Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2004-42

Re-evaluation of Sodium and Calcium Hypochlorite

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of sodium and calcium hypochlorite. The PMRA has determined that sodium and calcium hypochlorite are acceptable for continued registration provided that the proposed mitigation measures are adopted. Additional data requirements are identified. Upon finalization of the re-evaluation decision, the PMRA will provide registrants of products containing sodium or calcium hypochlorite with specific direction on how to address these measures and requirements.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for sodium and calcium hypochlorite. 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 the Publications Coordinator at the address below.

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1.0 Background

The PMRA is re-evaluating all pesticides, both active ingredients and formulated end-use products (EPs), that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Sodium and calcium hypochlorite have been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. Under Program 1, the PMRA relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents, to assess Canadian pest control products. For products to be re-evaluated under Program 1, there must exist a suitable foreign review that meets the following conditions:

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

Based on the outcome of foreign reviews, the PMRA will propose, under Program 1, a regulatory decision and appropriate mitigation measures for Canadian uses of an active ingredient.

The USEPA conducted a re-evaluation of sodium and calcium hypochlorite and concluded that, on the basis of health and environmental risk assessments, they were eligible for reregistration with the implementation of mitigation measures. These conclusions were published in a 1992 RED document for sodium and calcium hypochlorite. In its re-evaluation of sodium and calcium hypochlorite, the PMRA based its conclusions on this 1992 RED document, taking into account the Canadian use pattern and Canadian issues (e.g., the federal Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products was also conducted.

2.0 Re-evaluation of Sodium and Calcium Hypochlorite

Active substance:	Sodium hypochlorite	Calcium hypochlorite
Common name:	Sodium hypochlorite	Calcium hypochlorite
Chemical name:		
IUPAC:	Sodium hypochlorite	Calcium hypochlorite
CAS:	Hypochlorous acid, sodium salt	Hypochlorous acid, calcium salt
CAS number:	7681-52-9	7778-54-3

In Canada, sodium and calcium hypochlorite were first registered in 1973 and 1940, respectively. According to current EP labels, sodium and calcium hypochlorite are registered in Canada for the following uses:

Sodium hypochlorite

- laundries
- swimming pools
- spas/hot tubs
- post harvest treatment on various fruit and vegetable crops
- air washers
- pulp and paper process water systems
- industrial recirculating water systems
- farms
- milking equipment
- non-porous surfaces (such as milk cans, pails, metallic surfaces)
- food processing and beverage plants
- general sanitation, disinfecting and bleaching
- water treatment, waste treatment, sewage and wastewater treatment

Calcium hypochlorite

- swimming pools
- spas/hot tubs
- post harvest treatment on various fruit and vegetable crops
- recirculating cooling tower and heat exchange systems
- open cooling water systems
- wastewater treatment

Currently registered Canadian products containing sodium and calcium hypochlorite are listed in appendices I and II. Sodium and calcium hypochlorite are also used in "scheduled" swimming pool and spa products; a scheduled product is exempt from registration, as per section 5(*c*) of the Pest Control Products Regulations.

Based on the comparison of American and Canadian use patterns, the USEPA assessment described in the RED document for sodium and calcium hypochlorite is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the assessments conducted by the USEPA are presented in the USEPA RED for sodium and calcium hypochlorite.

The federal TSMP and Regulatory Directive DIR99-03 were taken into consideration during the review of sodium and calcium hypochlorite, and it was concluded that sodium and calcium hypochlorite are not TSMP Track 1 substances. 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 Appendix II of DIR99-03.

3.0 Proposed re-evaluation decision

The USEPA published a RED document for sodium and calcium hypochlorite addressing the main science areas that are necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of sodium and calcium hypochlorite that are also registered in Canada. Based on the USEPA RED and Canadian use pattern, the PMRA has determined that sodium and calcium hypochlorite are acceptable for continued registration provided that the mitigation measures specified in Section 4.0 are adopted. Additional data requirements are identified in Section 5.0.

It should be noted that for EPs that contain more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision. Registrants of products containing sodium or calcium hypochlorite should not apply for label amendments or submit the additional data described in Section 5.0 during this comment period; they will be informed by letter of the specific instructions for addressing label changes and data requirements once the re-evaluation decision has been finalized.

4.0 Proposed regulatory actions

Based on the USEPA RED conclusions as they relate to the Canadian use pattern, Canadian EP labels should be amended to include the following statements to further protect workers and the environment.

