



Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2010-4632
Application: New product chemistry: guarantee
Product: ClearBlue
Registration Number: 29954
Active ingredient (a.i.): Device, no guarantee required
PMRA Document Number: 2465123

Purpose of Application

The purpose of this application was to register a new device that releases copper ions into swimming pools, spas and hot tubs to help prevent algae growth.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessment

The concentrations of copper ions and other ions and elements in pool, spa and hot tub water resulting from the use of the device are expected to be very low. Consequently, occupational and bystander exposures to these ions and elements from the installation, operation, and/or maintenance of the device or from bathing in or accidentally ingesting pool, spa, and/or hot tub water treated by the device are also expected to be very low.

Based on a consideration of these very low exposures and a review of published toxicity information and drinking water guidelines and standards, the risk of human health effects from the copper ions and other ions and elements released from the device into pool, spa and hot tub water is expected to be not of concern.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

An efficacy test was carried out to demonstrate the ClearBlue copper output. The trial was done with triplicate tests. The device can generate a maximum of 6.74 grams of copper per day and the maximum pool/spa volume which can be treated with one ClearBlue is 151,400 L in order to obtain 0.2-0.4 ppm of copper ions in the pool water. Therefore, the claim that ClearBlue helps prevent algae growth in swimming pool and spa waters is supported and the use of the device in commercial pools and spas is acceptable.

Conclusion

The PMRA conducted an evaluation of the subject application and determined there was sufficient information to support full registration of ClearBlue.

References

List of studies/information submitted by registrant

PMRA Document Number: 1448470

Reference: 2007, Copper output test results, Data Numbering Code: 3.5.15 Confidential Business Information

PMRA Document Number: 1448471

Reference: 2010, Additional information on efficacy and value, Data Numbering Code: 10.2.2, 10.2.3, 10.6

PMRA Document Number: 1960552

Reference: 2010, CSA International certificate of compliance, Data Numbering Code: 10.6

Additional information considered

PMRA Document Number: 1979094

Reference: Agency for Toxic Substances and Disease Registry, 2005, Toxicological profile for zinc, <http://www.atsdr.cdc.gov/ToxProfiles/tp60.pdf>, Data Numbering Code: 12.5

PMRA Document Number: 1979096

Reference: Agency for Toxic Substances and Disease Registry, 2005, Toxicological profile for tin and tin compounds, <http://www.atsdr.cdc.gov/ToxProfiles/tp55.pdf>, Data Numbering Code: 12.5

PMRA Document Number: 1979099

Reference: Agency for Toxic Substances and Disease Registry, 2004, Toxicological profile copper, <http://www.atsdr.cdc.gov/ToxProfiles/tp132.pdf>, Data Numbering Code: 12.5

PMRA Document Number: 1979109

Reference: Agency for Toxic Substances and Disease Registry, 1990, Toxicological profile for silver, <http://www.atsdr.cdc.gov/ToxProfiles/tp146.pdf>, Data Numbering Code: 12.5

PMRA Document Number: 1979112

Reference: Drake PL, Hazelwood KJ, 2005, Exposure-related health effects of silver and silver compounds: A review, *Ann Occup Hyg* 49(7): 575-585, Data Numbering Code: 12.5

PMRA Document Number: 1979117

Reference: Boreiko CH, 2010, Overview of health risk assessments for zinc, *Journal of Toxicology and Environmental Health, Part A*, 73:166-174, Data Numbering Code: 12.5

PMRA Document Number: 1979118

Reference: Health Canada, 2008, Guidelines for Canadian drinking water quality summary table, Data Numbering Code: 4.8

PMRA Document Number: 1979151

Reference: United States Environmental Protection Agency, 2009, National primary drinking water regulations, EPA 816-F-09-004, <http://www.epa.gov/safewater/>, Data Numbering Code: 12.5

PMRA Document Number: 1979166

Reference: World Health Organization, 2008, Guidelines for drinking-water quality, Third edition, Incorporating the first and second addenda, Volume 1 recommendations, http://www.who.int/water_sanitation_health/dwq/fulltext.pdf, Data Numbering Code: 12.5

PMRA Document Number: 1979174

Reference: World Health Organization, 1998, Environmental Health Criteria 200: Copper, <http://www.inchem.org/documents/ehc/ehc/ehc200.htm>, Data Numbering Code: 12.5

PMRA Document Number: 1979181

Reference: World Health Organization, 1998, Environmental Health Criteria 221: Zinc, <http://www.inchem.org/documents/ehc/ehc/ehc221.htm>, Data Numbering Code: 12.5

PMRA Document Number: 1979185

Reference: Health Canada, 1992, Guidelines for Canadian drinking water quality: Copper-cuivre, http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/water-eau/copper-cuivre/copper-cuivre-eng.pdf, Data Numbering Code: 4.8

PMRA Document Number: 1979196

Reference: Health Canada, 1986, Guidelines for Canadian drinking water quality: Silver-argent, http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/water-eau/silver-argent/silver-argent-eng.pdf, Data Numbering Code: 4.8

PMRA Document Number: 1979201

Reference: Health Canada, 1987, Guidelines for Canadian drinking water quality: Zinc, http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/water-eau/zinc/zinc-eng.pdf, Data Numbering Code: 4.8

PMRA Document Number: 1979210

Reference: European Commission, 2000, IUCLID dataset: Silver, <http://ecb.jrc.ec.europa.eu/iuclid-datasheet/7440224.pdf>, Data Numbering Code: 12.5

PMRA Document Number: 1979227

Reference: Stern BR, 2010, Essentiality and toxicity in copper health risk assessment: Overview, update and regulatory considerations, Journal of Toxicology and Environmental Health, part A, 73: 114-127, Data Numbering Code: 12.5

PMRA Document Number: 1979246

Reference: Health Canada, 2005, Dietary reference intakes definitions, Cat. H44-87/2005E-PDF, ISBN 0-662-41133-1, http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/nutrition/dri_tables-eng.pdf, Data Numbering Code: 4.8

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