Proposed Re-evaluation Decision PRVD2011-01

1-bromo-3-chloro-5,5-dimethylhydantoin

1,3-dichloro-5,5-dimethylhydantoin

1,3-dichloro-5-ethyl-5-methylhydantoin

(publié aussi en français)

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the antimicrobials, 1-bromo-3-chloro-5,5-dimethylhydantoin, 1,3-dichloro-5,5-dimethylhydantoin, and 1,3-dichloro-5-ethyl-5-methylhydantoin (henceforth called halohydantoins), 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 these active ingredients in Canada.

An evaluation of available scientific information found that products containing the halohydantoins do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of uses, new risk-reduction measures must be included on the labels of all products containing these active ingredients. No additional data are being requested at this time.

This proposal affects all end-use products containing the halohydantoins 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 the halohydantoins and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

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 the halohydantoins.

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, *Pest Management Regulatory Agency 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.*

The three halohydantoins are part of 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 the active ingredient and the main 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 (for example, the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the 2007 RED, the USEPA concluded that the halohydantoins were eligible for reregistration provided risk-reduction measures were adopted and labels be revised accordingly. The 2007 RED also include assessments on other halohydantoins registered in Canada but that are not in the current re-evaluation cycle. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED 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 the Halohydantoins?

The three halohydantoins under re-evaluation are antimicrobials that are used to control bacteria and algae in industrial recirculating water systems, pulp and paper process waters, ornamental fountains, swimming pools, spas and as an in-tank toilet sanitizer. End-use products are typically placed or poured by workers or home owners.

Health Considerations

Can Approved Uses of the Halohydantoins Affect Human Health?

The three halohydantoins under re-evaluation are unlikely to affect your health when used according to the revised label directions.

People could be exposed to the halohydantoins by consuming food and water, by handling the pesticide product or through postapplication. 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 (for example, 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 the halohydantoins were unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are proposed.

Environmental Considerations

What Happens When the Halohydantoins Are Introduced Into the Environment?

The three halohydantoins under re-evaluation are unlikely to affect non-target organisms when used according to the revised label directions.

The USEPA concluded that the indoor and contained uses of the halohydantoins would not result in appreciable environmental exposure when products are used as labelled. Therefore, the USEPA did not anticipate ecological risk from these uses. Due to a similar use pattern in Canada, environmental exposure is expected to be limited and ecological risk is considered not to be of concern. The PMRA is proposing advisory label statements to prevent the release of these chemicals into the environment for the protection of non-target species.

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 the halohydantoins, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Additional statements warning about the severe skin and eye irritation properties and dermal sensitization potential of the product
- Additional protective equipment to protect handlers
- Advisory label statements to limit the use to non-food contact paper/paperboard or cans for the products that were not issued with a "no objection status" by Health Canada.

Environment

- Additional advisory label statements to prevent effluent discharge.

A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

Next Steps

Before making a final re-evaluation decision on the halohydantoins, 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

The halohydantoins, 1-bromo-3-chloro-5,5-dimethylhydantoin, 1,3-dichloro-5,5-dimethylhydantoin, and 1,3-dichloro-5-ethyl-5-methylhydantoin, are antimicrobial active ingredients that release, in water, chlorine and/or bromine which act as antimicrobial agents.

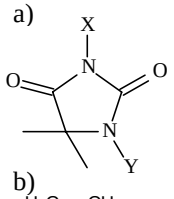
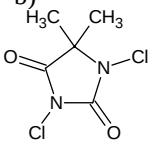
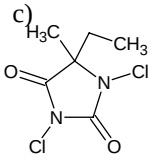
Following the re-evaluation announcement, the registrants of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the labels of commercial and domestic end-use products in Canada.

The PMRA used recent assessments of the halohydantoins from the United States Environmental Protection Agency (USEPA). These USEPA documents include assessments on other halohydantoins registered in Canada but that are not in the current re-evaluation cycle. The USEPA Reregistration Eligibility Decision (RED) document for the halohydantoins, dated September 2007, as well as other information on the regulatory status of the halohydantoins in the United States can be found on the USEPA Pesticide Reregistration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	a) BCDMH, halobrom, bromochlorodimethylhydantoin b) DCDMH, halane, dichlorodimethylhydantoin c) DCEMH, dichloroethylmethylhydantoin
Function	Fungicide and bactericide
Chemical Family	Halogenated hydantoins
Chemical Name	
1 International Union of Pure and Applied Chemistry (IUPAC)	a) 1-bromo-3-chloro-5,5-dimethyl-2,4-imidazolidinedione and 3-bromo-1-chloro-5,5-dimethyl-2,4-imidazolidinedione b) 1,3-dichloro-5,5-dimethyl-2,4-imidazolidinedione c) 1,3-dichloro-5-ethyl-5-methyl-2,4-imidazolidinedione

2	**Chemical Abstracts Service (CAS)**	a) 1-bromo-3-chloro-5,5-dimethylhydantoin and 3-bromo-1-chloro-5,5-dimethylhydantoin b) 1,3-dichloro-5,5-dimethylhydantoin c) 1,3-dichloro-5-ethyl-5-methylhydantoin
	CAS Registry Number	a) 16079-88-2 and 126-06-7 b) 118-52-5 c) 89415-87-2
	Molecular Formula	a) $C_5H_6BrClN_2O_2$ b) $C_5H_6Cl_2N_2O_2$ c) $C_6H_8Cl_2N_2O_2$
	Structural Formula	a)  X=Br, Y=Cl or X=Cl, Y=Br b)  c) 
	Molecular weight	a) 241.47 b) 197.03 c) 211.05

Based on the manufacturing process used, contaminants of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 139, No. 24, SI/2005-114 (2005-11-30), including TSMP Track 1 substances, are not expected to be present in the technical product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

	1-bromo-3-chloro-5,5-dimethylhydantoin	1,3-dichloro-5,5-dimethylhydantoin
Vapour pressure	Not determined	Not available
UV/Visible spectrum	Not applicable, the product is not stable in water or methanol.	Not available
Solubility in water	0.15 g / 100 ml	0.22 g / 100 g (25°C)
n-Octanol–Water partition coefficient	log K_{ow} = 0.35	log K_{ow} <1
Dissociation constant	not applicable	not applicable

[a] There are no data available for 1,3-dichloro-5-ethyl-5-methylhydantoin. It is expected that there would be very little difference between the physical and chemical properties of 1,3-dichloro-5-ethyl-5-methylhydantoin and 1,3-dichloro-5,5-dimethylhydantoin.

2.3 Comparison of Use Patterns in Canada and the United States

The three halohydantoins under re-evaluation are antimicrobial active ingredients registered in Canada to control bacteria and algae growth in water. When added to the water, these chemicals release chlorine/bromine by hydrolyzing from the rest of the molecule forming hypochlorous/hypobromous acid which acts as a general biocide killing bacteria, micro-organisms and algae.

