PRVD2008-09

Proposed Re-evaluation Decision

Sodium Chlorate and Sodium Chlorite

(publié aussi en français)

6 February 2008

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

ISBN: 978-0-662-47904-8 (978-0-662-47905-5)
Catalogue number: H113-27/2008-9E (H113-27/2008-9E-PDF)

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the industrial antimicrobial agents, sodium chlorate and sodium chlorite, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing sodium chlorate and sodium chlorite in Canada.

An evaluation of available scientific information found that products containing sodium chlorate and sodium chlorite do not present unacceptable risks to human health or the environment when used according to label directions. No additional data are being requested at this time.

This proposal affects all end-use products containing sodium chlorate and sodium chlorite registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for sodium chlorate and sodium chlorite and presents the reasons for the proposed re-evaluation decision. No additional risk-reduction measures to further protect human health and the environment are proposed at this time.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of sodium chlorate and sodium chlorite.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

Sodium chlorate and sodium chlorite, two of the active ingredients in the current re-evaluation cycle, have been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses sodium chlorate and sodium chlorite formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in two 2006 REDs, the USEPA concluded that sodium chlorate and sodium chlorite were eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in these REDs were an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Are Sodium Chlorate and Sodium Chlorite?

Sodium chlorate and sodium chlorite are precursors for the generation of chlorine dioxide in closed system generators. Chlorine dioxide controls slime-forming organisms in pulp and paper process waters, and in the waters of recirculating cooling towers. Factory workers may be exposed to sodium chlorite or sodium chlorate when loading these precursor chemicals into the generator for the production of chlorine dioxide.

Health Considerations

Can Approved Uses of Sodium Chlorate and Sodium Chlorite Affect Human Health?

Sodium chlorate and sodium chlorite are unlikely to affect your health when used according to label directions.

In Canada, workers could be exposed to sodium chlorate and sodium chlorite by loading these precursor chemicals into closed chlorine dioxide generators. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are

established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that sodium chlorate and sodium chlorite were unlikely to affect human health when used according to label directions. These conclusions apply to the Canadian situation.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Sodium chlorate and sodium chlorite are not currently registered in Canada for use as a pesticide on any food/feed crops but could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for sodium chlorate and sodium chlorite in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Sodium Chlorate and Sodium Chlorite Are Introduced Into the Environment?

Sodium chlorate and sodium chlorite are unlikely to affect non-target organisms when used according to label directions.

In Canada, sodium chlorite and sodium chlorate are used to generate chlorine dioxide in industrial process waters. Aquatic organisms could potentially be exposed to residues (chlorite ion) of these pesticides in the effluent if it is discharged. However, the process waters or effluent must not be released into the environment without the appropriate permits. Current Canadian labels require the treatment of effluent prior to discharge. Environmental exposure is not expected from the registered use of either sodium chlorate or sodium chlorite when used according to label directions.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of sodium chlorate and sodium chlorite, the PMRA is not proposing further risk-reduction measures for product labels.

Next Steps

Before making a final re-evaluation decision on sodium chlorate and sodium chlorite, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Sodium chlorate and sodium chlorite are slimicides registered in Canada to control slime-forming organisms in pulp and paper process waters; sodium chlorite is also used to control microbes in the waters of recirculating cooling towers. This is achieved through the generation of chlorine dioxide in closed system chlorine dioxide generators.

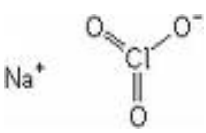
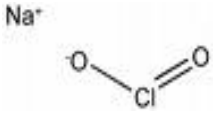
Following the re-evaluation announcement for sodium chlorate and sodium chlorite, the registrants of the technical grade sodium chlorate and sodium chlorite in Canada indicated that they intended to provide continued support for all uses included on the labels of commercial end-use products in Canada.

