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Proposed Registration Decision

Hankin Ozone Generator

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Overview

Proposed Registration Decision for Hankin Ozone Generator

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 use of Hankin Ozone Generator, which discharges ozone to control fouling from zebra mussels in service water intake pipes.

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 the Hankin Ozone Generator.

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 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 www.pmra-arla.gc.ca.

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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 the Hankin Ozone Generator, 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 Hankin Ozone Generator, 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 of this consultation document.

What Is the Hankin Ozone Generator?

The Hankin Ozone Generator is a device that is used to control zebra mussel fouling in service water intake pipes. In Canada, this registration is limited to the service water intake pipes of the Lennox Generating Station belonging to Ontario Power Generation. The device produces ozone on site that is then injected into the process water near the main intake pipes in order to control fouling from zebra mussels.

Health Considerations

Can Approved Uses of the Hankin Ozone Generator Affect Human Health?

The Hankin Ozone Generator is unlikely to affect your health when used according to the operating instructions for the ozonated water system (OWS) in the Lennox Generating Station and the label directions.

Potential exposure to ozone generated by the Hankin Ozone Generator may occur when operating the ozone generator or working within the Lennox Generating Station. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose 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 in animal testing are considered acceptable for registration.

Ozone is highly acutely toxic to rats when inhaled. Ozone did not cause eye irritation in animals. No information on skin irritation from ozone is available, but the compound could cause irritation. However, exposure levels that would severely affect the respiratory tract would be reached prior to skin irritation occurring. No information on skin sensitization from ozone is available, but it has caused asthma-like effects in animals exposed to various types of allergens.

There was no evidence that ozone can affect reproductive performance. Ozone has caused effects on behaviour and the brain, and depressed growth rates and body weights

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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*.

in offspring of female rats and mice, although at concentrations that have caused respiratory effects in adult animals. The acute, short- and long-term effects of exposure to ozone are mainly confined to the lung and respiratory tract and include inflammation of the airways, decreased lung function and effects on the clearance of inhaled contaminants from the lung. Associations between acute exposure to non-occupational ambient (outdoor) ozone and effects on the respiratory tract, hospitalizations and emergency department visits for respiratory symptoms and asthma, and increased mortality rates have been reported in epidemiology studies of human populations.

Ozone has been reported to be genotoxic in microorganisms, plants, and cultured mammalian and human cells. However, results of studies with laboratory animals are inconclusive. While there is some evidence of lung tumours following ozone exposure in strains of mouse susceptible to this type of tumour and in female mice from another strain exposed for a lifetime, there is no evidence of carcinogenicity from studies conducted with rats and hamsters. Also, the results of a limited number of epidemiological studies of ozone and cancer are inconclusive. Other international assessments of ozone have concluded that the available published scientific studies do not support ambient ozone as a pulmonary carcinogen.

While ozone from the Hankin Ozone Generator has the potential to induce toxic effects (primarily on the respiratory tract) in both animals and humans, exposure to levels that could induce these effects is very unlikely to occur due to the control measures in place at the Lennox Generating Station. These control measures include ozone analyzers, alarm systems, ventilation, and manual and automatic procedures for shutting down ozone production. These control measures are calibrated to occupational exposure limits (OELs) and ambient air quality criteria for ozone regulated under the Ontario *Occupational Health and Safety Act* and the Ontario *Environmental Protection Act*, respectively.

In addition, it is proposed that the label of the Hankin Ozone Generator include the statement, “Danger Poison”, and the precautionary statements, “Fatal if inhaled. DO NOT inhale/breathe gas. For workers who are checking readings on ozone in air analyzers using hand-held monitors under high or very high ozone alarm conditions, use positive pressure air lines with a mask or self-contained breathing apparatus” and “Prevent access by children and unauthorized personnel.” It is also proposed that the label include first aid statements describing procedures to follow if skin, clothing, eye or inhalation exposure occurs.

Residues in Water and Food

Dietary risks from food and water are not of concern.

There are no food-related uses of the Hankin Ozone Generator.

