Re-evaluation Decision

RVD2018-36

Sodium Bromide and Its Associated End-use Products

Final Decision

(publié aussi en français)

30 November 2018

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. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides hc.pmra.publications-arla.sc@canada.ca Facsimile: 613-736-3758 Information Service: 1-800-267-6315 or 613-736-3799 hc.pmra.info-arla.sc@canada.ca



ISSN: 1925-1017 (print) 1925-1025 (online)

Catalogue number: H113-28/2018-36E (print version)

H113-28/2018-36E-PDF (PDF version)

${\small \texttt{@}}\ \text{Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2018}$

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Table of Contents

Re-evaluation	on Decision	1
Outcome	of Science Evaluation	1
Regulator	y Decision for Sodium Bromide	2
Next Step	S	3
Other Info	ormation	3
Appendix I	Registered Products Containing Sodium Bromide as well as Bromine	
11	and Chlorine Electrolysis Devices ¹	4
Appendix II	Comments and Responses	
	ments Related to the Health Risk Assessment	
1.1 To	xicology	17
	Water additives	
1.2 Re	sidential Exposure	17
	Bromate formation from related active ingredient BCDMH	
((1-bromo-3-chloro-5,5-dimethylhydantoin)	17
	Bromate formation as a result of bromine electrolysis generators in spas	
	Ingestion of spa waters and the use of USEPA SWIMODEL for spas	
	Additional data to assess spa exposure	
	Ingestion of spa water compared to open ocean swimming	
	r Comments	
	ducing Dose Rates for Scheduled Uses of Sodium Bromide	
	I Label Amendments for Products Containing Sodium Bromide as well as	
11	Chlorine Electrolysis Devices	21
Appendix Γ	V References Considered Following Publication of PRVD2017-10	
1 1		

Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Sodium bromide is registered in Canada to control slime-forming bacteria and other microorganisms that form problematic biofilms on the surfaces of equipment in contact with process waters in pulp and paper mills, cooling towers, and air washers. It is also used as a sanitizer to control bacteria and algae in swimming pool and spa waters. Currently registered products containing sodium bromide and associated end-use products as well as bromine and chlorine electrolysis devices are listed in Appendix I.

This document presents the final regulatory decision¹ for the re-evaluation of sodium bromide, including the required risk mitigation measures to protect human health and the environment. All products containing sodium bromide that are registered in Canada, as well as electrolysis devices that may be used with sodium bromide products and sodium bromide spa products used in combination with potassium monopersulfate which appear in Schedule 2² of the Pest Control Product Regulations, are subject to this re-evaluation decision. This re-evaluation decision has undergone a 90-day consultation period on the Proposed Re-evaluation Decision PRVD2017-10, *Sodium Bromide*³, which ended on 29 October 2017.

Health Canada received comments relating to the health risk assessment. These comments are summarized in Appendix II along with the responses by Health Canada. The comments did not result in a change to the risk assessment. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2017-10. A reference list of data used as the basis for the proposed re-evaluation decision is included in PRVD2017-10. Further data used in the re-evaluation decision, including data received during the consultation period, are listed in Appendix IV.

Outcome of Science Evaluation

With respect to human health, risks of concern were identified for the use of sodium bromide products used in combination with bromine electrolysis devices and sodium bromide spa sanitizers used in combination with potassium monopersulfate. No risks of concern were identified for all other uses of sodium bromide when used according to the revised label directions. Also when used according to the revised label directions, sodium bromide is not expected to pose risks of concern to the environment.

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

² "Pest Control Products Exempt from Registration"

³ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Regulatory Decision for Sodium Bromide

Health Canada has completed the re-evaluation of sodium bromide. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of some uses of sodium bromide is acceptable. An evaluation of available scientific information found that some uses of sodium bromide products meet current standards for protection of human health and the environment when used according to the conditions of registration, which include required amendments to label directions. Certain uses of sodium bromide are cancelled as health risks have not been found to be acceptable. Label amendments, as summarized below and listed in Appendix III, are required for all remaining sodium bromide products as well as chlorine electrolysis devices. No additional data are required.

Risk Mitigation Measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law.

Human Health

To protect the general population from residential exposure, the following risk-reduction measures are required for continued registration of sodium bromide in Canada:

- Cancellation of all bromine swimming pool or spa electrolysis devices and sodium bromide products intended to be used with swimming pool or spa electrolysis devices.
- Sodium bromide spa products used in combination with potassium monopersulfate will be removed from Schedule 2 of the Pest Control Product Regulations as part of future regulatory amendments and will no longer be permitted for use.
- All chlorine swimming pool or spa electrolysis devices are to indicate that they are not to be used with bromide products.
- All remaining sodium bromide swimming pool and spa products are to indicate that they are not to be used in combination with electrolysis, ozonation or UV.

To protect industrial workers from occupational exposure, the following risk-reduction measures are required for continued registration of sodium bromide in Canada:

- Commercial industrial sodium bromide product labels are to require the use of protective
 eyewear, chemical-resistant coveralls over long-sleeved shirt, long pants, and chemicalresistant gloves and footwear when handling the concentrate and contacting treated
 process fluids.
- Commercial industrial sodium bromide product labels are to indicate that they are for use with closed loading and transfer systems only.