End-use products are formulated as dust/powder, granular, soluble granule, tablet, solution, or paste and are poured or placed by workers or home owners directly in the water to treat or into intermittent, slug, or continuous feeding systems. The commercial uses include ornamental fountains, paper/paperboard process water systems and recirculating water systems in industrial settings such as evaporative exchange water towers, heat exchange water systems, influent systems, industrial water scrubbing systems, brewery pasteurizers, cannery, and industrial air washers. The domestic uses include the treatment of swimming pools, spas and hot tubs and the use as an in-tank toilet sanitizer. Application rates are up to 3 ppm for residual bromine or chlorine (≤1.18 kg of active ingredient [a.i.] per 10 000 litres) for the commercial uses, up to 5 ppm for residual bromine or chlorine (~0.04 kg a.i. per 10 000 litres) for the residential pool and spa uses, and one product tablet per toilet tank for the use as an in-tank toilet sanitizer.

The American and Canadian use patterns were compared. The formulation types, the use sites, and the application methods registered in Canada are encompassed by those assessed by the USEPA in the 2007 RED. The application rates of the Canadian domestic end-use products are encompassed by those described in the RED. The maximum application rates of the Canadian commercial end-use products are higher than those described in the RED, in other words, ~30% higher for industrial recirculating water systems, ~18% higher for paper/paperboard process water systems, and ~50% higher for ornamental fountains. Based on this comparison of use patterns, it was concluded that the 2007 USEPA RED for the halohydantoins is an adequate basis for the re-evaluation of the Canadian uses.

All current uses are being supported by the registrants and were, therefore, considered in the present re-evaluation. Appendix I lists all products that are registered as of 6 October 2010, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In the 2007 RED, the USEPA concluded that the end-use products formulated with the halohydantoins met the safety standard under the *American Food Quality Protection Act* and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the revised product labels.

3.1 Human Health

Exposure to the halohydantoins may occur through dietary and residential exposure, while handling the pesticide product or through postapplication. 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 (for example, children and nursing mothers).

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 effects of a chemical than the most sensitive animal species.

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

The USEPA determined that the halohydantoins were severe eye and skin irritants (acute toxicity category I) and to be positive dermal sensitizers. Based on this, additional hazard statements should be required on product labels. Appendix III lists the proposed label amendments.

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.

Workers can be exposed to the halohydantoins when handling the pesticide and through postapplication.

3.1.1.1 Handler Exposure and Risk

The USEPA assessed inhalation and dermal exposures of short-/intermediate-term durations for different handling scenarios. Among the scenarios assessed in the RED, the following were considered relevant to the Canadian situation:

- Placing the tablets/pellets or pouring granules/powder into a feeder for process waters in industrial processes, in other words, recirculating cooling water, pulp and paper process water, air washer, evaporative cooler, and cannery water; and
- Placing/pouring the solid product in ornamental fountains.

For the cooling and process water systems scenarios, handler exposure analyses were performed using the Chemical Manufacturers Association (CMA) antimicrobial exposure study assuming handlers wearing long pants, a long-sleeved shirt, chemical-resistant gloves, and goggles or a face shield. The resulting short- and intermediate-term inhalation and dermal MOEs were ≥156, thus, not of concern (target MOE = 100).

For the commercial applications of halohydantoins in ornamental fountains, handler exposure analyses were performed using the CMA antimicrobial exposure study assuming handlers wearing long pants, a long-sleeved shirt and chemical-gloves. The resulting short-/intermediate-term inhalation and dermal MOEs, in other words, 1 010 000 and 13 450, respectively, were above the target MOE of 100, thus, not of concern.

The RED addressed the Canadian potential handler exposure scenarios associated with the use of the commercial products containing halohydantoins. The application rates, as described on the Canadian commercial end-use product labels, are higher than the application rates assumed by the USEPA in their risk assessments. However, considering these higher application rates, recalculated inhalation and dermal MOEs for short-/intermediate-term durations would remain above the target MOE of 100 with the exception of the short-/intermediate-term dermal MOE for paper/paperboard process water systems. When additional PPE, in other words, coveralls over single layer clothing, were considered for this scenario, an acceptable short-/intermediate-term dermal MOE, in other words, above the target MOE of 100, was achieved. Therefore, to further protect occupational handlers, the PMRA proposes handlers to wear a long sleeved-shirt, long pants, chemical-resistant gloves, goggles or a face-shield for all commercial uses and coveralls over the single layer clothing for the pulp and paper uses. Appendix III lists the proposed label amendments.

3.1.1.2 Postapplication Exposure and Risk

The postapplication occupational risk assessment considers exposure to workers entering treated sites. For the halohydantoins, the USEPA considered that there was potential postapplication exposure via inhalation and dermal routes of workers maintaining equipment around treated waters in industrial settings. The USEPA did not conduct a quantitative risk assessment of the risk to workers from postapplication exposure. The USEPA concluded, however, that the potential occupational postapplication exposure via dermal and inhalation routes would likely be minimal compared to handler exposure based on the dilution of the active ingredient during

industrial processes. Inhalation exposures were considered to be minimal because aerosol generation is not expected and due to the low vapour pressures of these chemicals. No mitigation measures were required by the USEPA to further protect workers from potential postapplication exposure.

This was considered applicable to the Canadian situation and no risk reduction measures are proposed to further protect workers from postapplication exposure.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

Residential exposure is estimated using the MOE approach described in Section 3.1.1.

Residents can be exposed to the halohydantoins when handling domestic products containing these chemicals or through postapplication. Among the homeowner handling scenarios and the residential postapplication exposure scenarios assessed in the RED, the following scenarios were considered relevant to the Canadian situation:

- adults handling pool/spa products;
- adults handling in-tank toilet sanitizer products; and
- children and adults (competitive and non-competitive) swimming in treated pools.

For the pool/spa products handled by homeowners, the USEPA assumed that clothing worn by homeowners during application would be short pants and a short-sleeved shirt. However, based on available data, the USEPA performed handler exposure analyses using the CMA antimicrobial exposure study assuming handlers wearing a long-sleeved shirt and long pants (no gloves). The resulting short-term inhalation and dermal MOEs were ≥139, thus, not of concern (target MOE = 100).

For the in-tank toilet cleaner scenario, the USEPA performed handler exposure analyses using the CMA antimicrobial exposure study assuming handlers wearing a long-sleeved shirt and long pants (no gloves) and one person placing one product tablet per toilet tank to maintain a house containing three toilets. The estimated short-term inhalation and dermal MOEs for this task were 110 000 and 11 000, respectively, thus, not of concern (target MOE = 100).

For swimmers, the USEPA considered that the amount of exposure would likely be much greater for swimming pools than for spas; therefore, only swimming pool scenarios were assessed. To calculate exposure for competitive and non-competitive children and adults to the chemical due to swimming in treated waters, the USEPA used the Swimmer Exposure Assessment Model. All generated short-/intermediate-term MOEs for inhalation, dermal and ingestion were above the target MOE of 100 ranging from 29 000 to 7 700 000, thus, not of concern.

