Proposed Registration Decision PRD2011-09

# Dolphin WaterCare

*(publié aussi en français)*

**11 August 2011**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2011-9E (print version)
H113-9/2011-9E-PDF (PDF version)

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# Overview

## Proposed Registration Decision for Dolphin WaterCare

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of the Dolphin WaterCare, which generates pulsed electromagnetic fields, to inhibit the bacterial growth and scaling of pipes in recirculating cooling systems process water.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Dolphin WaterCare.

## What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on Dolphin WaterCare, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on the Dolphin WaterCare, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

## What Is the Dolphin WaterCare?

The Dolphin WaterCare is a device that generates pulsed electromagnetic fields in the water. These pulsed electromagnetic fields inhibit the bacterial growth and scaling of the pipes in recirculating cooling systems process water.

## Health Considerations

### Can Approved Uses of the Dolphin WaterCare Affect Human Health?

**Electromagnetic fields and contact currents generated by the Dolphin WaterCare are unlikely to affect your health when the device is used according to the label directions.**

Occupational exposure to electromagnetic fields, and induced body and contact currents generated by the Dolphin WaterCare may occur when workers are required to monitor the device or are performing other tasks in the vicinity of the device. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The exposure levels used to assess risks are established to protect the most sensitive human population (*e.g.*, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects are considered acceptable for registration.

The most well established effect of exposure to electromagnetic fields in the frequency range generated by the Dolphin WaterCare (*i.e.*, 3 to 100 kHz) is the unintentional excitation of nerve and muscle tissues. Electromagnetic fields of this nature may, in some cases, cause contact shocks and burns because of the electric currents they induce between conducting objects and the persons contacting those objects while the electromagnetic fields are present.

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[3] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

[4] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

### Occupational Risks From the Dolphin WaterCare

There is a potential for workers to be exposed to electromagnetic fields, and induced body and contact currents generated by the Dolphin WaterCare when they are monitoring the signal generator panel on the device or performing other tasks several metres from the device.

Health Canada has established safety limits for human exposure to radiofrequency electromagnetic energy. These exposure limits have been established following a comprehensive review of all peer reviewed scientific studies on the effects of radiofrequency energy on biological systems and the application of a weight of evidence approach to the estimation of health risks. These exposure limits have been published in the document, *Limits of Human Exposure to Radiofrequency Electromagnetic Energy in the Frequency Range from 3 kHz to 300 GHz Safety Code 6 (2009).*

Magnetic and electric field strengths measured at the surface of the Dolphin WaterCare and as close as 0.2 metres from the device are well below the lowest magnetic and electric field limits in *Safety Code 6*. Contact currents generated on the surface of the device are also estimated to be well below the limits on contact and induced body currents established in *Safety Code 6*. In addition, there are precautionary and exposure mitigation measures on the label for the Dolphin WaterCare. Consequently, there is no concern regarding potential occupational exposures to electromagnetic fields, and induced body or contact currents generated during the normal operation of the Dolphin WaterCare.

### Risks in Residential and Other Non-Occupational Environments

The Dolphin WaterCare is used in recirculating cooling systems process water in commercial buildings. The device is not intended for use in residential or non-occupational environments.

Cooling systems are typically located in a building's mechanical room, on the roof of a building, or outside and adjacent to the building. Access to these areas is normally restricted to workers through the use of locked doors, locked ladders, and fencing with locked gates. Consequently, it is unlikely that there will be any exposure or risks to bystanders from electromagnetic fields, or induced and contact currents generated by the Dolphin WaterCare.

## Environmental Considerations

An Environmental Assessment was not required for this application as Dolphin WaterCare is proposed for use in recirculating cooling systems process water.

## Value Considerations

### What Is the Value of the Dolphin WaterCare?

**This device, by generating pulsed electromagnetic fields to control microorganisms, offers a valuable alternative to chemical water treatments.**

The Dolphin WaterCare is effective in reducing bacterial growth levels within an acceptable range in recirculating cooling systems process water. This device also helps control the scaling of the pipes, which is typically controlled with chemicals that can be corrosive to metal. Therefore, less chemical product handling is required from the cooling tower operator, and the water discharged does not contain biocides. In addition, because the device reduces scaling, it allows the same recirculating water to be re-used a greater number of times, reducing the water consumption in the cooling system.

## Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of the Dolphin WaterCare to address the potential risks identified in this assessment are as follows:

### Key Risk-Reduction Measures

### Human Health

The statement, “WARNING: UNIT PRESENTS A POSSIBLE ELECTRICAL SHOCK HAZARD” is included on the principal display panel of the label for the Dolphin WaterCare. Also, the statements, “KEEP OUT OF REACH OF CHILDREN AND PREVENT ACCESS BY UNAUTHORIZED PERSONNEL”, “Physical hazards associated with the Dolphin WaterCare include electrical shock and slip hazards due to unplanned system leakage. Electrical power must be removed when electrical equipment is inspected, serviced, or repaired.”, and “CAUTION: Radiofrequency energy emitting device” have been included in the precautions section of the secondary display panel of the label.

