



## Evaluation Report for Category B, Subcategory 2.1 Application

**Application Number:** 2011-1387  
**Application:** B.2.1 – New EP Chemistry  
**Product:** Nature<sup>2</sup> Fusion Soft  
**Registration Number:** 30481  
**Active ingredients (a.i.):** Device, no guarantee required  
**PMRA Document Number :** 220959

### Purpose of Application

The purpose of this application was to register the device Nature<sup>2</sup> Fusion Soft with a chlorine feeder and mineral cartridge which generates chlorine to control bacteria and algae in swimming pool and spa water.

### Health Assessment

The concentration of chlorine generated by the Nature<sup>2</sup> Fusion Soft 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

Efficacy laboratory trials were not provided in the data package as Nature<sup>2</sup> Fusion Soft is based on precedent products Apurem with PLC1400 Cell (PCP# 28193) for the device and Duoclear 130 (PCP# 28214) for the cartridge. The device can generate a maximum of 600 grams FAC per day and the maximum pool volume which can be treated with one Nature<sup>2</sup> Fusion Soft is 113,600 L. Therefore, the use of Nature<sup>2</sup> Fusion Soft 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 Nature<sup>2</sup> Fusion Soft.

## References

### A. List of Studies/Information Submitted by Registrant

- 2033339 Justification to use Data from PMRA Registered Product 28193 and 28214 for Nature2 Fusion Soft 1400., DACO: 10.6
- 2033335 3184719MPK-001, DACO: 10.6
- 2069395 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 Nature<sup>2</sup> 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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