The USEPA residential exposure assessment did not consider exposure from handling of treated paper and paperboard products. Halohydantoin commercial products are registered for treatment of paper and paperboard process water (not the paper product itself); however, residues may remain in the finished product leading to residential exposure. Based on the numerous processing steps during paper and paperboard production, and the indirect nature of the exposure, residential exposure from handling treated paper and paperboard is expected to be negligible (refer to section 3.1.2.2 for dietary exposure from paper and paperboard used for food packaging).

The potential residential exposure scenarios in Canada are encompassed by those assessed in the RED and the Canadian maximum application rates of the domestic products are encompassed by the American rates. Therefore, the USEPA conclusions regarding the halohydantoin residential exposure and risk are considered relevant to the Canadian situation.

The USEPA determined that the halohydantoins are skin sensitizers and severe skin and eye irritants. In addition, incident reports from the PMRA database and as summarized by the USEPA in their 2007 RED, relate sensitization and irritancy symptoms following eye and skin exposures associated with the use of halohydantoins:

- Available information from the PMRA database indicates that seven incident reports were submitted to the PMRA from 2007 to 2009. Of these, four incident reports occurred in the U.S. Causality for these incidents has not been established by the PMRA since they occurred in the U.S. The remaining three incidents occurred in Canada: two human and one domestic animal incidents were classified as minor. As such, causality has not been established by the PMRA.

- The 2007 RED includes a summary of the US human incident data. Most of the incidences related to irritation and/or allergic type reaction. The most common symptoms reported for cases of dermal exposure were skin irritation/burning, rash itching, skin discoloration/redness, blistering, allergic type reactions including hives/welts, allergic contact dermatitis, and bleeding. The most common symptoms reported for cases of ocular exposure were eye irritation/burning, eye pain and swelling of eyes. For cases of inhalation exposure, the most common symptoms reported were respiratory irritation/burning, irritation to mouth/throat/nose, coughing/choking, shortness of breath, dizziness, flu-like symptoms, headache, seizure and heart palpitation. Although oral exposure was considered a minor route of exposure, irritation to mouth/throat/nose, vomiting/nausea/abdominal pain has been reported. The causality of the symptoms have not been established by the USEPA.

As described in Section 3.1, additional hazard statements are recommended to further inform users on the skin sensitisation potential and the skin and eye irritancies of the halohydantoin products. Also, considering that the domestic end-use products contain high concentrations of the halohydantoins, to further protect residential handlers, rubber gloves and goggles are recommended during handling activities. Appendix III lists the proposed label amendments. The PMRA has concerns regarding the appropriateness of swimming pool and spa products that are dermal sensitizers and will be further exploring this issue within the context of its current approach to risk assessment. In the interim, the protective measures noted above will minimize

risk to individuals of greatest concern, namely those handling the undiluted product. In addition to these protective measures, the PMRA will continue to monitor incident reports.

3.1.2.2 Exposure from Food and Drinking Water

There are no food/feed uses regulated under the *Pest Control Products Act*. All the Canadian registered uses are considered indoor and contained uses; therefore, the possibility of residues in drinking water would be considered negligible. Based on this, an assessment of the dietary risk from exposure to residues in food/feed commodities and residues in drinking water is not required for the present re-evaluation.

Dietary risk from food residues resulting from the use of the halohydantoins in the manufacturing process of paper/paperboard intended for use in food packaging was assessed by the USEPA. Risk from food residues was not of concern with up to 1.6% of the acute population adjusted dose (PAD) for adult female population (13-50 years old) and up to 1.6% of the chronic PAD for the most sensitive subgroup (children). Appendix II lists the USEPA selected endpoints for the dietary risk assessment.

The uses in pulp/paper and the cannery industry allowed in food packaging and as incidental additives are regulated under the Food and Drug Act. All the commercial products containing the halohydantoins registered for use in pulp/paper and the cannery industry and that were not issued with a no objection status by the Health Canada's Bureau of Chemical Safety should have additional advisory label statements to limit the use to non-food contact paper/paperboard or cans. Appendix III lists proposed label amendments.

No water monitoring data were reported in the 2007 RED. The PMRA searched the available Canadian water monitoring data for detections of the three halohydantoins under re-evaluation and the major transformation products 5,5-dimethylhydantoin (DMH) and 5-ethyl-5-methylhydantoin (EMH). These chemicals were not monitored for in the water monitoring data available; therefore, it is unclear as to whether they are present in Canadian water sources.

3.1.2.3 Aggregate Risk Assessment

An aggregate risk assessment is not required for the present re-evaluation considering that:

- an assessment of the dietary risk from exposure to residues in food/feed commodities is not required on the basis that there are no food/feed uses registered under the *Pest Control Products Act*; and
- that the possibility of residues in drinking water are to be considered negligible on the basis that all Canadian registered uses are indoor and contained.

3.1.3 Cumulative Effects

The USEPA has not determined whether the halohydantoins have a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that the halohydantoins does 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 concluded that hydrolysis is an early step in the degradation process of the halohydantoins with 5,5-dimethylhydantoin (DMH) and 5-ethyl-5-methylhydantoin (EMH) being the major degredates. DMH and EMH are considered persistent and may possibly leach in the soil profile or move with surface water runoff posing environment concerns.

In Canada, the three halohydantoins under re-evaluation are registered for indoor and contained uses only and contaminated waters are considered to be held for treatment before they are released in the environment. There are no once-through cooling-water system uses registered in Canada. Based on this, direct discharge in the environment of these chemicals is unlikely. The two major degradates, DMH and EMH, are considered to be persistent in water; therefore, minimal release in the environment of these two degradates may be possible.

The USEPA did not perform a quantitative risk assessment for the indoor and contained uses of the halohydantoins and the USEPA concluded that these uses would not result in appreciable environmental exposure when products are used as labelled; therefore, the USEPA did not anticipate ecological risk from these uses.

The Canadian registered uses are considered indoor and contained uses and the USEPA conclusions are considered relevant to the Canadian situation. Based on PMRA general practices for antimicrobial active ingredients, an advisory statement, to prevent effluent discharge, is proposed. Appendix III lists the proposed label amendments.

3.3 Pest Control Product Policy Considerations

3.3.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, in other words, persistent (in air, soil, water and/or sediment), bioaccumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the re-evaluation process, the halohydantoins were assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy,* and evaluated against the Track 1 criteria.

The parent compounds do not meet the Track 1 criterion for bioaccumulation, as their octanol-water partition coefficient (log K_{ow} <1) are below the Track 1 criterion of 5.

The major transformation products in water, DMH and EMH, do not meet the Track 1 criterion for bioaccumulation, as their octanol-water partition coefficients (DMH[3] log K_{ow} = -0.48) are below the Track 1 criterion of 5.