Environment

To protect the environment, the following risk-reduction measures are required for continued registration of sodium bromide in Canada:

Commercial industrial sodium bromide products are to indicate that the detoxification of effluent prior to discharge is required due to the toxicity of hypobromous acid to aquatic organisms.

Next Steps

To comply with this decision, the required mitigation measures must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this decision document. Appendix I lists the products containing sodium bromide, as well as bromine and chlorine electrolysis devices, that are registered under the authority of the Pest Control Products Act.

In addition, products that are cancelled will be phased-out following the implementation timeline outlined below:

- One (1) year of sale by registrant from the publication date of this decision document, followed by;
- One (1) year of sale by retailer from the last date of sale by registrant, followed by;
- One (1) year of permitted use from the last date of sale by retailer.

Other Information

Any person may file a notice of objection⁴ regarding this decision on sodium bromide within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of Canada.ca or contact the PMRA's Pest Management Information Service.

As per subsection 35(1) of the Pest Control Products Act

Appendix I Registered Products Containing Sodium Bromide as well as Bromine and Chlorine Electrolysis Devices¹

Registration	Marketing	Registrant	Product Name	Formulation	Active Ingredient
Number	Class			Type	
21923	Technical Grade Active Ingredient	BWA Water Additives US LLC	Liquibrom 100	Soluble Powder	Sodium Bromide 97%
22737	Technical Grade Active Ingredient	Bromine Compounds Ltd	Sodium Bromide Technical Microbicide	Solid	Sodium Bromide 98%
24216	Manufacturing Concentrate	Bromine Compounds Ltd	Sodium Bromide MP Microbicide	Pellets	Sodium Bromide 98%
25331	Technical Grade Active Ingredient	Albemarle Corporation	Sanibrom 40 Biocide Technical	Solution	Sodium Bromide 40%
25701	Manufacturing Concentrate	BWA Water Additives US LLC	Liquibrom 4000T Manufacturing Concentrate	Solution	Sodium Bromide 40%
26578	Technical Grade Active Ingredient	Albemarle Corporation	Sanibrom 45 Biocide Technical	Solution	Sodium Bromide 45.0%
28480	Technical Grade Active Ingredient	Sani-Marc Inc	Cambrex NaBr	Soluble Granules	Sodium Bromide 99.2%
28824	Manufacturing Concentrate	Bromine Compounds Ltd	Sodium Bromide MP- SP	Soluble Powder	Sodium Bromide 98%
28825	Technical Grade Active Ingredient	Bromine Compounds Ltd	Sodium Bromide Technical Microbicide-SP	Soluble Powder	Sodium Bromide 98%
33122	Technical Grade Active Ingredient	Sani Marc Inc.	Sani Marc NaBr	Soluble Granules	Sodium Bromide 99.3%
21318	Commercial	Suez Water Technologies & Solutions Canada	Spectrus OX1201	Solution	Sodium Bromide 40%
21678	Commercial	Nalco Canada ULC	Acti-Brom 1338 Chlorine Enhancer Biodispersant	Solution	Sodium Bromide 42.8%
21922	Commercial	BWA Water Additives US LLC	Liquibrom 4000	Solution	Sodium Bromide 40.0%
22577	Commercial	Buckman Laboratories of Canada Ltd	Busan 1167 Liquid Microbicide	Solution	Sodium Bromide 40.0%
22578	Commercial	Buckman Laboratories of Canada Ltd	Bulab 6040 Liquid Microbicide	Solution	Sodium Bromide 40%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active Ingredient
23624	Commercial	Solenis Canada ULC	Biosperse XD9400	Solution	Sodium Bromide 40%
24770	Commercial	ICL – IP America Inc	Bromide Plus Microbiocide	Solution	Sodium Bromide 38%
24911	Commercial	Klenzoid Canada Inc.	Klenzoid Sodium Bromide	Solution	Sodium Bromide 40.0%
25202	Commercial	Solenis Canada ULC	Spectrum XD9400 Microbiocide Agent	Solution	Sodium Bromide 40%
25320	Commercial	Chemco Products Inc.	Eclipse 632 Microbicide	Solution	Sodium Bromide 40%
25478	Commercial	Nalco Canada ULC	Stabrex ST70	Solution	Sodium Hypochlorite 6.36% Sodium Bromide 9.23%
25930	Commercial	Occidental Chemical Corporation	Oxychem Towerbrom 90M Tablets	Tablet	Trichloro-s- Triazinetrione 83% Sodium Bromide 7%
26145	Commercial	Nalco Canada ULC	Stabrex ST100	Solution	Sodium Hypochlorite 6.36% Sodium Bromide 9.23%
26539	Commercial	Chemtreat Inc	Chemtreat CL-40	Solution	Sodium Bromide 40.0%
26557	Commercial	Baker Hughes Canada Company	Cl2out 1000 Slimicide	Solution	Sodium Bromide 40.0%
26856	Commercial	BASF Canada Inc	Basabrom 40	Solution	Sodium Bromide 40%
26945	Commercial	Kemira Chemicals Canada Inc	Fennosan 111-C	Solution	Sodium Bromide 40%
27275	Commercial	Occidental Chemical Corporation	Towerbrom 60M Granules	Granular	Sodium Dichloro-s- Triazinetrione 57% Sodium Bromide 6.86%
27275.01	Commercial	State Industrial Products	Bio-Bully	Granular	Sodium Dichloro-s- Triazinetrione 57% Sodium Bromide 6.86%
27663	Commercial	Nalco Canada ULC	Towerbrom 960	Solubles Granules	Sodium Dichloro-s- Triazinetrione 57% Sodium Bromide 6.86%
27674	Commercial	Nalco Canada ULC	Towerbrom 991	Tablet	Trichloro-s- Triazinetrione 83% Sodium Bromide 6.86%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active Ingredient
27759	Commercial	Nalco Canada ULC	Acti-Brom 1318 Chlorine Enhancer	Solution	Sodium Bromide 42.8%
27796	Commercial	Produits Chimiques Magnus Ltée	Magnatrol 47A	Solution	Sodium Bromide 40%
28357	Commercial	Dubois Chemicals Canada Inc	X-Cell 430	Solution	Sodium Bromide 40%
28729	Commercial	Aquarian Chemicals Inc	Aquabrom 4000	Solution	Sodium Bromide 40%
29141	Commercial	Nalco Canada ULC	Stabrex ST70 For Kits	Solution	Sodium Hypochlorite 6.36% Sodium Bromide 9.23%
29408	Commercial	Enviro Tech Chemical Services Inc	Brommax 7.1 Microorganism Control Chemical	Solution	Trichloro-s- Triazinetrione 7.45% Sodium Bromide 10.09%
29501	Commercial	IPAC Chemicals Ltd	Ipacide LWT 629	Solution	Sodium Bromide 40%
29880	Commercial	Chemtreat Inc	Cl-4907 Microorganism Control Chemical	Solution	Trichloro-s- Triazinetrione 7.45% Sodium Bromide 10.09%
29971	Commercial	Nalco Canada ULC	Controlbrom CB70	Solution	Sodium Bromide 30%
30035	Commercial	Produits Chimiques Magnus Ltée	Magnatrol 477a	Solution	Trichloro-s- Triazinetrione 7.45% Sodium Bromide 10.09%
30146	Commercial	Chemtreat Inc	Chemtreat Cl-41	Solution	Sodium Bromide 40%