Under the proposed use, the Hankin Ozone Generator would inject ozone into the service water system of the Lennox Generating Station to prevent biofouling and settlement of zebra mussels. A relatively low concentration of ozone in water is required for this purpose and discharges of ozonated water from the generating station must meet effluent requirements specified in an Ontario Ministry of the Environment (OME) Certificate of Approval issued for the OWS. In addition, the high reactivity of ozone means that it is unlikely that the low concentrations of ozone in water discharged from the generating station could affect the quality of drinking or recreational water derived from Lake Ontario.

Occupational Risks From Exposure to Ozone from the Hankin Ozone Generator

Occupational risks are not of concern when the Hankin Ozone Generator is used according to the operating instructions for the ozonated water system in the Lennox Generating Station and the label directions.

The chemical technician responsible for operation of the OWS and other workers in the Lennox Generating Station have the potential to be exposed to ozone in air from the Hankin Ozone Generator and ozonated water from the service water systems in the generating station. To control occupational exposures to airborne ozone, a combination of ozone analyzers, warning lights, audible alarms, automatic exhaust fans and ventilators, and manual and automatic shutdown procedures for ozone production are employed in the generating station. Because these control measures are calibrated to OELs and ambient air quality criteria for ozone regulated under the Ontario *Occupational Health and Safety Act* and the Ontario *Environmental Protection Act*, respectively, it is unlikely that workers in the generating station will be exposed to levels of ozone that could adversely affect human health.

It is unlikely that workers in the plant will be exposed to levels of ozone in water that could adversely affect human health for the following reasons:

- only a low concentration of ozone is used in the service water systems
- ozone in water is highly reactive
- levels of ozone in water discharged from the generating station must meet OME effluent requirements

In addition, a statement on the acute inhalation risk from ozone, precautionary statements on avoiding inhalation exposure and preventing access to unauthorized personnel, and first aid statements describing procedures to follow if skin, clothing, eye or inhalation exposure occurs are proposed for the label of the Hankin Ozone Generator.

Because of the control measures employed in the Lennox Generating Station, bystander exposure to ozone is expected to be negligible. Therefore, potential health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Ozone From the Hankin Ozone Generator Is Introduced Into the Environment?

The active ingredient, ozone, is released into the environment through discharge of process water treated with ozone. The discharge water does not contain a high enough concentration of ozone to cause detrimental effects to aquatic biota in the immediate vicinity of the discharge. The ozone is expected to dissipate rapidly once in the environment.

Value Considerations

The Hankin Ozone Generator is a device that produces ozone within the service water intake pipes to prevent fouling from zebra mussels.

When properly operated, the Hankin Ozone Generator will produce an ozone residual within the service water intake pipes that effectively reduces the degree of fouling from zebra mussels. The device generates ozone by corona discharge through concentrated oxygen, and the ozone is then injected into the cooling water at a maximum continuous rate of 0.5 ppm. At this treatment rate, the number of zebra mussels settling on the intake pipe surfaces is greatly reduced. In the absence of control, the zebra mussels settle in densely packed colonies, which impedes the flow of cooling water and contributes to corrosion. Prior to treating with ozone, the Lennox Generating Station used chlorine to control zebra mussel fouling. While also effective, the chlorine treatment produced undesirable byproducts. Ozone provides an effective treatment without these byproducts.

Measures to Minimize Risk

Risk-reduction measures for the Lennox Generating Station OWS to protect human health and the environment include a series of air analyzers, warning lights, audible alarms, automatic exhaust fans and ventilators, and manual and automatic shutdown procedures for ozone production. The analyzers and alarm systems are calibrated to OELs and ambient emission limits regulated under the Ontario *Occupational Health and Safety Act* and the Ontario *Environmental Protection Act*, respectively.