The PMRA used recent assessments of sodium chlorate and sodium chlorite from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) documents for sodium chlorate and sodium chlorite, dated July 2006 and August 2006 respectively, as well as other information on their regulatory status in the United States, can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredients, Their Properties and Uses

2.1 Identity of the Technical Grade Active Ingredients

Common name		Sodium chlorate	Sodium chlorite
Function		Slimicide	Slimicide
Chemical family		Sodium salt	Sodium salt
Chemical name			
1	**International Union of Pure and Applied Chemistry (IUPAC)**	Sodium chlorate	Sodium chlorite
2	**Chemistry Abstracts Service (CAS)**	Sodium chlorate	Sodium chlorite
CAS Registry Number		7775-09-9	7758-19-2
Molecular formula		$NaClO_3$	$NaClO_2$

Structural formula		
Molecular weight	106.4 amu	90.44 amu
Purity of the technical grade active ingredient	25141: 99.9 NS (limits: 99.5–99.95) 25859: 99.7 NS (limits: 99.5–100)	80.0% NS (limits: 77.5–82.5%)
Registration Number	25141, 25859	25361

Based on the manufacturing process, the products are not expected to contain impurities of human health or environmental concern as identified in Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, Section 2.13.4, or Toxic Substances Management Policy (TSMP) Track 1 substances as identified in Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Appendix II.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredients

Property	Result for Sodium Chlorate	Result for Sodium Chlorite
Vapour pressure	Not applicable, the product is an ionic compound	Not applicable
UV–visible spectrum	Not required in the absence of UV chromophores	Not provided λ max (in water) = 261 nm
Solubility in water	790 g/L at 0°C 2300 g/L at 100°C	370 g/L
***n*-Octanol–water partition coefficient**	Not required for an inorganic salt (estimated to be -7.08 in RED)	Not applicable (reported as "low" in RED)
Dissociation constant	Not applicable, an inorganic salt that completely dissociates in water	pKa = 2.44 (at 20°C)

2.3 Comparison of Use Patterns in Canada and the United States

Sodium chlorate and sodium chlorite are slimicides registered in Canada to control slime-forming organisms in pulp and paper process waters; sodium chlorite is also used to control microbes in the waters of recirculating cooling towers. This is achieved through the generation of chlorine dioxide in closed system chlorine dioxide generators.

In Canada, there are two registered technical grade active ingredients for both sodium chlorate and sodium chlorite. The end-use products are for commercial use only and are formulated as solutions and solids (soluble granules, dust or powder). End-use products are metered from totes or bulk containers for reaction within the chlorine dioxide generator. The reaction of precursor chemicals in the closed generators produces an aqueous solution of chlorine dioxide, which is then delivered below the surface of the process water, far enough to prevent release of chlorine dioxide into the air. The Canadian labels indicate specific equipment for use with the products.

The American and Canadian use patterns were compared for both sodium chlorate and sodium chlorite and were found to be more extensive in the U.S. than in Canada. In addition to the slimicide uses in industrial process waters, the U.S. use pattern includes the following: herbicide/defoliant use on various food and non-food crops; hard surface and air disinfection (agricultural/ institutional and residential); drinking water treatment; food process water treatment (poultry and vegetable packing plants); vegetable storage; swimming pools/spas as well as preservative uses (pulp and paper, metalworking fluids, etc.). Therefore, based on the formulation types, use sites, guarantees, application methods and application rates for sodium chlorate and sodium chlorite, it was concluded that the USEPA REDs for sodium chlorate and sodium chlorite are an adequate basis for the re-evaluation of Canadian uses of these actives.

All current uses are being supported by the registrants and were therefore considered in the re-evaluation of sodium chlorate and sodium chlorite. Appendix I lists all sodium chlorate and sodium chlorite products that are registered under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In the 2006 REDs, the USEPA concluded that the end-use products formulated with sodium chlorate and sodium chlorite met the safety standard under the American *Food Quality Protection Act* (FQPA) and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended product labels.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to the effects of a chemical than the most sensitive animal species.

In Canada, exposure to sodium chlorate and sodium chlorite may occur while loading the chemicals into the generators. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

The USEPA's toxicological endpoints for assessing risk from occupational exposure are summarized in Appendix II.

The USEPA considered the risk from potential exposure to handlers during application and postapplication of sodium chlorite and sodium chlorate products.

Workers can be exposed to sodium chlorate and sodium chlorite when mixing, loading or when applying the pesticides and when entering a treated site to conduct activities such as scouting and/or handling of crops treated with sodium chlorate.