30291	Commercial	NCH Canada Inc	Chem-Aqua 42171	Solution	Trichloro-s- Triazinetrione 7.45% Sodium Bromide 10.09%
30659	Commercial	IPAC Chemicals Ltd	Ipacide LWT 639A	Solution	Trichloro-s- Triazinetrione 7.45% Sodium Bromide 10.09%
31031	Commercial	Water Sciences Technologies LLC	K-Brom 40	Solution	Sodium Bromide 38%
31106	Commercial	Québec-O-Chimie Inc	Unica 310	Solution	Trichloro-s- triazinetrione 7.45% Sodium Bromide 10.09%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active Ingredient
31359	Commercial	Centrale Thermique BC- Plus	A-210	Solution	Trichloro-s- triazinetrione 7.45% Sodium Bromide 10.09%
32155	Commercial	U.S. Water Services, Inc	Biotrol 407	Solution	Trichloro-s- triazinetrione 7.45% Sodium Bromide 10.09%
32521	Commercial	U.S. Water Services, Inc	Biotrol C140	Solution	Sodium Bromide 40%
32654	Commercial	Klenzoid Canada Inc	Aquacide STBR	Solution	Trichloro-s- Triazinetrione 7.45% Sodium Bromide 10.09%
33031	Commercial	Solesco Inc	Solubact-BR	Solution	Sodium Hypochlorite 6.36% Sodium Bromide 9.23%
33059	Commercial	Nalco Canada ULC	Stabrex ST70CAN	Solution	Sodium Hypochlorite 6.36% Sodium Bromide 9.23%
25299	Domestic	KIK Holdco Company Inc	Spaguard Brominating Concentrate	Granular	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.7%
26561	Domestic	KIK Holdco Company Inc	Aqua Chem Clear And Simple Spa Brominating Concentrate	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.7%
26562	Domestic	KIK Holdco Company Inc	Omni Brominating Concentrate For Spas & Hot Tubs	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.7%
26563	Domestic	KIK Holdco Company Inc	Spa Essentials Sanitizer Brominating Concentrate	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.7%
26579	Domestic	Sani-Marc Inc	Easy Brome Sanitizer For Spas	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
27197	Domestic	Sani-Marc Inc	Calypso Spa Power Brome # 15	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active Ingredient
27308	Domestic	Beachcomber Hot Tubs Plus Inc	Bromo Blast	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
27329	Domestic	I.P.G/G.P.I Independent Pool Group Inc	Aquapro Spa Easy Brome	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
27589	Domestic	Capo Industries Ltd	Spaboss Brominating Granules	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
27589.02	Domestic	Aqua Coastal Imports Inc	Aqua Coastal Brominating Granules	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
27589.04	Domestic	Capo Industries Ltd	Jacuzzi Brominating Granules	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
27888	Domestic	Sani-Mare Inc	Spa Sani Brom	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
28099	Domestic	Capo Industries Ltd D.B.A. Pool Chemical Industries	Spachem Brominating Granules	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.7%
28100	Domestic	Catalina Spas	Catalina Spas Bromine Granules	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.7%
28101	Domestic	Arctic Spas	Arctic Pure Peak Boost Brominating Granules	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.7%
28230	Domestic	Canadian Tire Corp. Ltd	Aquarius Spa Gran- Brom	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
29102	Domestic	Backyard Brands Inc	Dazzle Bromine Granules For Hot Tub	Granular	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active Ingredient
29396	Domestic	Lawrason's Inc	Spa Life EZ Brom	Soluble Granules	Sodium Dichloro-s- Triazinetrione 47.5% Sodium Bromide 14.88%
29782	Domestic	Bromitron Corporation	Bromicharge	Solid	Sodium Bromide 98%
29878	Domestic	Le Club Piscine Plus Québec C.P.P.Q. Inc.	Bromine Gran	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
30023	Domestic	Lawrason's Inc	Clear Spa EZ Brom	Soluble Granules	Sodium Dichloro-s- Triazinetrione 47.5% Sodium Bromide 14.88%
30289	Domestic	Hydropool Inc	EZ Brome +	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
30290	Domestic	Mursatt Chemicals Ltd	Brome +	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
30776	Domestic	Arch Chemicals Inc	GLB Green Free Algaecide	Soluble Powder	Sodium Bromide 98%
30804	Domestic	KIK Holdco Company Inc	Soft Soak Clearly Clean For Bromine Spas	Granular	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.7%
30986	Domestic	Alliance Trading Inc	Brom Granules	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
31109	Domestic	KIK Holdco Company Inc	Soft Soak Brominating Granules	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.7%
31691	Domestic	Backyard Brands Inc	Mineraluxe Bromine Granules For Hot Tub	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
31880	Domestic	Easy 123 Pool Care LLC	Clorox Spa Brominating Concentrate	Granular	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.7%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active Ingredient
31956	Domestic	Sani-Marc Inc	Halogen	Soluble Granules	Sodium Bromide 99.2%
32027	Domestic	Trevi	Brom-Gen	Soluble Granules	Sodium Bromide 99.2%
32075	Domestic	Central Spa & Pool Supply	Bromine Generator Salt	Soluble Granules	Sodium Bromide 99.2%
32085	Domestic	Le Club Piscine Plus Québec C.P.P.Q. Inc. D.B.A. Club Piscine Super Fitness	Eclipse	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.79% Sodium Bromide 14.6%
32182	Domestic	Sani-Marc Inc	Bromide Salt	Soluble Granules	Sodium Bromide 99.2%
32214	Domestic	Capo Industries Ltd	Marquis 1 Step Bromine Granules	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
32519	Domestic	Trevi	EZ San	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.6%
32874	Domestic	Groupe D'Achat MP Inc	Fusion	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.85%
33159	Domestic	Capo Industries Ltd D.B.A. Pool Chemical Industries	PoolSuppliesCANADA.CA Spa Brominating Granules	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.7%
33205	Domestic	Capo Industries Ltd D.B.A. Pool Chemical Industries	The Cover Guy Brominating Granules	Soluble Granules	Sodium Dichloro-s- Triazinetrione 52.7% Sodium Bromide 14.7%
		В	romine Electrolysis Dev	ices	
27890	Domestic	Hot Tub Solutions Inc, DBA Bluwater Technology Inc.	Genesis Automatic Bromine Generator	Device	Not applicable
27890.01	Domestic	Hot Tub Solutions Inc, DBA Bluwater Technology Inc.	Cal Clarity Automatic Bromine Generator	Device	Not applicable