In addition, the label instructs that the Dolphin WaterCare should be installed and started up by a qualified technician, and service should be done by a qualified service provider. Also, the label indicates that the start-up, operations, and maintenance manual for the device should be read prior to start-up.

## Next Steps

Before making a final registration decision on the Dolphin WaterCare, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

## Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on Dolphin WaterCare (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

# Science Evaluation

## Dolphin WaterCare

## 1.0 The Active Ingredient, Its Properties and Uses

### 1.1 Identity of the Active Ingredient

A Chemistry Assessment was not required for this application.

### 1.2 Directions for Use

The Dolphin WaterCare is for controlling bacteria levels and preventing the establishment of biofilm in recirculating cooling systems process water. Fouled systems must be cleaned before treatment is begun. The Dolphin WaterCare must be installed by a qualified technician and is controlled by an electronic module.

### 1.3 Mode of Action

Field data suggest that the pulsed electromagnetic fields produced by the Dolphin WaterCare modify the charges on the particles present in the water, which can prevent scale build-up and bacterial growth.

## 2.0 Methods of Analysis

A determination of the methods of analysis were not required for this application.

## 3.0 Impact on Human and Animal Health

The Dolphin WaterCare is a new commercial device not registered before in Canada. The proposed use pattern for the device is to generate electromagnetic fields to inhibit bacterial growth and scaling of pipes in commercial recirculating cooling systems process water (Use Site Category 17 – Industrial process fluids).

### 3.1 Toxicology Summary

The unintentional excitation of nerve and muscle tissues is the most well established effect of exposure to electromagnetic fields of the same frequency range as the fields generated by the Dolphin WaterCare.

### 3.2 Occupational and Residential Risk Assessment

There is a potential for workers to be exposed to electromagnetic fields, and induced body and contact currents generated by the Dolphin WaterCare when they are monitoring the signal generator panel on the device or performing other tasks several metres from the device.

Health Canada has established safety limits for human exposure to electromagnetic fields, and induced and contact currents which have been published in the document, *Limits of Human Exposure to Radiofrequency Electromagnetic Energy in the Frequency Range from 3 kHz to 300 GHz Safety Code 6 (2009).* These exposure limits have been established following a comprehensive review of all peer reviewed scientific studies on the effects of radiofrequency energy on biological systems and the application of a weight of evidence approach to the estimation of health risks.

For electromagnetic fields with frequencies in the range of 3 to 100 kHz, which encompasses the frequencies of the fields generated by the Dolphin WaterCare, the critical potential health effect is the unintentional stimulation of excitable tissues (i.e., nerves and muscles). Limits on electromagnetic fields strengths have been established in *Safety Code 6* to prevent this health effect. Limits have also been established on induced body and contact currents to prevent the occurrence of painful shocks and burns.

Magnetic and electric field strengths measured at the surface of the Dolphin WaterCare and as close as 0.2 metres from the device are well below the lowest magnetic and electric field limits in *Safety Code 6*. Contact currents generated on the surface of the device are also estimated to be well below the limits on induced body and contact currents established in *Safety Code 6.*

Precautions on the label for the Dolphin WaterCare include preventing access to the device by children and unauthorized personnel, and noting that the device presents a possible electrical shock hazard and emits radiofrequency energy. The label also instructs that the device should be installed, started, and serviced by qualified personnel, that the manual should be read prior to start-up, and that the electrical power should be removed before inspecting, servicing or repairing the device.

## 4.0 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 devices similar to the Dolphin WaterCare. As of May 16, 2011, there have been no incidents reported for devices of the type that includes the Dolphin WaterCare.

## 5.0 Impact on the Environment

An Environmental Assessment was not required for this application as the Dolphin WaterCare is proposed for use in recirculating cooling systems process water.

# 6.0 Value

## 6.1 Effectiveness Against Pests

Data were provided from four operational trials carried out in recirculating cooling water settings that were representative of the typical use pattern. The studies monitored free-floating bacteria, and one study also measured actual biofilm growth on glass slides within recirculating cooling systems process water. The trials compared the amount of bacteria in water treated with chemical biocides versus water treated with the Dolphin WaterCare over timeframes ranging from six weeks to 16 months. The trials showed that the Dolphin WaterCare can perform as well as chemical treatment, most of the time controlling the bacterial growth at levels below the Cooling Technology Institute Guidelines (<10 000 CFU/mL). The device was also found to prevent the establishment of biofilm.

### 6.1.1 Acceptable Efficacy Claims

The submitted data established that the Dolphin WaterCare is effective at controlling bacteria levels and preventing the establishment of biofilm.