In the "Precautions" section,

- For commercial products registered for sanitizing uses involving indoor spray or fogging application:

  "Do not re-enter treated area until two hours after spray or fogging application."

- For commercial products formulated as solutions:

  "Wear goggles or a face shield, chemical-resistant gloves, long pants, a long-sleeved shirt, shoes and socks when handling this product."

- For all commercial products, except those formulated as solutions:

  "Wear chemical-resistant gloves, long pants, a long-sleeved shirt, shoes and socks when handling this product."

- For domestic products (considering that quantities handled are much lower than in the case of commercial products):

  "Rubber gloves should be worn when handling this product."

In the "Environmental Hazards" sub-section of the "Precautions" section,

- For industrial uses:

  "ENVIRONMENTAL HAZARDS: This product is toxic to fish and other aquatic organisms. It is not to be used in circumstances that would cause or allow it to enter lakes, streams, ponds, estuaries, oceans or other waters in contravention of federal or provincial regulatory requirements. The requirements of applicable laws should be determined before using the product."

Disinfectant uses of sodium hypochlorite were not re-evaluated as they are regulated under the *Food and Drugs Act* by the Therapeutic Products Directorate (TPD) of Health Canada. Any reference to disinfectant uses must be removed from pest control product labels and registrants are encouraged to contact TPD regarding registration of these uses.

Sodium and calcium hypochlorite can be used for "water treatment" or "waste water treatment". However, no claim is made on labels of currently registered EPs other than "ask your technical distributor for assistance". Based on this, these uses could not be re-evaluated. The PMRA is currently undertaking intiatives to address labelling deficiencies. The nature of these initiatives will be announced in the near future.

The label amendments presented above do not include all label requirements for individual EPs, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions is required within 90 days of finalization of the re-evaluation decision.

5.0 Additional data requirements

The technical registrants of sodium and calcium hypochlorite are required to submit the following within 24 months of finalization of the re-evaluation decision:

- all data (as they relate to the Canadian use pattern) submitted to the USEPA in response to the data call-in prior to the reregistration in the United States and USEPA Data Evaluation Reports (DERs);

- a commitment and schedule to address Canadian requirements that are not addressed through submission of the data outlined above. For sodium hypochlorite, these are outlined in the PMRA's data code (DACO) tables for use-site categories (USCs) # 2, # 12, # 15, # 17, # 19 and # 29. For calcium hypochlorite, these are outlined in DACO tables for USCs # 12, # 17, # 19 and # 29. Registrants are required to address are the following sections of DACO tables:
  - for the TGAI: DACOs 2 through 9, inclusive
  - for the EP: DACOs 5 though 9, inclusive

The above data and additional data may be required sooner if expansion of current uses of sodium and calcium hypochlorite is requested.

The PMRA is currently undertaking initiatives to address the labelling deficiencies for certain kinds of antimicrobial products, especially with respect to the "Directions for Use" section of product labels. The PMRA will announce in the near future the nature of these initiatives and any requirements to be addressed by registrants.

6.0 Supporting documentation

PMRA documents, such as DIR2001-03, and DACO tables can be found on our web site at www.hc-sc.gc.ca/pmra-arla. 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 web site at www.ec.gc.ca/toxics.

The USEPA RED document (*Sodium and Calcium Hypochlorite Salts*) is available on the Office of Pesticide Programs' web site at www.epa.gov/pesticides/reregistration under Chemical Status.

Appendix I Products containing sodium hypochlorite registered in Canada as of 31 March 2004