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active Ingredient
27890.03	Domestic	Hot Tub Solutions Inc, DBA Bluwater Technology Inc.	Hydropool Salt Water Bromine System	Device	Not applicable
29628	Domestic	Groupe Gecko Alliance Inc.	In. Clear	Device	Not applicable
30525	Domestic	Hot Tub Solutions Inc, DBA Bluwater Technology Inc.	Genesis Blu Fusion Automatic Bromine Generator for Spa Sanitizing	Device	Not applicable
		C	hlorine Electrolysis Dev	ices	
20151	Domestic	C.L. Marketing Inc.	Lectranator Salt Chlorine Generator Model 840	Device	Not applicable
24583	Commercial	Goldline Controls Inc.	Aqua Rite (Canada) Electrolytic Chlorine Generator	Device	Not applicable
25615	Domestic	Lectranator Systems Inc.	Cubby Salt Water Purifier Model AC5	Device	Not applicable
26962	Commercial	Lectranator Systems Inc.	Lectranator II Model 7200	Device	Not applicable
26966	Domestic	KIK Holdco Company Inc.	Mineral Springs (Model V1)	Device	Not applicable
26967	Domestic	KIK Holdco Company Inc.	Mineral Springs (Model V2)	Device	Not applicable
27476	Commercial	Lectranator Systems Inc.	Lectranator Soft Touch Model ST840C (.91KG/CL2/DAY)	Device	Not applicable
27477	Commercial	Lectranator Systems Inc.	Lectranator Digital Model DIG 840C (.91KG/CL2/DAY)	Device	Not applicable
27840	Domestic	Lectranator Systems Inc.	Lectranator Soft Touch Model ST60	Device	Not applicable
27841	Domestic	Lectranator Systems Inc.	Lectranator Soft Touch Model ST48	Device	Not applicable
27842	Domestic	Lectranator Systems Inc.	Lectranator Soft Touch Model ST36	Device	Not applicable
27843	Domestic	Lectranator Systems Inc.	Lectranator Digital Model DIG 60	Device	Not applicable
27844	Domestic	Lectranator Systems Inc.	Lectranator Digital Model DIG 48	Device	Not applicable