3.1.1.1 Mixer/Loader/Applicator Exposure and Risk

Sodium Chlorate

A screening-level assessment was used to determine the risk to handlers from loading the largest commercially available chlorine dioxide generator to full capacity. The chlorine dioxide generator is a closed system with precursor chemicals piped in from storage tanks for reaction within the generator. Surrogate data for industrial process fluids was used to estimate the exposure to sodium chlorate used in chlorine dioxide generation in pulp and paper mills. As the end-use product is pump metered, exposure (short- and intermediate-term) during handling of the sodium chlorate was only expected when changing the couplers of the sodium chlorate containers.

No dermal toxicological endpoints of concern were identified; thus, dermal exposure was not estimated. An inhalation NOAEL of 30 mg/kg/day from a sub-chronic rat study was selected by the USEPA for both short- and intermediate-term exposure. Exposures were estimated for the maximum amount of sodium chlorate potentially handled, determined by the largest chlorine dioxide generator manufactured for antimicrobial use, i.e. 2721.5 kg chlorine dioxide generated per day from 4354.5 kg sodium chlorate. The USEPA calculated an inhalation MOE of 800 (target = 100). It concluded the occupational risk to handlers exposed to sodium chlorate was below the level of concern.

Handler exposure to the aqueous solution of chlorine dioxide or off-gassing of chlorine dioxide during application is not expected because a closed system is utilized.

The USEPA's occupational mix and loading assessment of short- and intermediate-term inhalation exposure to sodium chlorate's use in industrial process fluids is relevant to the Canadian situation. In Canada, use information indicates that chlorine dioxide generators have a capacity of up to 1134 kg chlorine dioxide generated per day, which is encompassed by the U.S. assessment of the largest (2721.5 kg capacity) generators.

Sodium Chlorite

The RED for chlorine dioxide and sodium chlorite assessed several scenarios associated with the occupational exposure to sodium chlorate, sodium chlorite and chlorine dioxide. The USEPA considered these scenarios representative of high-end exposures for the industrial applications. Of the several scenarios the USEPA assessed, the dermal risk associated with the application of sodium chlorite to industrial process waters and water systems (pulp and paper white water systems and recirculating cooling towers) was most relevant to the Canadian situation. The risk assessment of inhalation exposures, however, considered the exposure to chlorine dioxide as the worst case scenario, and this is not relevant to the Canadian situation since exposure to the aqueous solution of chlorine dioxide or release of chlorine dioxide during application is not expected because a closed system is utilized.

Based on a dermal endpoint from a rat study for chlorine dioxide of 3 mg/kg bw/day and surrogate data for unit exposure (0.0138 mg/kg a.i.) from both an antimicrobial study and the Pesticide Handlers Exposure Database (PHED), dermal risk to the occupational handler in pulp and paper settings was determined. For short- and intermediate-term exposures, the MOE for gloved handlers pump metering sodium chlorite to industrial process waters was 2300, well above the target of 100.

The assessment of dermal risks to mixers/loaders, from sodium chlorite use in chlorine dioxide generators used to treat industrial process waters is relevant and encompasses the Canadian situation.

The assessment of inhalation exposure conducted by the U.S. was conservative for estimating potential risks to Canadian workers using sodium chlorate/chlorite in industrial process waters. Short- or intermediate-term inhalation exposure to sodium chlorite in the Canadian scenario would potentially only occur from the changing of tote container couplings. Risks are expected to be negligible and therefore not of concern. Exposure to chlorine dioxide during mixing and loading would not be expected as the generator is a closed system.

3.1.1.2 Postapplication Exposure and Risk

Postapplication exposure (dermal or inhalation) to sodium chlorite and sodium chlorate is not expected from slimicide use in industrial process waters as these chemicals react in a closed system to produce chlorine dioxide. In Canada, the postapplication exposure to chlorine dioxide in the workplace environment is not expected to pose an unacceptable risk (dermal or inhalation) based on the method of application and use site. Closed generators apply aqueous chlorine

dioxide well below the surface of industrial process waters to prevent the release of chlorine dioxide into the workplace atmosphere

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

There are no residential uses of sodium chlorate and sodium chlorite in Canada; therefore, residential exposure is not expected based on the current use pattern.

