

Evaluation Report for Category B.2.1 Application

Application Number: 2011-1658
Application: New EP product Chemistry: Guarantee
Product: Isis Bromine Generator For Spa Sanitizing
Registration Number: 30525
Active ingredients (a.i.): Bromine Generating Device
PMRA Document Number: 2223748

Purpose of Application

The purpose of this category B.2.1.-S-N-EP submission is to register a new domestic bromine generator device, ISIS Automatic Bromine Generator for Spa Sanitizing, as an algaecide / bactericide for spa water. The use site category (USC) is 29 – Swimming Pools.

Chemistry Assessment

No chemistry assessment was required for this application.

Health Assessments

Bromine generator type spa devices have been registered and used in Canada for many years including similar devices previously registered by the current registrant. The electrolytic cell in the ISIS Bromine Generator for Spa Sanitizing uses similar components as the electrolytic cell in a previously registered device from the same registrant, the Genesis Automatic Bromine Generator for Spa Sanitizing (Reg. No. 27890). The recommended minimum levels of free available bromine for spas treated by the device are the same as for the previously registered devices and correspond to Health Canada recommended minimum levels of spa sanitizers. While the ISIS Automatic Bromine Generator is capable of generating more bromine than previously registered devices, the recommended concentrations of sodium bromide to be used with the device and the levels of other spa parameters (e.g., pH, total alkalinity, calcium hardness, etc.) are similar to those for the previously registered devices.

The likelihood of exposure to water treated by the devices during the installation, operation, and maintenance of the devices is low. Limited dermal exposure could occur when the pool water is tested for free bromine, bromide and other parameters. Recreational users of pools (i.e., bathers) could have dermal exposure to treated pool water for varying periods of time and oral exposure through accidental ingestion of small amounts of water.

Given the history of the registration and use of these types of devices, the fact that the proposed device uses the same electrolytic cell components and has very similar operating parameters to previously registered devices from the same applicant, it is not expected that the installation, operation or maintenance of the proposed device or recreational use of water treated by it will increase exposures to free bromine, sodium bromide, bromination by-products or other parameters compared to similar exposures from the use of the previously registered devices. Consequently, a quantitative exposure assessment is not required, and the potential risks to human health from the installation, operation, and maintenance of the devices or recreational use of water treated by the devices are not expected to be of concern.

Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the PMRA website. Incidents from Canada were searched and reviewed for spa bromination devices.

As of March 22, 2012, there have been no incidents reported for spa bromination devices in Canada. A search of the California Department of Pesticide Regulation Pesticide Illness Surveillance Program identified one report of respiratory and skin problems in a security guard exposed to three different pesticides including bromine in bathroom premises, various structures, and swimming pool water systems. The report was not related to a bromination device and the relationship between the pesticide exposure and the effects was classified as probable due to the limited or circumstantial evidence available.

Environmental Assessment

No environmental assessment was required for this application.

Value Assessment

Efficacy data was submitted to confirm the daily free available bromine output of the ISIS Bromine Generator for Spa Sanitizing. The maximum free available bromine generated per day is sufficient (0.04 kg/day), based on the maximum spa volume stated on the label (1 900 L), to provide free available bromine residuals within the recommended 3-5 ppm range. The use of ISIS Bromine Generator for Spa Sanitizing for use in domestic spas is acceptable.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of information available in support of Isis Bromine Generator For Spa Sanitizing and has found the information sufficient to register the new domestic bromine generator device as an algaecide/bactericide for spa water.

References

PMRA Document Number	Reference
1778925	2009, Attestation de conformite UL aux normes de securite electrique canadienne, DACO: 0.8.9,10.6
2041755	2009, INSPECTION, TESTS AND EVALUATION OF A BROMINE GENERATOR, DACO: 2.12 CBI
2041757	2011, CISPR 14-1 (Ed.5) 2005 (EN55014-1: 2006) IEC 61000-3-2 (Ed. 3) 2005 +A1,A2 (EN 6100-3-2:2006) IEC 61000-3-3 (Ed. 2) 2008 (EN 61000-3-3: 1995 +A1:2001 +A2:2005), DACO: 2.12 CBI
2041758	CISPR 14-2 Ed 1.2 2008 (EN 55014-2/A2: 2008) – Electromagnetic compatibility – Requirements for household Appliances, electric tools and similar apparatus Part 2: Immunity – Product family standard, DACO: 2.12 CBI
2041759	2010, Determination of free bromine output of Pioneer H2O Technologies, Inc., Genesis II bromination unit., DACO: 10.2.3.4
2172326	WHO, 2006, Guidelines for Safe Recreational Water Environments, Volume 2: Swimming Pools and Similar Environments, Chapter 4 Chemical Hazards, DACO: 5.2_DOC
2172376	Health Canada, 1999, Bromate, Guidelines for Canadian Drinking Water Quality, DACO: 5.2_DOC

Additional Information considered:

Published

PMRA Document Number	Reference
2172864	EMA, 1997, Committee for Veterinary Medicinal Products Bromide, Sodium Salt Summary Report, DACO: 12.5
2172882	US EPA, 1993, Reregistration Eligibility Decision Bromine List D Case 4015, DACO: 12.5
2173012	WHO, 2011, Guidelines for Drinking-Water Quality Fourth Edition, DACO: 12.5
2173092	Health Canada, 2009, Trihalomethanes, Guidelines for Canadian Drinking Water Quality Guideline Technical Document, DACO: 4.8
2173207	Lehmann, G. and Knoefel, P.K., 1938, Trichloethanol, tribromethanol, chloral hydrate and bromal hydrate, J. Pharmacol. Exptl. Therap. 63: 453-465, DACO: 12.5

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