

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2009-1199
Application: B.2.1 - New / Changes EP or MA Product Chemistry-Guarantee
Product: In. Clear
Registration Number: 29628
Active ingredients (a.i.): Device [ZZZ]
PMRA Document Number: 1868872

Purpose of Application

The purpose of this application is to register a new spa bromine generating devise, In. Clear, for domestic use.

Chemistry and Environmental Assessment

No chemistry or environmental assessments were required for this application.

Health Assessments

Since similar bromine generating devices are currently registered in Canada and no increased exposure is expected to result from this device, no toxicology data were required.

Value Assessment

Efficacy data was submitted to confirm the daily free available bromine output of the In Clear bromine generating device. The maximum free available bromine generated per day is sufficient (0.04 kg/day), based on the maximum spa volume stated on the label (2 000 L), to provide free available bromine residuals within the recommended 3-5 ppm range. The use of In Clear bromine generating device for use in domestic spas is acceptable.

Conclusion

Following the assessment of all available data, the PMRA is able to support the registration of this application.

References

Applicant Submitted Information

PMRA Number	Document	Reference
1740562		10.6 CSA/UL Approval Letters
1778925		10.6 Attestation de conformite UL aux normes de securite electrique canadienne
1778931		10.2.3.1, Efficacy Trial Summary and Protocol
1778932		10.2.3.2, Efficacy Trial Raw Data
1791396 1740561		10.6 CSA IPI Inspection Approval 2009, Correspondance - Etude Prealable - 21 janvier 2009.pdf, DACO : 0.8

Additional Information

- 1460765 1983, Internation Symposium of Residues and Toxicity of BromideL
Summary and Conclusions, DACO: 0.8.24
- 867921 2004, Tox input to PACR, Program 1 Re-evaluation of Sodium
bromide

DIR93-05, Regulatory directive: Scheduling of Selected Pool and Spa Chemicals, February 18, 1993

Joint Meeting on Pesticide Residues (1988). Bromide ion (pesticide residues in food: 1988 evaluations Part II Toxicology).

European Agency for the Evaluation of Medicinal Products (1997). Summary report on sodium bromide. EMEA/MRL/182/97-FINAL, March 1997.

World Health Organization (2000). Guidelines for safe recreational-water environments. Final draft for consultation. Vol. II: Swimming pools, spas, and similar recreational-water environments.

World Health Organization (2000). Disinfectants and disinfectant by-products (Environmental Health Criteria 216).

Klinefelter et al. (2000). Reproductive and developmental toxicity associated with disinfection by-products of drinking water. In: Health Effects and Management of Risks. U.S. Environmental Protection Agency, USA. pp. 309-323

Poisoning & drug overdose By Kent R. Olson Edition: 4 - 2004 - pp. 140

<http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/trihalomethanes/addendum-eng.php>

<http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/bromate/index-eng.php>

Nachum Vaiseman, Gideon Koren, and Paul Pencharz, (1986) Pharmacokinetics of oral and intravenous bromide in normal volunteers. CLINICAL TOXICOLOGY, 24 (5), 403-413

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