3.1.2.2 Exposure From Food and Drinking Water

Chronic dietary risk is estimated by determining how much of a pesticide residue may be ingested with the daily diet and comparing this potential exposure to an acceptable daily intake, which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. The acceptable daily intake is referred to as the ADI in Canada, and, in the RED, it is expressed as the chronic population adjusted dose (cPAD). The acceptable daily intake is based on a relevant endpoint from toxicology studies and on safety factors protective of the most sensitive subpopulation (see Appendix II).

Many of the uses of sodium chlorite and sodium chlorate assessed by the USEPA for potential dietary exposure are either not registered uses in Canada (e.g. herbicidal/defoliant uses on food crops, bacterial control on mushrooms) or are not regulated under the *Pest Control Products Act* (e.g. sanitizer use on fruit, vegetables and eggs, uses in meat and poultry processing and in pecan cracking/dyeing waters, treatment of drinking water). Only the slimicide use in pulp and paper process waters was of relevance to this re-evaluation of products regulated under the *Pest Control Products Act*.

The use of sodium chlorite/chlorine dioxide in process waters for production of paper may result in indirect exposure to chlorite residues when food is packaged in the paper. Dietary risks resulting from this exposure were determined to represent 0.33% of the cPAD for adults and 0.77% for children. The cumulative risk from all pulp and paper uses (aqueous mineral/slurries, paper adhesive and coating preservative) was 5.13% of the cPAD for adults and 11.83% of the cPAD for children. These risks did not present a concern to the USEPA.

There are no direct food contact uses regulated under the *Pest Control Products Act* associated with sodium chlorite or sodium chlorate that would result in dietary exposure to Canadians. As well, exposure to the Canadian population through drinking water from uses regulated under the *Pest Control Products Act* is not expected. The registered use in the process waters of pulp and paper mills could potentially result in residues from paper or paper board that may contact food. This indirect food use was approved by the Food Directorate of Health Canada and both active ingredients have received letters of no objection for use in manufacture of paper or paper board that may contact food.

The RED addressed the risks from sodium chlorate and sodium chlorite use in paper production. The conclusions are relevant as they not only address the indirect dietary risks from paper manufactured in Canada but also the risks from paper or paper board that is imported into Canada for packaging food. Thus, dietary exposure to chlorate/chlorite ion residues from food packaged in such paper is not of concern in Canada.

3.1.2.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to sodium chlorate, sodium chlorite and chlorine dioxide from sodium chlorate or sodium chlorite (i.e. from food, water and residential exposures). Acute and chronic aggregate risk assessments are comprised of contributions from food and drinking water exposures. Short-term and intermediate aggregate risk assessments are comprised of contributions from food, drinking water and non-occupational exposure (dermal, inhalation).

Exposure to residues of sodium chlorate/chlorite are not expected from either drinking water or to homeowners from products regulated under the *Pest Control Products Act*, based on the current use pattern. Therefore, the assessment of aggregate risks was not relevant to the Canadian situation and is not discussed here.

3.1.3 Cumulative Effects

The USEPA has not determined whether sodium chlorate and sodium chlorite have a common mechanism of toxicity with other substances or whether they share a toxic metabolite produced by other substances. Therefore, it was assumed that sodium chlorate and sodium chlorite do not share a common mechanism of toxicity with other substances, and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Environmental Risk Assessment

The USEPA assessed chlorine dioxide and sodium chlorite together because chlorine dioxide can be produced in the environment from sodium chlorite (or sodium chlorate). In addition, chlorite ion is a degradation product of chlorine dioxide. Chlorine dioxide has a short half-life and in the presence of sunlight, breaks down into chloride and chlorate ions (between pH 4 and 7). At pH lower than 4, degradation products were chlorite and chlorate ions. Chlorite is the dominant degradation product. Sodium chlorite dissolves in water, breaking down into chloride and chlorate ions under similar conditions as chlorine dioxide. Chemical degradation of sodium chlorite commonly occurs in water as well as in the presence of suspended soil particles containing ions, like Fe(II), Mn(II), I^- and S^{-2}. The final breakdown products are chloride and oxygen. These are the same products of thermal degradation.