On this basis, it is concluded that the use of the halohydantoins are not expected to result in the entry of Track 1 substances in the environment.

3.3.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of the halohydantoins, contaminants in the technical active ingredients are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol).

The PMRA concluded that the technical grade active ingredients of the halohydantoins do not contain any contaminants of health or environmental concern identified in the *Canada Gazette.*

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

4.0 Organization for Economic Co-operation and Development Status

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 33 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.

[3] It is expected DMH and EMH would have similar physical and chemical properties.

The halohydantoins are antimicrobial active ingredients registered for use in liquid cooling systems and processing fluids and as a slimicide in the European Union (EU). Bromochlorodimethylhydantoin is registered for the treatment of pools and spas in Australia and for post-harvest sanitization of fruits and vegetables in New Zealand.

As described earlier in this document, the United States, also an OECD member, assessed the registration of all uses of the halohydantoins in a 2007 RED and concluded that the use of the halohydantoins as pesticides do not result in unreasonable adverse effects to human health or the environment when used according to the revised label directions.

The Canadian re-evaluation of the halohydantoins is largely based on the USEPA conclusions in the 2007 RED. As described in Section 3.1 and 3.2 above, the PMRA has found the USEPA human health and environmental risk conclusions to be relevant to the Canadian uses of the halohydantoins and requires measures to further protect workers, bystanders and the environment.

5.0 Proposed Re-evaluation Decision

The PMRA has determined that the products containing the halohydantoins, 1-bromo-3-chloro-5,5-dimethylhydantoin, 1,3-dichloro-5,5-dimethylhydantoin and 1,3-dichloro-5-ethyl-5-methylhydantoin, are acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment. The labels of Canadian end-use product must be revised to include the label statements listed in Appendix III. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. No additional data are being requested at this time.

6.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, *Pest Management Regulatory Agency Re-evaluation Program*, and DACO tables can be found on the Pesticides and Pest Management portion of Health Canada's website at www.healthcanada.gc.ca/pmra. 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/toxiques-toxics/.
The USEPA RED document for the halohydantoins is available on the USEPA Pesticide Reregistration Status page at www.epa.gov/pesticides/reregistration/status.htm.
The registration status on the chemicals in the European Union is available at www.eur-lex.europa.eu.
The registration status on the chemicals in Australia is available at www.apvma.gov.au.
The registration status on the chemicals in New Zealand is available at www.nzfsa.govt.nz

List of Abbreviations

a.i.	active ingredient
aPAD	acute population adjusted dose
bw	body weight
CAS	Chemical Abstracts Service
CMA	Chemical Manufacturers Association
cPAD	chronic population adjusted dose
DMH	5,5-dimethylhydantoin
EMH	5-ethyl-5-methylhydantoin
EU	European Union
FQPA	*Food Quality Protection Act*
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
LOAEL	lowest observed adverse effect level
MOE	margin of exposure
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PAD	Population Adjusted Dose
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
SF	safety factor
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
U.S.	United States
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Registered Products Containing 1-bromo-3-chloro-5,5-dimethylhydantoin, 1,3-dichloro-5,5-dimethylhydantoin and 1,3-dichloro-5-ethyl-5-methylhydantoin as of 6 October 2010

Registration Number	Marketing Type	Registrant Name	Product Name	Formulation Type	Guarantee	
16857	Commercial	BWA Water Additives US LLC	Bromicide SF For Control Of Algal, Bacterial & Fungal Slimes	Dust or Powder	1-bromo-3-chloro-5,5-dimethylhydantoin	96%
19355	Commercial	BWA Water Additives US LLC	Bromicide Tablets	Tablet	available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	28% 64%
19356	Commercial	BWA Water Additives US LLC	Bromicide Granules	Granular	available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	28% 64%
20902	Commercial	Lonza Inc.	Dantobrom RW Briquettes Microbicide	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 1,3-dichloro-5,5-dimethylhydantoin 1,3-dichloro-5-ethyl-5-methylhydantoin available bromine available chlorine	60% 27.4% 10.6% 39.2% 44.4%
21467	Commercial	GE Water And Process Technologies Canada	Spectrus OX1203	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin	96%
21591	Commercial	Nalco Canada Company	Nalco 7346	Soluble Granules	1-bromo-3-chloro-5,5-dimethylhydantoin 1,3-dichloro-5,5-dimethylhydantoin 1,3-dichloro-5-ethyl-5-methylhydantoin available bromine available chlorine	60% 27.4% 10.6% 39.2% 44.4%
22302	Commercial	Lonza Inc.	Dantobrom RW Microbicide	Tablet	1,3-dichloro-5,5-dimethylhydantoin 1,3-dichloro-5-ethyl-5-methylhydantoin minimum available chlorine	81.1% 16.1% 68%
23246	Commercial	Lonza Inc.	Dantobrom RW Canister	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 1,3-dichloro-5,5-dimethylhydantoin 1,3-dichloro-5-ethyl-5-methylhydantoin available bromine available chlorine	60% 27.4% 10.6% 39.2% 44.4%
23332	Commercial	Klenzoid Co. Ltd.	Halobriq BCD Microbicide	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin	96%
23336	Commercial	Drew Canada, Ashland Canada Corp.	Biosperse 261T Biocide	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin	96%
23561	Commercial	GE Water and Process Technologies Canada	Spectrus OX1200	Granular	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	64% 28%
23816	Commercial	Chemfil Canada Ltd.	Bromtab 417	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin	96%
23956	Commercial	Buckman Laboratories of Canada Ltd.	Bulab 6058 Liquid Microbicide	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin	96%

Registration Number	Marketing Type	Registrant Name	Product Name	Formulation Type	Guarantee
23965	Commercial	Clearon Corporation	Halogene-T Microbiocidal Bactericide	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 98%
23966	Commercial	Clearon Corporation	Halogene G Bromo-Chloro Dimethylhydanton Granules	Granular	bromochloro-5,5-dimethylhydantoin 98%
24194	Commercial	State Chemical Ltd.	Alg-Erase	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 96%
24277	Commercial	Aquarian Chemicals Inc.	Aquarian C450 Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 92.5%
24305	Commercial	Guardian Chemicals Inc.	Aquaguard 606	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 96%
24591	Commercial	Controlchem Canada Ltd.	Controlchem 2623 Bromo-Chloro-Dimethylhydantoin Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 98%
25252	Commercial	Buckman Laboratories of Canada Ltd.	Eclipse 630 Microbicide	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 94%
25261	Commercial	Lonza Inc.	Dantobrom RW Granular Microbicide	Granular	1-bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-dichloro-5,5-dimethylhydantoin 27.4% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.6% available bromine 39.2% available chlorine 44.4%
25347	Commercial	Klenzoid Co. Ltd.	Halobriq Granules	Granular	1-bromo-3-chloro-5,5-dimethylhydantoin 96%
25351	Commercial	Jacklyn Industries Inc.	WC 8317 Bromicide Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 96% available bromine 64% available chlorine 28%
25406	Commercial	Hercules Canada Inc.	Spectrum XD8800 Microbicide Agent	Granular	1-bromo-3-chloro-5,5-dimethylhydantoin 96%
25555	Commercial	Buckman Laboratories of Canada Ltd.	Eclipse 631 Microbicide	Granular	1-bromo-3-chloro-5,5-dimethylhydantoin 96%
25765	Commercial	NCH Canada Inc.	CB-3939	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-dichloro-5,5-dimethylhydantoin 27.4% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.6% available bromine 39.2% available chlorine 44.4%
25916	Commercial	IPAC Chemicals Ltd.	Ipacide LWT 928	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
26538	Commercial	Chemtreat Inc	Chemtreat C-2189T	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
26930	Commercial	IPAC Chemicals Ltd.	Ipacide LWT 938 G	Granular	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%