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active Ingredient
27845	Domestic	Lectranator Systems Inc.	Lectranator Digital Model DIG 36	Device	Not applicable
27899.0	Domestic	Lectranator Systems Inc.	Tubby Model ST1	Device	Not applicable
27899.01	Domestic	Artic Spas	Onzen	Device	Not applicable
27899.02	Domestic	Coast Spas Manufacturing Inc.	Ecoclean	Device	Not applicable
28193	Domestic	Zodiac Pool Systems Inc.	Apurem with PLC1400 Cell	Device	Not applicable
28324	Commercial	Goldline Controls Inc.	H40 Electronic Chlorine Generator	Device	Not applicable
28324.01	Commercial	Goldline Controls Inc.	Swimpure Plus Electronic Chlorine Generator	Device	Not applicable
28324.03	Commercial	Goldline Controls Inc.	Ritepro Electronic Chlorine Generator	Device	Not applicable
28324.2	Commercial	Goldline Controls Inc.	Aqua Logic Electronic Chlorine Generator	Device	Not applicable
28325	Domestic	Goldline Controls Inc.	Aquarite Cul Electrolytic Chlorine Generator	Device	Not applicable
28325.1	Domestic	Goldline Controls Inc.	GEN-R-8 Electrolytic Chlorine Generator	Device	Not applicable
28325.3	Domestic	Hayward Pool Products Canada Inc.	DIY Electrolytic Chlorine Generator	Device	Not applicable
28325.4	Domestic	Hayward Pool Products Canada Inc.	Omnilogic Electrolytic Chlorine Generator	Device	Not applicable
28325.5	Domestic	Goldline Controls Inc.	Aquarite Long Life	Device	Not applicable
28365	Domestic	Pentair Water Pool and Spa Inc.	Intellichlor Electronic Chlorine Generator Model IC40	Device	Not applicable
28366	Domestic	Pentair Water Pool and Spa Inc.	Intellichlor Electronic Chlorine Generator Model IC20	Device	Not applicable
28593	Domestic	Hayward Pool Products Canada Inc.	Aqua Trol Above- Ground Pool Automation	Device	Not applicable

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active Ingredient
28593.01	Domestic	Hayward Pool Products Canada Inc.	Swimpure RJ Above Ground Pool Automation	Device	Not applicable
28651	Commercial	Chlorking Inc.	Chlorking Saline Chlorination System	Device	Not applicable
28816	Commercial	Ecolab Inc.	Ecolab Aqua Balance Pure Comfort Mineral Pool & Spa System	Device	Not applicable
29088	Commercial	Chlorking Inc.	Chlorking Saline Chlorination System, Model CHLOR-5.0	Device	Not applicable
29220	Commercial	Ecolab Inc.	Ecolab Aqua Balance Pure Comfort Mineral Pool & Spa System Model 5.0	Device	Not applicable
29376	Commercial	C.L. Marketing Inc.	Zilvoldhf	Device	Not applicable
29541	Commercial	Chlorking Inc.	Chlorking Saline Chlorination System, Model Mini 2.0	Device	Not applicable
29705	Commercial	Ecolab Inc.	Ecolab Aqua Balance Pure Comfort Mineral Pool & Spa System Model 2.0	Device	Not applicable
29954	Commercial	Clearblue Ionizer Inc.	Clearblue	Device	Not applicable
30130	Domestic	Blue Falls Manufacturing Ltd.	Onzen II Salt Water Spa Chlorinator	Device	Not applicable
30232	Domestic	Zodiac Pool Systems Inc.	Zodiac Aquapure EI Series APURE35C	Device	Not applicable
30251	Domestic	Watkins Manufacturing Corporation	Ace Salt Water Sanitizing System	Device	Not applicable
30295	Commercial	Davey Water Products Proprietary Ltd.	Eco-Matic COMM 360 Automatic Chlorine Generator	Device	Not applicable
30296	Commercial	Davey Water Products Proprietary Ltd.	Eco-Matic COMM 1200 Automatic Chlorine Generator	Device	Not applicable
30297	Commercial	Davey Water Products Proprietary Ltd.	Eco-Matic COMM 2400 Automatic Chlorine Generator	Device	Not applicable
30298	Commercial	Davey Water Products Proprietary Ltd.	Eco-Matic COMM 4000 Automatic Chlorine Generator	Device	Not applicable