To assess the ecological risk of sodium chlorate, sodium chlorite and chlorine dioxide to both terrestrial and aquatic non-target plants and animals, the USEPA calculated risk quotients (RQs) based on appropriate toxicity endpoints and expected environmental concentrations (EECs). The resulting RQs were compared to corresponding levels of concern (LOCs).

The USEPA assessment of the cooling water tower use of chlorine dioxide estimated the concentrations in the receiving waters from once-through use. In Canada, cooling water treated with chlorine dioxide is re-circulated and not discharged as in the once-through use. This assessment represents a conservative estimate of risk for the Canadian scenario.

The discharge of wastewater or effluent from industrial processes is regulated by the *Fisheries Act*. Provincial permits are required for the disposal of wastewater and this means that discharge must be treated such that levels of chemicals in the effluent would not pose an unacceptable risk to the environment.

The ENVIRONMENTAL HAZARD section of all sodium chlorate and sodium chlorite end-use products currently indicate the following:

"This product is highly toxic to aquatic invertebrates and moderately toxic to waterfowl. Do not contaminate lakes, ponds, rivers streams, estuaries or oceans, by direct application, cleaning of equipment or disposal of wastes. Do not discharge effluent that has been treated with chlorine dioxide generated by this product into these waters, unless the effluent has been detoxified by suitable means such as waste treatment. Open dumping is prohibited."

In Canada, sodium chlorite, sodium chlorate and chlorine dioxide are not expected to enter the environment based on their use pattern.

Ecological exposure and risk

Exposure to the environment is not expected from the registered use of sodium chlorate and sodium chlorite in Canada. As such, the ecological exposure and risk assessment conducted by the USEPA is a worst case scenario and overestimates the potential for environmental exposure for the Canadian situation. Details of the assessment will not be discussed; instead, the hazard characterization is presented here.

Terrestrial species

Birds and Mammals

For terrestrial animals, the results of studies showed that the toxicity of chlorine dioxide/sodium chlorite to birds ranged from highly toxic to slightly toxic to birds on an acute oral basis, and from slightly toxic to practically non-toxic on a subacute dietary basis. Sodium chlorate showed no signs of mortality or toxicity in avian subacute and acute studies.

Terrestrial and Semi-Aquatic Plants

For terrestrial plants, results of toxicity tests showed that chlorine dioxide and sodium chlorite are moderately toxic to terrestrial plants. Chlorate is a non-selective herbicide. Risks to plants were presumed to non-target plants. However, the EPA required data to address this uncertainty.

Aquatic species

Freshwater and Marine/Estuarine Fish and Invertebrates

For freshwater aquatic animals, the results indicated that for chlorine dioxide and sodium chlorite, toxicity to freshwater fish ranged from slightly toxic to practically non-toxic on an acute basis. For aquatic invertebrates, the studies indicate that chlorine dioxide and sodium chlorite range from very highly toxic for the technical grade sodium chlorite to practically non-toxic for the formulated product on an acute basis. Results of the toxicity studies indicated that chlorine dioxide and sodium chlorite were slightly toxic to estuarine/marine fish on an acute basis and ranged from highly toxic to slightly toxic to estuarine/marine invertebrates on an acute basis. No chronic data were available to the USEPA to assess chronic risk to marine/estuarine organisms from chlorine dioxide/sodium chlorite.

Aquatic Plants

For aquatic plants, toxicity study results indicated chlorine dioxide and sodium chlorite were moderately toxic to aquatic plants.

Overall conclusions and mitigation measures

Acute risk to mammals from the use of chlorine dioxide and sodium chlorite products was not expected due to low exposure and toxicity. For aquatic organisms, acute risk was anticipated from the use of chlorine dioxide in once-through cooling towers based on the modelled results. However, the USEPA did not require any additional mitigation measures to specifically address the risk to the environment. The environmental risk assessment was conducted using sodium chlorite endpoints because, under environmental conditions, chlorine dioxide converts mostly to chlorite ions.

As environmental exposure is not expected from the labelled use of Canadian products containing sodium chlorite or sodium chlorate, no further mitigation measures are required by the PMRA.