Registration Number	Marketing Type	Registrant Name	Product Name	Formulation Type	Guarantee	
26950	Commercial	D.H. Jutzi Limited	Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	64% 28%
26986	Commercial	Johnsondiversey Canada, Inc.	B.I.O. Blast 650	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 1,3-dichloro-5,5-dimethylhydantoin 1,3-dichloro-5-ethyl-5-methylhydantoin available bromine available chlorine	60% 27.4% 10.6% 39.2% 44.4%
27022	Commercial	NCH Canada Inc.	MB-1000 Microbiocide	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 1,3-dichloro-5,5-dimethylhydantoin 1,3-dichloro-5-ethyl-5-methylhydantoin available bromine available chlorine	60% 27.4% 10.6% 39.2% 44.4%
27065	Commercial	BWA Water Additives US LLC	Aquate Slimicide	Solution	1-bromo-3-chloro-5,5-dimethylhydantoin	40%
27236	Commercial	Nalco Canada Company	Nalco 7346 Gran	Granular	1-bromo-3-chloro-5,5-dimethylhydantoin 1,3-dichloro-5,5-dimethylhydantoin 1,3-dichloro-5-ethyl-5-methylhydantoin available bromine available chlorine	60% 27.4% 10.6% 39.2% 44.4%
27261	Commercial	Lonza Inc.	Dantochlor RW Microbicide Granular	Granular	1,3-dichloro-5,5-dimethylhydantoin 1,3-dichloro-5-ethyl-5-methylhydantoin minimum available chlorine	81.1% 16.1% 68%
27408	Commercial	Kemira Chemicals, Inc.	Redibrom T-C	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	64% 28%
27795	Commercial	Produits Chimiques Magnus Ltee	Magnatrol 49S	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	64% 28%
27900	Commercial	Johnsondiversey Canada Inc.	B.I.O. Blast 650G	Granular	1-bromo-3-chloro-5,5-dimethylhydantoin 1,3-dichloro-5,5-dimethylhydantoin 1,3-dichloro-5-ethyl-5-methylhydantoin available bromine available chlorine	60% 27.4% 10.6% 39.2% 44.4%
27918	Commercial	Buckman Laboratories of Canada Ltd.	Busan 1332 Microbicide	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	64% 28%
28062	Commercial	BWA Water Additives US LLC	Bromicide Gel	Paste	1-bromo-3-chloro-5,5-dimethylhydantoin	35%
28305	Commercial	Power Chemicals Ltd	Ipacide LWT 968 G	Paste	1-bromo-3-chloro-5,5-dimethylhydantoin	35%
28337	Commercial	Drew Canada, Ashland Canada Corp.	Biosperse 262 Slimicide	Paste	1-bromo-3-chloro-5,5-dimethylhydantoin	35%
28419	Commercial	Nalco Canada Company	Solid Oxipro	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 1,3-dichloro-5,5-dimethylhydantoin 1,3-dichloro-5-ethyl-5-methylhydantoin available bromine available chlorine	60% 27.4% 10.6% 39.2% 44.4%

Registration Number	Marketing Type	Registrant Name	Product Name	Formulation Type	Guarantee	
28420	Commercial	Produits Chimiques Magnus Ltee	Magnatrol 48A	Paste	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	23.3% 10.2%
28534	Commercial	Buckman Laboratories of Canada Ltd.	Bulab 6148 Slimicide	Paste	1-bromo-3-chloro-5,5-dimethylhydantoin	35%
28747	Commercial	Buckman Laboratories of Canada Ltd.	Bulab 6017 Microbicide	Granular	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	64% 28%
28830	Commercial	Ciba Canada Ltd.	Irgacide PT 945	Paste	1-bromo-3-chloro-5,5-dimethylhydantoin	35%
28557	Commercial	Hercules Canada Inc.	Spectrum XD8904 Microbicid	Granular	1,3-dichloro-5,5-dimethylhydantoin 1,3-dichloro-5-ethyl-5-methylhydantoin minimum available chlorine	81.1% 16.1% 68%
28558	Commercial	Hercules Canada Inc.	Spectrum XD8904W	Granular	1,3-dichloro-5,5-dimethylhydantoin 1,3-dichloro-5-ethyl-5-methylhydantoin minimum available chlorine	81.1% 16.1% 68%
29061	Commercial	Controlchem Canada Ltd	Controlchem 2624	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin	96%
29086	Commercial	Baker Petrolite Corporation	BPC 68968	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	65.0% 28.95%
29438	Commercial	Aptech Group Inc.	Durobrom	Granular	1-bromo-3-chloro-5,5-dimethylhydantoin 1,3-dichloro-5,5-dimethylhydantoin 1,3-dichloro-5-ethyl-5-methylhydantoin available bromine available chlorine	60% 27.4% 10.6% 39.2% 44.4%
20102	Domestic	Bio-Lab Canada Inc.	Bioguard Sanitizer Brominating Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	64% 28%
20102.01	Domestic	Asepsis Inc.	Proguard Brominating Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin available bromine content available chlorine content	96% 64% 28%
20103	Domestic	Asepsis Inc.	Omni Durabrome Brominating Tablets	Tablet	available bromine present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine present as 1-bromo-3-chloro-5,5-dimethylhydantoin	64% 28%
20838	Domestic	Lonza Inc.	Dantobrom P Brominating Disinfectant Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1,3-dihalogen-5,5-dialkylhydantoin	39.2% 44.4%
22322	Domestic	Hydrotech Chemical Corporation	Guardex Hydrobrome Brominating Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	64% 28%
23642	Domestic	Sani-Marc Inc.	PPP Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	64% 28%
23642.06	Domestic	Canadian Tire Corp. Ltd.	Aquarius Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	64% 28%
23643	Domestic	Sani-Marc Inc.	Bromi-Bec	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	61% 27%
23643.05	Domestic	Canadian Tire Corp. Ltd.	Aquarius Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	61% 27%
23643.06	Domestic	Sani-Marc Inc.	Clearwater Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	61% 27%