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active Ingredient
30299	Commercial	Davey Water Products Proprietary Ltd.	Eco-Matic COMM 160 Automatic Chlorine Generator	Device	Not applicable
30383	Domestic	Bestway Inflatables & Materials Corporation	Hydro-Force Flowclear Chlorinator Model 58215	Device	Not applicable
30479	Domestic	Zodiac Pool Systems Inc.	Nature2 Fusion Inground	Device	Not applicable
30480	Domestic	Zodiac Pool Systems Inc.	Nature2 Vision Pro	Device	Not applicable
30481	Domestic	Zodiac Pool Systems Inc.	Nature2 Fusion Soft	Device	Not applicable
30493	Domestic	Lectranator Systems Inc.	Pool Pilot Deluxe	Device	Not applicable
30494	Domestic	Lectranator Systems Inc.	Pool Pilot Digital Nano	Device	Not applicable
30794	Domestic	Les Équipements de Piscines Carvin Inc.	Saniclear 40	Device	Not applicable
30927	Commercial	Hayward Pool Products Canada Inc.	Saline C(TM) 6.0 Salt Chlorine Generator	Device	Not applicable
30930	Domestic	Pentair Water Pool and Spa Inc.	Intellichlor Electronic Chlorine Generator Model IC60	Device	Not applicable
30931	Domestic	Pentair Water Pool and Spa Inc.	Intellichlor Electronic Chlorine Generator Model IC15	Device	Not applicable
30942	Domestic	Les Équipements de Piscines Carvin Inc.	Saniclear20	Device	Not applicable
30976	Commercial	Ecosmarte Planet Friendly Inc.	Chem-Saver Swimming Pool System	Device	Not applicable
31002	Domestic	Intex Development Company Ltd.	Krystal Clear(TM) Ozone & Saltwater System Model ZS8110	Device	Not applicable
31003	Domestic	Intex Development Company Ltd.	Krystal Clear Saltwater System Model CS7110	Device	Not applicable
31004	Domestic	Intex Development Company Ltd.	Krystal Clear Saltwater System & Pump Model CS7111	Device	Not applicable

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active Ingredient
31016	Domestic	Watkins Manufacturing Corporation	Ace Retro Salt Water Sanitizing System	Device	Not applicable
31158	Commercial	TMI Salt Pure Corporation	XMCG Automatic Chlorine Generator	Device	Not applicable
31159	Commercial	TMI Salt Pure Corporation	2XMCG Automatic Chlorine Generator	Device	Not applicable
31186	Domestic	Astral Pool PTY Ltd.	VX7 Salt Chlorine Generator	Device	Not applicable
31187	Domestic	Astral Pool PTY Ltd.	VX7T Salt Chlorine Generator	Device	Not applicable
31268	Domestic	Solaxx	Saltron Mini	Device	Not applicable
31362	Commercial	Hayward Pool Products Canada Inc.	AQR-XL-LS-CUL	Device	Not applicable
31672	Domestic	Solaxx	Saltron Retro	Device	Not applicable
32055	Domestic	Intex Development Company Ltd.	Krystal Clear Saltwater System Model Eco 7111	Device	Not applicable
32056	Domestic	Intex Development Company Ltd.	Krystal Clear Saltwater System Model Eco 8110	Device	Not applicable
32057	Domestic	Intex Development Company Ltd.	Sand Filter Pump & Krystal Clear Saltwater System Model Eco 15110	Device	Not applicable
32058	Domestic	Intex Development Company Ltd.	Sand Filter Pump & Krystal Clear Saltwater System Model Eco 20110	Device	Not applicable
32059	Domestic	Intex Development Company Ltd.	Krystal Clear Saltwater System Model Eco 7110	Device	Not applicable
32203	Domestic	Les Équipements de Piscines Carvin Inc.	Saniclear 10	Device	Not applicable
32253	Domestic	Blue Falls Manufacturing Ltd.	Spaboy	Device	Not applicable

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active Ingredient
32277	Domestic	Blue Falls Manufacturing Ltd.	Trainers Pal Salt Water Spa Chlorinator	Device	Not applicable
32473	Domestic	Zodiac Pool Systems Inc.	Jandy Pro Series Truclear Chlorine Generating System	Device	Not applicable
32550	Domestic	Intex Development Company Ltd.	86IN X86IN X28IN Purespa Jet and Bubble Deluxe Set Model SJB- HS-11	Device	Not applicable
32551	Domestic	Intex Development Company Ltd.	77IN Purespa Jet and Bubble Deluxe Massage Set Model SJB-HS-10-1	Device	Not applicable
32552	Domestic	Intex Development Company Ltd.	77IN Purespa Jet Massage Set Model SPJ-HS-10-2	Device	Not applicable
32769	Commercial	TMI Salt Pure Corporation	TMI Salt Pure ZX-5	Device	Not applicable
32813	Domestic	Les Équipements de Piscines Carvin Inc.	Klor 17/3	Device	Not applicable
32946	Domestic	Astral Pool PTY Ltd.	E25 Salt Chlorine Generator	Device	Not applicable
32947	Domestic	Astral Pool PTY Ltd.	E35 Salt Chlorine Generator	Device	Not applicable
33004	Commercial	Chlorking Inc.	Chlorking Saline Chlorination System Model "NEXGEN"	Device	Not applicable

¹as of 30 August 2018, excluding discontinued products, products with a submission for discontinuation, and scheduled spa sanitizers.

