

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2011-1380
Application: B.2.1 – New EP Product Chemistry
Product: Nature² Vision Pro
Registration Number: 30480
Active ingredients (a.i.): Device, no guarantee required
PMRA Document Number: 2200522

Purpose of Application

The purpose of this application was to register the device Nature² Vision Pro with a chlorine feeder and mineral cartridge which generates chlorine to control bacteria and algae in swimming pool and spa water.

Health Assessments

The concentration of chlorine generated by the Nature² Vision Pro is within the range of other currently registered pool devices. The concentrations of copper and silver ions in pool water resulting from the use of the device are expected to be very low. Based on a review of published toxicity information as well as drinking water guidelines and standards, these levels do not exceed a level that would be of concern to human health. Furthermore, 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 water treated by the device are also expected to be very low. Therefore, the risk of human health effects from the copper and silver ions released from this device is expected to be not of concern.

Value Assessment

No efficacy trials were required as the device is made of a cartridge identical to a precedent product Vision Purifier for Vinyl Lined Pools (PCP# 24575) and of a chlorine feeder. Therefore, the use of Nature² Vision Pro for use in domestic swimming pools is acceptable.

Conclusion

The PMRA conducted an evaluation of the subject application and determined there was sufficient information to support registration of Nature² Vision Pro.

References

A. List of Studies/Information Submitted by Registrant

- 2069397 clarification for Nature 2 Subs 2011-1372/80/87, DACO: 10.6
- 2032681 Fusion Inground Vessel Assembly Drawing, DACO: 10.6,4.8 CBI
- 2032684 Media Production and Blending Procedures, DACO: 10.6,4.8 CBI
- 2032685 Fusion 130 cartridge Assembly Drawing, DACO: 10.6,4.8 CBI
- 2032686 ZPCI.RawMtl.Spec.W14030, DACO: 10.6,4.8 CBI
- 2032687 ZPCI.RawMtl.Spec.W14038., DACO: 10.6,4.8 CBI
- 2032689 ZPSI.RawMtl.Spec.W14015., DACO: 10.6,4.8 CBI
- 2032690 Fusion Inground IO manual, DACO: 5.2
- 2032691 Fusion DuoClear Comparison, DACO: 10.6 CBI
- 2069395 clarification for Nature² Subs 2011-1372/80/87, DACO: 10.6

B. Additional Information Considered

i) Published Information

- 1979099 Toxicological Profile for Copper. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service Agency for Toxic Substances and Disease Registry August 2004, DACO: 12.5
- 1979109 Toxicological Profile for silver. Agency for Toxic Substances and Disease Registry U.S. Public Health Service December 1990, DACO: 12.5
- 1979112 Drake, P.L., and Hazelwood, K.J., 2005, Exposure-Related Health Effects of Silver and Silver Compounds: A Review, Ann. occup. Hyg., Vol. 49, No. 7, pp. 575-585, 2005, DACO: 12.5
- 1979151 National Primary Drinking Water Regulations. US EPA 816-F-09-004, May 2009, <http://www.epa.gov/safewater/>, DACO: 12.5
- 1979166 Guidelines for Drinking-water Quality THIRD EDITION INCORPORATING THE FIRST AND SECOND ADDENDA Volume 1 Recommendations Geneva 2008, Guidelines for drinking-water quality [electronic resource]:incorporating 1st and 2nd addenda, Vol.1, Recommendations. – 3
- 1979174 INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY, ENVIRONMENTAL HEALTH CRITERIA 200, COPPER, GENEVA, 1998, DACO: 12.5
- 1979185 Copper (02/92)- Cuivre January 1979 (Updated February 1992), DACO: 4.8
- 1979196 Silver-argent, April 1979 (Updated September 1986),, DACO: 4.8
- 1979210 2000, Zinc, January 1979 (Updated November 1987), IUCLID silver 2000.pdf, DACO: 12.5
- 1979246 Dietary Reference Intakes Definitions. Cat. H44-87/2005E-PDF ISBN 0-662-41133-1, DACO: 4.8

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