Registration Number	Marketing Type	Registrant Name	Product Name	Formulation Type	Guarantee
23643.10	Domestic	Sani-Marc Inc. D.B.A. Calypso	Calypso Brom Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 61% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 27%
23643.35	Domestic	Purity	Bromine Disc Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 61% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 27%
23682	Domestic	Clearon Corporation	Halobrom Bromine Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 92.5% Available bromine 61% Available chlorine 27%
23696	Domestic	Capo Industries Ltd.	Bromine Tablets Brominating Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 61% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 27%
23725	Domestic	Mursatt Chemicals Limited	Brom'n8 Tablets Brominating Disinfectant Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 96% available bromine 64% available chlorine 28%
24347	Domestic	Lonza Inc.	Dantobrom S Brominating Disinfectant For Spas, Hot Tubs & Pools	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-dichloro-5,5-dimethylhydantoin 27.4% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.6% available bromine 39.2% available chlorine 44.4%
24347.01	Domestic	Advantis Technologies, Inc.	Rendezvous Brominating Disinfectant Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 39.2% available chlorine, present as 1,3-dihalogen-5,5-dialkylhydantoin 44.4%
24381	Domestic	Poolsport Inc.	Poolsport Brominating Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 96% available bromine 64% available chlorine 28%
25068	Domestic	Lonza Inc.	Dantobrom TBS	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-dichloro-5,5-dimethylhydantoin 27.4% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.6% available bromine 39.2% available chlorine 44.4%
25259	Domestic	Recreational Water Products Inc.	Aqua Chem Brominating Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
25400	Domestic	Lawrason's, Inc.	Aqua Brominating Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 92.5% available bromine 61% available chlorine 27%
25402	Domestic	Emagin Leisure Concepts Inc	Clear Choice Brominating Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 92.5% available bromine 61% available chlorine 27%
25404	Domestic	Pool and Spa Chemical Company	Pool Life Brominating Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 92.5% available bromine 61% available chlorine 27%
25460	Domestic	Aqua Coastal	Aqua Coastal Brominating Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 92.5% available bromine 61% available chlorine 27%
25479	Domestic	C.L. Marketing Inc.	Tabex Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%

Registration Number	Marketing Type	Registrant Name	Product Name	Formulation Type	Guarantee
25498	Domestic	Capo Industries Ltd.	Aqua King Bromine Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 92.5% available bromine 61% available chlorine 27%
25542	Domestic	Bio-Lab Canada Inc.	Spaguard Sanitizer Brominating Tablets For Spas	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
26175	Domestic	Capo Industries Ltd.	Spaboss Brominating Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 94% available bromine content 61% available chlorine content 27%
26272	Domestic	Capo Industries Ltd. D.B.A. Pool Chemical Industries	Spachem Brominating Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 94% available bromine content 61% available chlorine content 27%
26397	Domestic	Mursatt Chemicals Limited	Brominating Tablets For Spas and Hot Tubs	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 96% available bromine content 64% available chlorine content 28%
26432	Domestic	C.L. Marketing Inc.	Foxxx Brom-A-Gard Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
26555	Domestic	Hydrotech Chemical Corporation	Spa Essentials Brominating Tablets For Spas & Hot Tubs	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
26558	Domestic	Recreational Water Products Inc.	Aqua Chem Clear & Simple Brominating Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
26566	Domestic	Lonza Inc.	Dantobrom Tbs-2 Sanitizer	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 57% 1,3-dichloro-5,5-dimethylhydantoin 26% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.1% available bromine 37.2% available chlorine 42.2%
26567	Domestic	Lonza Inc.	Dantobrom TBS-2.5 Sanitizer	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 57% 1,3-dichloro-5,5-dimethylhydantoin 26% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.1% available bromine 37.2% available chlorine 42.2%
26568	Domestic	Mursatt Chemicals Limited	Brom'n 8 Super Tabs Brominating Disinfectant Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 96% available bromine 64% available chlorine 28%
26573	Domestic	Asepsis Inc.	Omni Brominating Tablets For Spas & Hot Tubs	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
27037	Domestic	Arctic Spas	Arctic Pure Brominating Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 94% available bromine content 61% available chlorine content 27%
27255	Domestic	Sani-Marc Inc.	SM Brom	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 66% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 29%

Registration Number	Marketing Type	Registrant Name	Product Name	Formulation Type	Guarantee
27499	Domestic	Sani-Marc Inc. D.B.A. Calypso	Calypso Spa Bromine 16	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 61% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 27%
27500	Domestic	Sani-Marc Inc.	Spa Bromine Sanitizer Brominating Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 66% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 29%
27501	Domestic	Sani-Marc Inc.	Spa Brom	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 61% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 27%
27502	Domestic	Sani-Marc Inc. D.B.A. Perfect Logic	Perfect Logic Spa Bromine	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
27590	Domestic	I.P.G/G.P.I Independent Pool Group Inc	Aquapro Spa Bromine	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 94% Available bromine content 62.4% Available chlorine content 25%
27591	Domestic	Beachcomber Hot Tubs Plus Inc.	Bromine Disc	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 94% Available bromine content 62.4% Available chlorine content 25%
27623	Domestic	I.P.G/G.P.I Independent Pool Group Inc	Aquapro Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 66% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 29%
27693	Domestic	RBF International Ltee	Solutions Spa Bromo Tab	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
27698	Domestic	RBF International Ltee	Sparadise Brome Tab	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
27699	Domestic	Les Piscine Trévi Inc.	Trevinergy Brome Tablets 1	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
27729	Domestic	Lawrason's, Inc.	Spa Life Brominating Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-dichloro-5,5-dimethylhydantoin 27.4% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.6% available bromine 39.2% available chlorine 44.4%
27730	Domestic	Pool and Spa Chemical Company	Spa Pure Brominating Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-dichloro-5,5-dimethylhydantoin 27.4% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.6% available bromine 39.2% available chlorine 44.4%
27765	Domestic	Housechem Inc.	No Name Long-Lasting Bleach Tab Automatic Toilet Bowl Cleaner	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-dichloro-5,5-dimethylhydantoin 27.4% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.6% available bromine 39.2% available chlorine 44.4%
27869	Domestic	Arch Chemicals, Inc	Brilliance For Spas Bromine Tabs	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-dichloro-5,5-dimethylhydantoin 27.4% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.6% available bromine 39.2% available chlorine 44.4%