Appendix II Comments and Responses

In response to the consultation for the sodium bromide proposed re-evaluation decision, the following comments were received:

1.0 Comments Related to the Health Risk Assessment

1.1 Toxicology

1.1.1 Water additives

A comment was received from Blu Water Technologies, Inc. indicating that water additives such as pH adjusters and water balancers in spa water may reduce bromide risk, similar to other ions that decrease bromide toxicity in seawater as indicated in PRVD2017-10.

PMRA Response

As noted in PRVD2017-10, evidence from rat toxicity and toxicokinetic data available in the published literature indicate that other ions (for example, chloride, sodium and iodide) decrease the toxicity of bromide. No such information was available for the water additives, and therefore no refinement to the risk assessment can be made.

1.2 Residential Exposure

1.2.1 Bromate formation from related active ingredient BCDMH (1-bromo-3-chloro-5,5-dimethylhydantoin)

A comment was received from Mursatt Chemicals Ltd. regarding the safety of continued use of BCDMH given the concerns identified with the disinfection by-product bromate, which is common to both active ingredients.

PMRA Response

While data for bromate formation as a result of BCDMH use in swimming pools was taken into consideration and used qualitatively in the sodium bromide re-evaluation, this will be considered separately.

Upon completion of the re-evaluation of the individual chemicals (sodium bromide and BCDMH), it will be determined whether a cumulative effects assessment is necessary and if so, this will be performed with all relevant chemicals of the common mechanism group.

1.2.2 Bromate formation as a result of bromine electrolysis generators in spas

A comment was received from Blu Water Technologies, Inc. indicating that bromate formation as a result of spa electrolysis devices is low. These comments suggested that bromate formation would not increase with the higher levels of bromide ion in the water, that operational conditions would limit bromate formation, that bather load would limit bromate formation, and that spas would not be subject to UV exposure. A separate comment from Bromitron Corporation included data on bromate levels in a spa scenario using their specific electrolysis device.

PMRA Response

Robust and reliable data on the concentration of bromate in spas where bromine electrolysis generators are used would be required to confirm whether and by how much their presence affects bromate formation in spas.

The submitted data were for a spa electrolysis device labelled for use with indoor spas or outdoor covered spas which required an initial dosing in the water of 1440 ppm sodium bromide. Bromate was measured after 90 days. A single measurement was taken for each use scenario, therefore the data are not adequate for use in the risk assessment. However, it has been considered as supporting information.

The measured levels of bromate were similar to the mean values from BCDMH which were used in the risk assessment. This supports the registrant comment that bromate formation may not increase with higher levels of bromide ion in the water, and that the use of this type of electrolysis may not significantly increase bromate levels. However, it also shows that bromate formation for a specific electrolysis device was similar to the BCDMH data and therefore supported the use of the surrogate BCDMH bromate information in the risk assessment.

As described in PRVD2017-10, cancer risks associated with bromate and non-cancer risks associated with bromide ion were of concern for all subpopulations for the spa electrolysis devices. The submitted data supports the qualitative bromate assessment. The data did not measure bromide ion levels in the water, and therefore the risk assessment for bromide ion cannot be refined. Risks of concern remain for the spa electrolysis devices.

1.2.3 Ingestion of spa waters and the use of USEPA SWIMODEL for spas

Comments were received from Blu Water Technologies, Inc., Bromitron Corporation, and Gecko Alliance Group Inc. indicating that spa users do not ingest spa water, and therefore the use of the USEPA SWIMODEL for ingestion is not appropriate. They provided comments on dermal and ingestion exposure which were consistent with the risk assessment. They felt that the exposure duration, frequency and life stages in SWIMODEL were not appropriate for spas. They specified that PMRA relied on SWIMODEL exposure for competitive swimmers for the decision not to allow bromine generators in spas.

PMRA Response

It is acknowledged that the USEPA SWIMODEL is based on swimming pool uses rather than spa uses; however, it is the best available model and uses the best available exposure data. Exposure data for competitive swimmers was applied only for products with a swimming pool use, where the activities of a competitive swimmer (swimming laps) would be applicable. For spa uses, only the exposure data from non-competitive swimmers was used in the assessment.

Spa use cannot be considered to have negligible exposure via all routes. Adult users are typically seated in the spa water, and the spa water is heated and moving which is expected to result in a mist of treated water above the water line.

