.

In a carcinogenicity study, sodium chlorate and potassium chlorate were tested for promoting renal tumours in N-ethyl-N-hydroxyethylnitrosamine-initiated Fischer 344 (F344) rats. A non significant increase in the number of renal tumours was observed with sodium chlorate. No treatment-related effect was seen with potassium chlorate (CIR, 1995; WHO, 2005; EPA, 2006; Health Canada, 2008; HSDB; REACHa; REACHb).

In a two-year carcinogenicity study, the potential of sodium chlorate to induce thyroid tumours was tested on rats and mice. An imbalance of thyroid hormones (reduced T3 and T4 and elevated TSH) was observed, but these effects were reported as not likely to be relevant in humans (CIR, 1995; WHO, 2005; EPA, 2006; Health Canada, 2008; HSDB).

Reproductive and Developmental Toxicity

Reproductive and developmental toxicity were not observed for this group of chemicals. Results from a reproductive and developmental toxicity study on pregnant Charles River (CD) rats showed no treatment-related effects. No maternal or foetal toxicity was seen at doses up to 1000 mg/kg bw in rats (WHO, 2005; EPA, 2006; RTECS, 2006; Health Canada, 2008; HSDB).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include acute toxicity from oral and inhalation exposure.

Public Risk Characterisation

The general public could be exposed through the skin or inhalation when using domestic products containing the chemicals. However, based on limited US information derived from the National Library of Medicine (NLM) Household Products Database, the concentration in these products is not considered to be sufficiently high to cause acutely toxic effects. Therefore, the risk to public health is not considered to be unreasonable and further risk management is not considered necessary for public safety.

Occupational Risk Characterisation

During product formulation, oral, dermal and inhalation exposure may occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemicals at lower concentrations could also occur while using formulated products containing the chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

NICNAS Recommendation

Assessment of these chemical are 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, 2015).

Work Health and Safety

The chemicals are 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.

The hazard classification 'Harmful by inhalation' (Xn; R20) is current for potassium chlorate and barium chlorate. The same hazard classification is recommended for the other salts of chloric acid.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Harmful if swallowed (Xn; R22) Harmful by inhalation (Xn; R20)	Harmful if swallowed - Cat. 4 (H302) Harmful if inhaled - Cat. 4 (H332)

[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 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 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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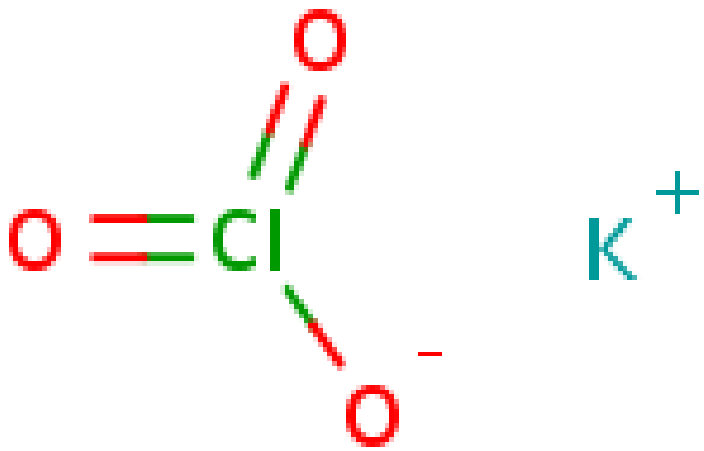
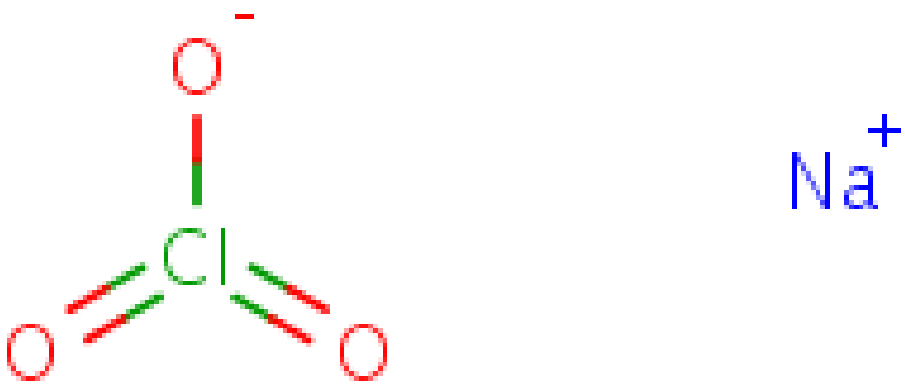
Last Update 03 July 2015