3.2.2 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1995 federal Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

The federal Toxic Substances Management Policy and PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of sodium chlorate and sodium chlorite. The PMRA has reached the following conclusions:

- Sodium chlorite or sodium chlorate are not expected to bioaccumulate. The *n*-octanol–water partition coefficient (log K_{ow}) for sodium chlorite is -7.17 and for sodium chlorate was reported as "low," which are below the TSMP Track 1 cut-off criterion of $\geq$5.0.
- Sodium chlorite and sodium chlorate were not found to be persistent. Aerobic soil half-lives were not reported in either RED but are expected to be below the TSMP Track 1 criterion of 180 days.
- Sodium chlorate and sodium chlorite do not meet any Track 1 criteria; thus, they are not candidates for Track 1 classification.
- Based on a review of the available chemistry information (see Section 2.1), the technical products are not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04, or TSMP Track 1 substances as identified in Regulatory Directive DIR99-03, Appendix II.

No other impurities of toxicological concern as identified in Regulatory Directive DIR98-04, Section 2.13.4, or TSMP Track 1 substances as identified in Regulatory Directive DIR99-03, Appendix II, are expected to be present in the technical products of sodium chlorite or sodium chlorate.

Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document,* published on 31 May 2006.

4.0 OECD Status of Sodium Chlorate and Sodium Chlorite

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which includes 30 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Current available information on the status of sodium chlorate in other OECD member countries indicates that its use as a herbicide has been assessed in Sweden and Norway. It has been prohibited since 1990 in Sweden due to "high mobility in the soil," and since 1992 in Norway because of "mobility, water solubility and risk of pollution." Notification of this action was published in Prior Informed Consent (PIC) circular X, 1999.[3]

The use of sodium chlorate as a herbicide is not registered in Canada. Based on the registered use pattern of industrial process waters, environmental exposure to sodium chlorate is not expected. Therefore, the concerns identified in the OECD relating to the environmental properties of the active ingredient were not of relevance to the re-evaluation of sodium chlorate in Canada.

Based on the current available information, sodium chlorite has not been prohibited for use in any of the OECD member states.

5.0 Proposed Re-evaluation Decision

The PMRA has determined that sodium chlorate and sodium chlorite are acceptable for continued registration without any further risk-reduction measures. No additional data are being requested at this time.

6.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03 and DACO tables, can be found on our website at www.pmra-arla.gc.ca. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra_infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics. The USEPA RED documents for sodium chlorate and sodium chlorite are available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

Information regarding regulations and Letters of No Objection for food packaging materials is available through Health Canada's website at www.hc-sc.gc.ca/fn-an/securit/packag-emball/index_e.html.

Information on the OECD status of sodium chlorate and sodium chlorite can be found at www.pic.int/home.php?type=t&id=5&sid=16.

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[3] PIC circulars are published by the Rotterdam Convention Secretariat. Under this Convention, parties to the Convention have committed to inform other parties about legislative bans or severe restrictions on the use of chemicals and to notify recipient countries of any exports of regulated substances. This procedure is called Prior Informed Consent (PIC). When a party has adopted a final regulatory action to ban or severely restrict a chemical, the party notifies the Rotterdam Convention Secretariat; notifications are published in PIC circulars.

List of Abbreviations

µg	microgram(s)
ADI	acceptable daily intake
a.i.	active ingredient
aPAD	acute population adjusted dose
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
atm	atmosphere(s)
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetre(s)
cPAD	chronic population adjusted dose
cRfD	chronic reference dose
CSFII	Continuing Survey of Food Intakes by Individuals
DEEM	Dietary Exposure Evaluation Model
DT_{50}	dissipation time to 50%
EEC	expected environmental concentration [also estimated environmental concentration]
FQPA	*Food Quality Protection Act*
g	gram(s)
ha	hectare(s)
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LOAEC	lowest observed adverse effect concentration
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOD	limit of detection
LOEC	lowest observed effect concentration
LOEL	lowest observed effect level
m	metre(s)
m^3	metre(s) cubed
mg	milligram(s)
mm	millimetre(s)
mm Hg	millimetre mercury
MOE	margin of exposure
MRL	maximum residue limit
nm	nanometre(s)
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration

NOEL	no observed effect level
NS	nominal by specifications
OECD	Organisation for Economic Co-operation and Development
PCPA	*Pest Control Products Act*
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PIC	Prior Informed Consent
pKa	-log10 acid dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
RfD	reference dose
RVD	Re-evaluation Decision
RQ	risk quotient
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Registered Products Containing Sodium Chlorate and Sodium Chlorite as of 1 September 2007

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
SODIUM CHLORATE					
25141	Technical	ERCO Worldwide, a Division of Superior Plus LP	Technical Sodium Chlorate (Solid)	Solid	99.9%
25143	Commercial	ERCO Worldwide, a Division of Superior Plus LP	Ercocide CP (Solid)	Solid	99.99%
25632	Commercial	Drew Ashland Canada	Drew 3025 Biocide	Solution	25%
25800	Commercial	ERCO Worldwide, a Division of Superior Plus LP	Ercocide SP (Liquid) for Microorganism control	Solution	45%
25859	Technical	Canexus Chemicals Canada LP	Sodium Chlorate Crystal	Soluble granules	99.7%
SODIUM CHLORITE					
24801	Manufacturing Concentrate	ERCO Worldwide, a Division of Superior Plus LP	Sodium Chlorite Solution 37	Solution	37%
24802	Commercial	ERCO Worldwide, a Division of Superior Plus LP	Sodium Chlorite Solution 25	Solution	25.2%
24807	Commercial	Drew Ashland Canada	Drewchlor 4107	Solution	25%
24808	Commercial	Drew Ashland Canada	Drewchlor 7107	Solution	25%
25258	Commercial	Buckman Laboratories of Canada Ltd.	Busan 1367 Liquid Microbicide	Solution	25%
25361	Technical	Occidental Chemical Corporation	Technical Sodium Chlorite	Soluble granules	80%
26203	Commercial	Occidental Chemical Corporation	Sodium Chlorite Solution 31.25	Solution	25%
26534	Technical	S.C. Johnson and Son Ltd.	Sodium Chlorite Powder 80%	Dust or powder	80%
27052	Manufacturing Concentrate	S.C. Johnson and Son Ltd.	Aseptrol Dry Carpet Sanitizer 17-1	Dust or powder	1%
27053	Manufacturing Concentrate	S.C. Johnson and Son Ltd.	DP 7.02 Manufacturing Concentrate	Dust or powder	2%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
27361	Commercial	Klenzoid Co. Ltd.	React 8	Solution	25%
27601	Commercial	Nalco Canada Company	Nalco HYG-25	Solution	25%
28510	Commercial	Hercules Canada Inc.	Spectrum XD7900 Microbicide	Solution	25.2%
28674	Commercial	Johnsondiversey Canada Inc.	Closure Central PM	Solution	25%

Appendix II Toxicological Endpoints for Sodium Chlorate and Sodium Chlorite Health Risk Assessments

Exposure Scenario (route and period of exposure)	Dose (mg/kg bw/day)	Study	Target UF/SF or MOE or Q_1* [a]
SODIUM CHLORITE			
Short- and intermediate-term inhalation	NOAEL = 30 mg/kg/day	Rat reproductive	100
Short- and intermediate-term incidental oral	NOAEL = 30 mg/kg/day oral	Rat sub-chronic study.	100
Chronic dietary	BMDL = 0.9 mg/kg/day cRfD = 0.03 mg/kg/day	Rat chronic study	UF = 30 (3× interspecies and 10× intraspecies
	cPAD = 0.03 mg/kg/day (i.e. acceptable daily intake)		
SODIUM CHLORATE			
Short- and intermediate-term inhalation	NOAEL = 0.28 mg/m^3	Inhalation toxicity studies in the rat	100
Short- and intermediate-term incidental oral	Oral NOAEL = 3 mg/kg/day	Two-generation reproductive toxicity study in the rat	100
Chronic dietary	Oral NOAEL = 3 mg/kg/day	Rat chronic study	100
	cPAD = 0.03 mg/kg/day (i.e. acceptable daily intake)		

[a] UF/SF refers to total of uncertainty and/or safety factors for dietary assessments. MOE refers to desired margin of exposure for occupational or residential assessments. Q_1* refers to cancer potency factor. BMDL refers to a benchmark dose analysis.