Registration Number	Marketing Type	Registrant Name	Product Name	Formulation Type	Guarantee
27870	Domestic	Arch Chemicals, Inc	Spacare Bromine Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-dichloro-5,5-dimethylhydantoin 27.4% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.6% available bromine 39.2% available chlorine 44.4%
27877	Domestic	Sani-Marc Inc. D.B.A. Calypso	Calypso Brom Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 66% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 29%
27880	Domestic	King Technology Inc.	Spa Frog Bromine Cartridge	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
27881	Domestic	Canadian Tire Corp. Ltd.	Aquarius Spa Bromine	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 94% available bromine content 62.4% available chlorine content 25%
28059	Domestic	Reckitt Benckiser Canada Inc.	Lysol Brand Continuous Action Toilet Bowl Cleaner	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-dichloro-5,5-dimethylhydantoin 27.4% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.6% available bromine 39.2% available chlorine 44.4%
28068	Domestic	Catalina Spas	Catalina Spas Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
28180	Domestic	I.P.G/G.P.I Independent Pool Group Inc	Aquapro Bromine Plus	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 39.2% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 44.4%
28186	Domestic	Purity	Bromine Disc	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 66% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 29%
28255	Domestic	RBF International Ltee	Rona Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 66% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 29%
28333	Domestic	Sani-Marc Inc. D.B.A. Calypso	Brom Plus	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 39.2% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 44.4%
28334	Domestic	Groupe D'achat M.P. Inc.	Pisci-Brom Super	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 39.2% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 44.4%
28335	Domestic	Sani-Marc Inc.	Extra Brom	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 39.2% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 44.4%
28476	Domestic	Poolsport Inc.	Poolsport Brominating Super-Tabs	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
28586	Domestic	Lorchem Industries Inc.	Spas Atlantic Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64.9% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28.2%
28587	Domestic	Canada Spas Depot	Canada Spas Depot Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
28845	Domestic	Housechem Inc.	No Name Long-Lasting Bleach Tab Automatic Toilet Bowl Cleaner I	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-dichloro-5,5-dimethylhydantoin 27.4% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.6% available bromine 39.2% available chlorine 44.4%
29097	Domestic	Backyard Brands Inc.	Dazzle Bromine Tablets For Pools	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 66% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 29%

Registration Number	Marketing Type	Registrant Name	Product Name	Formulation Type	Guarantee
29108	Domestic	Backyard Brands Inc.	Dazzle Spa Bromine Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 61% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 27%
29112	Domestic	Reckitt Benckiser Canada Inc.	Lysol Brand Power Plus Toilet Bowl Cleaner	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-dichloro-5,5-dimethylhydantoin 27.4% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.6% available bromine 39.2% available chlorine 44.4%
29135	Domestic	RBF International Ltee	Coral Brome Tab	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
29136	Domestic	RBF International Ltee	Atlantis Bromo-Tab	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
29148	Domestic	Alliance Trading Inc.	E-Z Clor Brominating Tablets	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 61% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 27%
29170	Domestic	RBF International Ltee	Coral Bromine Tab	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
29171	Domestic	RBF International Ltee	Atlantis Mini Brome Tab	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28%
29492	Domestic	Sun Ray Manufacturing	Sun Rays Spas Brominating Tables	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 64..9% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 28.2%
29649	Domestic	Chimes International Inc.	Elite Bromine	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 61% available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin 27%
29879	Domestic	Club Piscine	Bromine Tab	Tablet	
19357	Manufacturing concentrate	Bio-Lab Incorporated	Dihalo Tablets	Tablet	1-bromo-3-chloro-5,5-dimethylhydantoin 96% available bromine 64% available chlorine 28%
25150	Manufacturing concentrate	Bio-Lab Incorporated	Dihalo Granular (For Manufacturing, Repacking And Formulating)	Granular	1-bromo-3-chloro-5,5-dimethylhydantoin 96% available bromine 64% available chlorine 28%
18674	Technical	Lonza Inc.	Lonza Glychlor Powder	Dust or Powder	1,3-dichloro-5,5-dimethylhydantoin 97% Available chlorine 69.2%
19358	Technical	Bio-Lab Incorporated	Dihalo Technical	Dust or Powder	1-bromo-3-chloro-5,5-dimethylhydantoin 96% available bromine 64% available chlorine 28%
20901	Technical	Lonza Inc.	Dantobrom	Not Available	1-bromo-3-chloro-5,5-dimethylhydantoin 60% 1,3-dichloro-5,5-dimethylhydantoin 27.4% 1,3-dichloro-5-ethyl-5-methylhydantoin 10.6% available bromine 39.2% available chlorine 44.4%
22301	Technical	Lonza Inc.	Dantochlor Technical	Soluble Powder	1,3-dichloro-5,5-dimethylhydantoin 81.1% 1,3-dichloro-5-ethyl-5-methylhydantoin 16.1% Available chlorine 68%
23638	Technical	Bromine Compounds Ltd.	Halobrom Technical Microbicide	Granular	Available bromine present as bromo/chloro-5,5-dimethylhydantoin 65% Available chlorine present as bromo/chloro-5,5-dimethylhydantoin 28.95%

Registration Number	Marketing Type	Registrant Name	Product Name	Formulation Type	Guarantee	
28416	Technical	Sani-Marc Inc.	Sani-Marc Bcdmh	Soluble Granules	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	61% 27%
28624	Technical	Sani-Marc Inc.	Sani-Marc Bromine	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	66% 29%
29179	Technical	Cambrian Chemicals Inc.	Cambrex Bcdmh Tabs	Tablet	available bromine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin available chlorine, present as 1-bromo-3-chloro-5,5-dimethylhydantoin	65.6% 27.6%

Appendix II Toxicological Endpoints Selected by the USEPA for the Halohydantoin Residential and Occupational Risk Assessments

Exposure Scenario	Dose Used in Risk Assessment (mg/kg bw/day)	Study	Toxicological Effects	MOE [a]
DIETARY				
Acute dietary – Female 13-50 years of age	NOAEL = 100	Developmental toxicity – Rabbit	LOAEL = 500 mg/kg/day based on skeletal variations	UF = 100 fold FQPA = 1 fold aPAD = 1 mg/kg/day
Chronic dietary – All populations	NOAEL = 300	Chronic toxicity / carcinogenicity – Rats	LOAEL = 1000 mg/kg/day based on decreased/gained body weight and lymph node hyperplasia	UF = 100 fold FQPA = 1 fold cPAD = 3 mg/kg/day
Chronic dietary – Females 13-50 years of age	NOAEL = 100	Developmental toxicity – Rabbit	LOAEL = 500 mg/kg/day based on skeletal variations	UF = 100 fold FQPA = 1 fold cPAD = 1 mg/kg/day
RESIDENTIAL				
Short-Term Oral (1-30 days) – Incidental	Oral NOAEL = 500	Developmental toxicity – Rabbit	LOAEL = 1000 mg/kg/day based on decreased body weight gain in maternal rabbits.	MOE = 100 (UF = 100 fold; FQPA = 1 fold)
Intermediate-Term Oral (1 to 6 months) – Incidental	Oral NOAEL = 300	Subchronic oral toxicity – Rat	LOAEL = 1000 mg/kg/day based on decreased body weight and liver weight.	MOE = 100 (UF = 100 fold; FQPA = 1 fold)
Dermal – All time periods (short-, intermediate and long-term)	Dermal NOAEL = 390 (highest dose tested)	Subchronic dermal toxicity – Rat	No systemic toxicity at the highest dose tested.	MOE = 100 (UF = 100 fold; FQPA = 1 fold)
Short-Term Inhalation (1-7 days)	Oral NOAEL = 100 (inhalation absorption rate = 100%)	Developmental toxicity – Rabbit	LOAEL = 500 mg/kg/day based on skeletal effects on offsprings	MOE = 100 (UF = 100 fold; FQPA = 1 fold)
OCCUPATIONAL				
Dermal – All time periods (short-, intermediate and long-term)	Dermal NOAEL = 390 (highest dose tested)	Subchronic dermal toxicity – Rat	No systemic toxicity at the highest dose tested.	MOE = 100 (UF = 100 fold)
Short-Term Inhalation (1-7 days)	Oral NOAEL = 100 (inhalation absorption rate = 100%)	Developmental toxicity – Rabbit	LOAEL = 500 mg/kg/day based on skeletal effects on offsprings	MOE = 100 (UF = 100 fold)