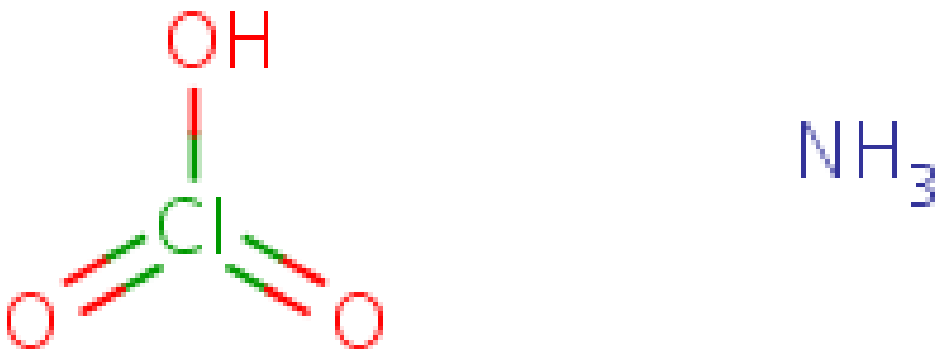
Chemical Identities

Chemical Name in the Inventory and Synonyms	**Chloric acid, potassium salt** potassium chlorate Anforstan Berthollet salt salt of tarter
CAS Number	3811-04-9
Structural Formula	
Molecular Formula	ClHO3.K
Molecular Weight	122.5

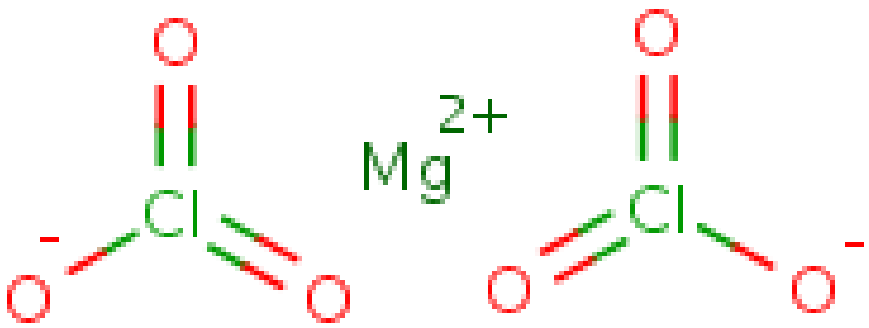
Chemical Name in the	**Chloric acid, sodium salt**

Inventory and Synonyms	sodium chlorate Agrosan Travex Weed-killer
CAS Number	7775-09-9
Structural Formula	
Molecular Formula	ClHO3.Na
Molecular Weight	106.4

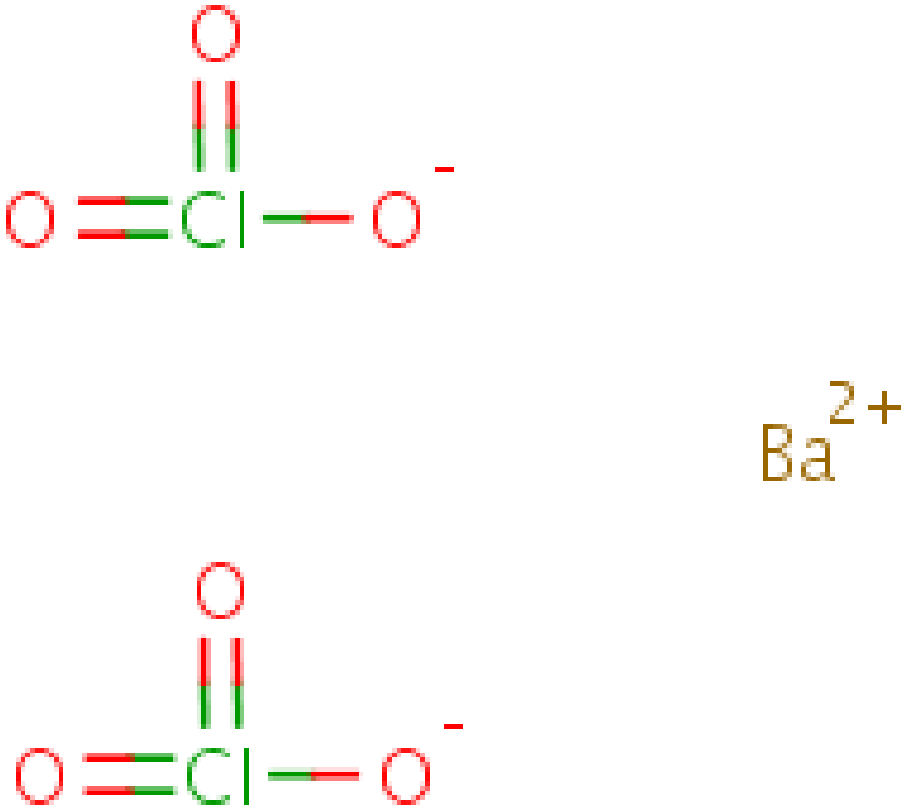
Chemical Name in the Inventory and Synonyms	**Chloric acid, ammonium salt** ammonium chlorate
CAS Number	10192-29-7
Structural Formula	

	
Molecular Formula	ClHO3.H3N
Molecular Weight	101.4

Chemical Name in the Inventory and Synonyms	**Chloric acid, magnesium salt** magnesium chlorate Magron MC Defoliant
CAS Number	10326-21-3
Structural Formula	

	
Molecular Formula	ClHO3.1/2Mg
Molecular Weight	191-2

Chemical Name in the Inventory and Synonyms	**Chloric acid, barium salt** barium chlorate barium chlorate monohydrate
CAS Number	13477-00-4
Structural Formula	

	
Molecular Formula	Ba.2ClHO3
Molecular Weight	304.2

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