Splashing from jets or occupants would be common, as well as incidental oral ingestion from water on the skin or from the ingestion of food or drink kept near the spa. While adults will attempt to minimize their ingestion of spa water, children are likely to play in a spa similarly to how they would play in a small pool.

SWIMODEL notes that exposure estimates via the dermal and inhalation routes should not be calculated for inorganic chemicals, which includes bromide and bromate ions. The overall exposure from dermal, inhalation and oral exposure was considered to be addressed by SWIMODEL's screening-level oral exposure estimate, which contains assumptions that would be protective of the additional exposure from other routes that could not be quantitatively assessed. Spa-specific data could refine this estimate, but data has not been submitted for this reevaluation.

1.2.4 Additional data to assess spa exposure

A comment was received from Blu Water Technologies, Inc. indicating that further information on spa exposure to bromide and bromate would refine the risk assessment. They identified that the following would improve the assessment: spa user exposure factors (frequency, duration, life-stages, etc.), primary routes of exposure, levels of bromide ion and bromate ion, and bromate ion levels as a result of electrolysis devices. With the exception of the bromate data described in comment 1.2.2, no additional data were submitted.

PMRA Response

Data were not submitted for spa-specific exposure factors during the consultation period. Given this, the risk assessment could not be refined.

1.2.5 Ingestion of spa water compared to open ocean swimming

Comments were received from Arch Chemicals, Inc., Bromitron Corporation, and Gecko Alliance Group Inc. suggesting that the risk from spa water is lower than that of open ocean swimming or bathing as oral ingestion in spas would be lower, while total salt concentration may be higher in ocean water, and exposure time may be longer in open ocean swimming or bathing.

PMRA Response

The comparison of the exposure to bromide in spa and pool water to seawater was considered in the risk assessment. However, the presence of bromide in the environment does not preclude risks of concern from spa water. Spa-specific data could refine the exposure estimate for spas (see 1.1.1, 1.2.3, and 1.2.4), but data were not submitted for this re-evaluation.

2.0 **Other Comments**

2.1 **Reducing Dose Rates for Scheduled Uses of Sodium Bromide**

A comment was received from Arch Chemicals suggesting to reduce the dose rates for scheduled uses of sodium bromide to use rates comparable to other registered sodium bromide products, which were proposed for continued registration.

PMRA Response

The risks of concern identified from the scheduled use of sodium bromide used in combination with potassium monopersulfate as an oxidizer were not addressed in the comments received during the consultation period. Therefore, Schedule 2 of the Pest Control Product Regulations will be revised to remove sodium bromide used in combination with potassium monopersulfate as part of future regulatory amendments.

Notwithstanding the above, the PMRA is considering scheduling the lower rate of sodium bromide for spa products used in combination with available chlorine, present as sodium dichloro-s-triazinetrione, which is acceptable for continued registration.

Appendix III Label Amendments for Products Containing Sodium Bromide as well as Chlorine Electrolysis Devices

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

HUMAN HEALTH

- 1. Label Amendments for solid Technical Grade Active Ingredients, as well as Manufacturing Concentrates and End-use Products that are Repackaged solid Technical Grade Sodium Bromide:
 - Add the signal words "WARNING POISON" to the primary display panel.
 - Add "May be fatal if inhaled. DO NOT inhale dusts." to the PRECAUTIONS section.
- 2. Label Amendments for Products Containing Sodium Bromide with Industrial Uses:

Add the following to the DIRECTIONS FOR USE section:

"Wear protective eyewear, chemical-resistant coveralls over long-sleeved shirt, long pants, and chemical-resistant gloves and footwear when handling the concentrate and contacting treated process fluids."

"For use with closed loading and transfer systems only."

3. Label Amendments for Products Containing Sodium Bromide with Swimming Pool and Spa Uses:

Add the following to the PRECAUTIONS section:

"Do not use this product with an electrolysis device (for example, a chlorine generator)."

"Do not use this product with ozonation."

"Do not use this product with ultraviolet (UV)."

4. Label Amendments for Chlorine Swimming Pool or Spa Electrolysis Devices:

Add the following to the PRECAUTIONS section:

"Do not use this device with bromide products"

ENVIRONMENT

1. Label Amendments for Products Containing Sodium Bromide with Industrial Uses:

Add the following to the DIRECTIONS FOR USE section:

"Toxic to aquatic organisms."

"DO NOT discharge effluent containing this product or the biocide produced into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters unless the effluent has been detoxified by suitable means."

Appendix IV References Considered Following Publication of PRVD2017-10

Information Considered in the Occupational and Non-Occupational Assessment

List of Studies/Information Submitted by Registrant

PMRA	Reference		
Document			
Number			
2820762	2004, Bromate Sampling 12/09/04. Data Numbering Code: 5.14		
2820780	2017, PRVD2017 – Proposed Re-evaluation Decision – Sodium Bromide. Data		
	Numbering Code: 5.14		
2820791	2003, A Residential Spa Field Test (Pages 1 to 59). Data Numbering Code: 5.14		
2820792	2003, A Residential Spa Field Test (Pages 60 to 119). Data Numbering Code:		
	5.14		