[a] MOE refers to desired margin of exposure for occupational or residential assessments (100 fold = 10 fold for interspecies and 10 fold for intraspecies variabilities) and the FQPA safety factor of 1 fold was considered for the residential assessments.

NOAEL: No Observed Adverse Effect Level

LOAEL: Low Observed Adverse Effect Level

Appendix III Label Amendments for Products Containing 1-bromo-3 chloro-5,5-dimethylhydantoin, 1,3-dichloro-5,5-dimethylhydantoin and 1,3-dichloro-5-ethyl-5-methylhydantoin

The label amendments presented below do not include all label requirements for individual end-use products, 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 label statements below.

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

The labels of the Canadian products containing 1-bromo-3 chloro-5,5-dimethylhydantoin, 1,3-dichloro-5,5-dimethylhydantoin and 1,3-dichloro-5-ethyl-5-methylhydantoin must be revised to include the following statements to further protect workers, bystanders and the environment.

I) Add to the primary display panel of all products:

DANGER – CORROSIVE TO EYES AND SKIN

POTENTIAL SKIN SENSITIZER

II) Add to **TOXICOLOGICAL INFORMATION** of all products:

This product is corrosive to skin and eyes and may produce a sensitization response or allergic reaction in some individuals.

III) Add to **FIRST AID** of all products:

If irritation or other adverse effects develop, wash with soap and water immediately. Seek medical attention if symptoms persist.

IV) Add to **PRECAUTIONS**:

For all commercial end-use products:

Wear long pants, a long-sleeved shirt, chemical-resistant gloves and goggles or a face-shield while cleaning equipment and handling product.

For all commercial end-use products registered for pulp and paper uses:

Wear coveralls over long pants and a long-sleeved shirt, chemical-resistant gloves, and goggles or a face-shield while cleaning equipment and handling product.

For all the domestic end-use products:

It is recommended to wear rubber gloves and goggles when handling the product.

V) Add to the **DIRECTIONS FOR USE**, unless a 'no objection status' was issued by the Health Canada's Bureau of Chemical Safety:

For all the commercial end-use products registered for pulp and paper:

DO NOT use this product in the production of paper or paperboard that will come into contact with food.

For the commercial end-use product registered for the cannery industry:

DO NOT use this product in the production of cans that will come into contact with food.

VI) Add to the **DIRECTIONS FOR USE**:

For all the end-use products:

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposable of wastes.

For all the commercial end-use products:

DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

For all the domestic end-use products:

DO NOT apply to any body of water.

References

A. Information Considered for the Chemistry Assessment Studies/Information Submitted By Applicant/Registrant (Unpublished)

PMRA Document Number: 1754929
Reference: 1995, BCD-GLL-1 Product Chemistry for Bromicide, Bromo-Tabs, DiHalo, DACO: 2.1, 2.10, 2.11, 2.12, 2.13, 2.14, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9

PMRA Document Number: 1472609
Reference: 1988, Halobrom - Product Identity, Chemical and Physical Properties and Storage Stability, DACO: 2.1, 2.10, 2.14.1, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.16, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9

PMRA Document Number: 1134744
Reference: 2. 0 Chemistry information, DACO: 2.1, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13.1, 2.13.2, 2.13.3, 2.13.4,2.14,2.16,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9

PMRA Document Number: 1074208
Reference: Chemistry Information, DACO: 2.1, 2.11, 2.12, 2.13, 2.14, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9

PMRA Document Number: 1402557
Reference: 2007, Cambrian Chemicals Inc, Chemisty Requirement for a TGAI, DACO: 2.0, 2.1, 2.10, 2.11, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.12.2, 2.13, 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.15

PMRA Document Number: 1472789
Reference: 1994, Halobrom (BCDMH) - Outstanding Product Chemistry Questions. UV-VIS Spectrum, Analysis of Halobrom by 1H-NMR, A Search for Impurities, Analysis of Halobrom by Reduction to Dimethylhydantoin, Abstract, Analyses of Ten Production Batches, Analytical Method

PMRA Document Number: 1395935
Reference: 2007, Analytical Profile of Five Batches, DACO: 2.13.1, 2.13.2, 2.13.3, 2.13.4

PMRA Document Number: 1395936
Reference: 2007, Analytical Profile of Five Batches, DACO: 2.13.1, 2.13.2, 2.13.3, 2.13.4

PMRA Document Number: 1134627
Reference: 2004, Revision: Common name, Discussion of formation of purities, confirmation of identity, batch data, certificate of analysis., DACO: 2.11.4, 2.13.2, 2.13.3, 2.4

PMRA Document Number: 1304462
Reference: 2006, Sani-Marc Bromine, sub # 2005-1297 - Response to Clarification Request [of 2006-07-31], DACO: 2.13.1, 2.13.3

PMRA Document Number: 1402557
Reference: 2007, Cambrian Chemicals Inc, Chemisty Requirement for a TGAI, DACO: 2.0, 2.1,2.10, 2.11, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.12.2, 2.13, 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.15

PMRA Document Number: 1582870
Reference: 2008, Required Clarification, DACO: 2.13.3

PMRA Document Number: 1793970
Reference: DDJ-LOZ-4 Preliminary Analysis of Glychlor (6836-1 09) and Dantochlor (6836-1 14).

PMRA Document Number: 1737816
Reference: DDH-LOZ-4 Chemistry for Glychlor Powder. Manufacturing method, Specifications, Quality Control Method, Analytical data and methodology, Chemical and Physical Properties.

PMRA Document Number: 1663280
Reference: Chemistry data used to support a technical class product (BCD/DDH/DDM-LOZ-4).

PMRA Document Number: 1793897
Reference: DDJ-LOZ-4 Product Chemistry for Dantochlor. Manufacturing Methods, Specifications, Quality Control, Analytical Data and Methodology, Chemical and Physical Properties and Infrared.

PMRA Document Number: 1793968
Reference: DDJ-LOZ-4 Nominal Concentration and Certified Limits for Dantochlor, EPA Reg. No. 6836-114 and Dantochlor RW, EP Reg. No. 6836-113 and Spec Form.