## 6.2 Economics

No data were provided.

## 6.3 Sustainability

### 6.3.1 Survey of Alternatives

Several chemical-based slimicides with many different active ingredients are registered for the treatment of cooling water. However, only one different type of device (with five models registered) is available as a chemical treatment alternative.

**Table 6.3.1 registered devices for cooling tower use**

| Registration number | Product name | Active ingredient |
|---|---|---|
| 28756 | Sonoxide™ B-300 | Ultrasound |
| 28757 | Sonoxide™ B-15 | |
| 28758 | Sonoxide™ B-106 | |
| 28759 | Sonoxide™ B-154 | |
| 28760 | Sonoxide™ B-70 Ultrasonic Water Treatment System | |

### 6.3.2 Compatibility with Current Management Practices Including Integrated Pest Management

Chemicals that are reactive or not recommended for contact with Schedule 80 PVC are not compatible with Dolphin WaterCareTM operation. Chemical treatment additives such as crystal modifiers, dispersants or flocculants are not compatible with Dolphin WaterCareTM operation. Contact the qualified service provider before using any chemicals."

There are two issues to consider. One, some chemicals are reactive to Schedule 80 PVC and need to be avoided to prevent damage to the Dolphin WaterCare equipment. The other issue is that some chemical treatment additives oppose the mechanism of action of the Dolphin WaterCare device and will affect Dolphin WaterCare performance. The chemical treatment additives that can affect Dolphin WaterCare performance, and thus should be avoided, are crystal modifiers, dispersants and flocculants.

### 6.3.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Due to the non-chemical and broad-spectrum mode of action of the pulsed electromagnetic fields of the Dolphin WaterCare, it is not expected that resistance will be developed to this device.

## 7.0 Summary

### 7.1 Human Health and Safety

The available published information is sufficient to identify the potential risks associated with exposure to the electromagnetic fields, and induced body and contact currents generated by the Dolphin WaterCare.

Workers could be exposed to electromagnetic fields, and induced body and contact currents generated by the Dolphin WaterCare when monitoring the device or performing other tasks in the vicinity of the device. However, the magnitude of the electromagnetic fields, and induced body and contact currents from the device are estimated to be well below exposure limits established in Health Canada's *Safety Code 6* which have been designed to prevent the occurrence of human health hazards from exposure to radiofrequency energy.

### 7.2 Environmental Risk

An Environmental Assessment was not required for this application as the Dolphin WaterCare is proposed for use in recirculating cooling systems process water.

### 7.3 Value

The data submitted in support of the Dolphin WaterCare were adequate to demonstrate its efficacy for the treatment of recirculating cooling systems process water. The availability of this product will provide a new biocide-free possibility for controlling bacterial growth and preventing biofilm build-up in recirculating cooling water.

## 8.0 Proposed Regulatory Decision

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of the Dolphin WaterCare, which generates pulsed electromagnetic fields, to inhibit the bacterial growth and scaling of pipes in recirculating cooling systems process water.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

# List of Abbreviations

| | |
|---|---|
| CFU | colony forming units |
| DBNPA | 2,2-dibromo-3-nitrilopropionamide |
| kHz | kilohertz |
| mL | millilitre |
| PMRA | Pest Management Regulatory Agency |
| PVC | polyvinyl chloride |

# References

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

### 1.0 Human and Animal Health

PMRA No. 1770804 Certificate of Compliance, CSA International, DACO: 10.6

PMRA No. 1770808 Use Description Scenario, DACO: 5.2

### 2.0 Value

PMRA No. 1770809 Mode of Action, DACO: 10.2.1
PMRA No. 1904437 Mode of Action, DACO: 10.2.1
PMRA No. 1904438 Laboratory/Small-scale trials, DACO: 10.2.3.3
PMRA No. 1904439 Operational trials, DACO: 10.2.3.4
PMRA No. 1904440 Additional data, DACO: 10.2.3.4

## B. Additional Information Considered

## i) Published Information

### 1.0 Human and Animal Health

PMRA No. 2028601 Health Canada, Limits of Human Exposure to Radiofrequency Electromagnetic Energy in the Frequency Range from 3 kHz to 300 GHz Safety Code 6 (2009), DACO: 4.8

PMRA No. 2037695 2009, Ontario Ministry of Labour, Radiofrequency and Microwave Radiation in the Workplace, DACO: 4.8

PMRA No. 2037696 2010, ICNIRP Guidelines, Guidelines for Limiting Exposure to Time-Varying Electric and Magnetic Fields (1 Hz TO 100 kHz), DACO: 4.8

PMRA No. 2039499 Environmental Health Criteria 238. Extremely Low Frequency Fields, Published under the joint sponsorship of the International Labour Organization, the International Commission on Non-Ionizing Radiation Protection, and the World Health Organization. 2007, DACO: 4.8