Product name	Registrant	Registration number	Active code*	Guarantee (%)	Class
Lavo 12 Sodium Hypochlorite	Groupe Lavo Inc.	12419	SHC	10.8	Commercial
Sodium Hypochlorite	Brenntag Canada Inc.	13731	SHC	10.8	Commercial
Swish-Brite 12	Charlotte Products Ltd.	15692	SHC	10.8	Commercial
CSW 20 Biocide	Drew Canada, Ashland Canada Corp.	17076	SHC	10.8	Commercial
Premier 12 Chlorinating Liquid	Charette, R.E.M. Ltd.	17361	SHC	10.8	Commercial
Guardsman-12 Sodium Hypochlorite	Univar Canada Ltd.	17363	SHC	10.8	Commercial
Spectrus OX1205C	GE Betz Canada	17469	SHC	10.8	Commercial
Unique-12 Sodium Hypochlorite	Produits Sanitaire Unique	18177	SHC	10.8	Commercial
Formula MMD-3404 Industrial Liquid Microbicide	Nalco Canada Co.	18417	SHC	10.8	Commercial
Flochem 12 Sodium Hypochlorite	Flochem Ltd.	21159	SHC	10.8	Commercial
Javex-12 P/B Chlorinating Liquid	Colgate Palmolive Canada Inc.	21159	SHC	10.8	Commercial
Chlore-12 Sodium Hypochlorite	Bel-O-Bleu	21217	SHC	10.8	Commercial
2001 Sodium Hypochlorite	S & B Distributing	21520	SHC	10.8	Commercial
JPC “12” Sodium Hypochlorite	Les produits industriels Jean-Paul Cote Inc.	21674	SHC	10.8	Commercial
Unicoop Chlorinating Liquid	Bel-O-Bleu	22643	SHC	10.8	Commercial
Old Dutch 12 Concentrated Bleach	Groupe Lavo Inc.	22749	SHC	10.8	Commercial
Société coopérative agricole des Appalaches Sodium Hypochlorite	Bel-O-Bleu	23012	SHC	10.8	Commercial
Waterloo Sodium Hypochlorite	Bel-O-Bleu	23497	SHC	10.8	Commercial
Agclor 310	Decco Cerexagri Inc.	23722	SHC	10.8	Commercial
Clor-12 Chlorinating Liquid	Glen Chemicals Ltd.	24387	SHC	10.8	Commercial
Acti-Plus 2818 Stabilized Sodium Hypochlorite	Nalco Canada Co.	24610	SHC	8.34	Commercial
Javel - 12 Sodium Hypochlorite	Groulx & Robertson	24655	SHC	10.8	Commercial
Bulab 6044 Anti-microbial Agent Industrial	Buckman Labs of Canada Ltd.	24661	SHC	10.8	Commercial
Advance 12A	Advance Chemicals Ltd.	24922	SHC	10.8	Commercial
Busan 1125 Antimicrobial Agent	Buckman Labs of Canada Ltd.	24954	SHC	10.8	Commercial
Javel-12 Sodium Hypochlorite	Javel-12 St-Césaire Inc.	25152	SHC	10.8	Commercial
Eclipse 633 Microbicide	Buckman Labs of Canada Ltd.	25327	SHC	10.8	Commercial
Stabrex ST90 Microorganism Control Chemcial	Nalco Canada Co.	25478	SHC SBR	6.36 9.23	Commercial
Atlantic-12 Sodium Hypochlorite	Atlantic Chemical & Aquatics Inc.	25506	SHC	10.8	Commercial
Javex-12 P/B Sodium Hypochlorite	Colgate Palmolive Canada Inc.	25506	SHC	10.8	Commercial
Stabrex ST95 Microorganism Control Chemical in Recirculating Water Systems	Nalco Canada Co.	25535	SHC SBR	6.36 9.23	Commercial
Flochem-12 Sodium Hypochlorite	Flochem Ltd.	26126	SHC	10.8	Commercial
Stabrex ST100 Microorgansim Control Chemical Pulp & Paper Mills	Nalco Canada Co.	26145	SHC SBR	6.36 9.23	Commercial
Nalco Stabrex ST30 Microorganism Control Chemical	Nalco Canada Co.	26204	SHC SBR	6.36 9.23	Commercial

Product name	Registrant	Registration number	Active code*	Guarantee (%)	Class
Dixichlor Max Sodium Hypochlorite Solution	DPC Industries Inc.	26675	SHC	12.5	Commercial
Actichlor Chlorinating Liquid	Chem-Aqua, Division of/de NCH Canada Inc.	27035	SHC	10.8	Commercial
Stabrom 910 Biocide	Albemarle Corporation	27155	SHC SBR	6.36 9.23	Commercial
Algaecide - C	Klenzoid Co. Ltd.	27296	SHC	10.8	Commercial
Sanerex 311 Stabilized Liquid Hypochlorite	Basic Packaging Industries Inc.	23276	SHC	10.8	Domestic
12% Liquid Sodium Hypochlorite	UBA Inc.	21271	SHC	10.8	Manufacturing
Javex TA	Colgate Palmolive Canada Inc.	22709	SHC	10.8	Technical
Sodium Hypochlorite	Brenntag Canada Inc.	23344	SHC	10.8	Technical
20% w/v Sodium Hypochlorite	UBA Inc.	25136	SHC	16.0	Technical
Vertex CSS-12	Vertex Chemical Corporation	25486	SHC	12.5	Technical
Sodium Hypochlorite Solution	Olin Corp.	25619	SHC	15.0	Technical
Javex Sodium Hypochlorite Solution	Colgate Palmolive Canada Inc.	26206	SHC	15.0	Technical
Vertex CSS-16 Sodium Hypochlorite Technical	Vertex Chemical Corporation	26615	SHC	16.40	Technical
Lavo “12” Technical	Groupe Lavo Inc.	26684	SHC	10.8	Technical
Aquachlor Sodium Hypochlorite	Altivia Corporation	26838	SHC	14.5	Technical
Dixichlor Max Sodium Hypochlorite Solution Technical	DPC INDUSTRIES INC	26868	SHC	12.5	Technical
Lavo “20” Technical	Groupe Lavo Inc.	27344	SHC	16.2	Technical
Lavo “15.5” Technical	Groupe Lavo Inc.	27346	SHC	16.8	Technical
Sodium Hypochlorite 12% Technical	Groupe Lavo Inc.	27459	SHC	10.8	Technical

* SHC = sodium hypochlorite; SBR = sodium bromide

Appendix II Products containing calcium hypochlorite registered in Canada as of 31 March 2004

Product name	Registrant	Registration number	Active code	Guarantee (%)	Class
Specialty CSW 2 Biocide	Drew Canada, Ashland Canada Corp.	18779	CHC	65	Commercial
Jet-Chlor Concentrated Chlorinating Compound	Jet Inc.	20462	CHC	65	Commercial
Pulsar Plus Dry Chlorinator Briquettes	Arch Chemicals Inc.	22468	CHC	65	Commercial
Bio-Sanitizer Disinfecting Tablets	Norweco Inc.	23425	CHC	65	Commercial
Accu-Tab White Calcium Hypochlorite Tablets	PPG Industries Inc.	24052	CHC	65	Commercial
Pulsar Plus Super Chlorinator Shock	Arch Chemicals Inc.	22180	CHC	75	Domestic
HTH Extra Bactericide & Algaecide for Swimming Pools	Arch Chemicals Inc.	22181	CHC	75	Domestic
HTH Extra Super Shock for Swimming Pools	Arch Chemicals Inc.	23324	CHC	75	Domestic
HTH Kiddie Pool Sanitizer	Arch Chemicals Inc.	26144	CHC	75	Domestic
Repak Calcium Hypochlorite Granular	PPG Industries Inc.	18123	CHC	65	Technical
Sask-Chlor Calcium Hypochlorite 65%	ERCO Worldwide, a Division of Superior Plus Inc.	21924	CHC	65	Technical
Calcium Hypochlorite Granular 65	Arch Chemicals Inc.	21958	CHC	65	Technical
Calcium Hypochlorite Granular 70	Arch Chemicals Inc.	21959	CHC	70	Technical
Calcium Hypochlorite Tablets 65%	Arch Chemicals Inc.	22828	CHC	65	Technical
Calcium Hypochlorite Tablets 70%	Arch Chemicals Inc.	22829	CHC	70	Technical
Hi-Chlon Chlorinating Tablets	Nippon Soda Co. Ltd.	22831	CHC	70	Technical
Hi-Chlon Chlorinating Granules	Nippon Soda Co. Ltd.	22832	CHC	70	Technical
Hi-Chlon Chlorinating Granules	Nippon Soda Co. Ltd.	22833	CHC	65	Technical
Niclon 65% Tablets	Tosoh Corporation	22840	CHC	65	Technical
Niclon 65% Chlorinating Granules	Tosoh Corporation	22841	CHC	65	Technical
Niclon 70% Tablets	Tosoh Corporation	22842	CHC	70	Technical
Niclon 70% Chlorinating Granules	Tosoh Corporation	22843	CHC	70	Technical
Pittabs Calcium Hypochlorite 65% Tablets	PPG Industries Inc.	23256	CHC	65	Technical
Calcium Hypochlorite Granular 75%	Arch Chemicals Inc.	23258	CHC	75	Technical
Chlore Sani-Marc Chlorinating Granules	Sani-Marc Inc.	25243	CHC	65	Technical

* CHC = calcium hypochlorite