In addition, 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 Hankin Ozone Generator to address potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because ozone is highly acutely toxic via inhalation, the label is to include the statement "Danger Poison" and the precautionary statements, "Fatal if inhaled. DO NOT inhale/breathe gas. For workers who are checking readings on ozone in air analyzers using hand-held monitors under high or very high ozone alarm conditions, use positive pressure air lines with a mask or self-contained breathing apparatus" and "Prevent access by children and unauthorized personnel".

Next Steps

Before making a final registration decision on the Hankin Ozone Generator, 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

At the time the PMRA makes its registration decision, it will publish a Registration Decision on the Hankin Ozone Generator (based on the Science Evaluation 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

Hankin Ozone Generator

1.0 The Active Ingredient, Its Properties and Uses

A chemical assessment was not required for this application.

2.0 Methods of Analysis

An assessment of methods of analysis was not required for this application.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The PMRA has conducted a detailed review of the publicly available toxicological information on ozone generated from the Hankin Ozone Generator in the OWS of the Lennox Generating Station. The database consists of a full array of laboratory animal (in vivo) and cell culture (in vitro) toxicity studies, along with numerous epidemiological studies of human populations. Most studies have been previously considered in published national and international authoritative reviews and assessments. Raw test data were not available, but the publicly available data were considered adequate to qualitatively characterize the risks of exposure to this pest control product, taking into account existing regulatory limits on occupational exposure and environmental emissions.

The primary route of exposure to ozone is inhalation and the compound is considered to be highly acutely toxic in rats, with observations of somnolence, pulmonary edema, dyspnea and haemorrhage. Associations between acute exposure to ambient (outdoor) ozone and decrements in lung function, increased respiratory symptoms, inflammation of the airways, increased respiratory-related school absenteeism and cardiac effects have been observed in a number of epidemiological field studies. Other types of epidemiological studies have reported associations between acute ambient ozone exposure and hospitalization for respiratory symptoms, emergency department visits for asthmatic episodes and mortality rates, especially during summer.

No evidence of eye irritation was observed in studies with rabbits and dogs. No information on the skin irritation potential was identified, but because it is an oxidant, it is expected that ozone can irritate skin. However, exposure levels that would cause severe respiratory effects would be reached prior to skin irritation occurring. No information was identified on the sensitization potential of ozone, but acute and short-term exposures have induced airway hyper-responsiveness to allergens in a variety of animal species.

The uptake of ozone across the respiratory tract is via reactive absorption in which the compound reacts with components of the epithelial lung fluid to produce oxidation products that

are the chemical mediators of ozone toxicity. The fractional uptake of ozone is approximately 0.80–0.95 in humans with the majority of the uptake occurring in the nose, mouth, throat and lungs. The rate of uptake increases directly with exposure concentration, lung tidal volume and inversely with flow rate, and the largest tissue dose of inhaled ozone occurs in the centriacinar region of the lung. Because of its high reactivity, ozone has a very limited potential to accumulate in the body.

Short-term (acute and subchronic) inhalation exposure to ozone has induced morphological changes to the respiratory tract of a number of laboratory animal species, affecting cells in the centriacinar region of the lung, ciliated epithelial cells in the nasal cavity and airways and Type I epithelial cells in the gas exchange region of the lung. Ciliated and Type I cells are replaced with non-ciliated and Type II cells, respectively, and there is inflammation and an accumulation of collagen and fibrosis. In several strains of rats and mice, short-term exposure to ozone has induced alterations to pulmonary function, including increased breathing frequency, decreased tidal volume, increased airway resistance, decreased forced vital capacity and changes to expiratory flow-volume curves. Systemic effects observed in laboratory animals following acute and short-term exposures to ozone include neurobehavioural and neuroendocrine effects, and effects on the cardiovascular system, the liver enzymes and T-cell-mediated immunity.

Similar to short-term exposures, morphological changes to the respiratory tract have also been observed in a number of mammalian species following longer-term exposure to ozone. These changes include inflammation and epithelial hyperplasia in the respiratory tract, effects on the nasal mucosa (atrophy of the turbinates, epithelial hyperplasia and mucous cell metaplasia), fibrosis of the lung, remodelling of airways, reduced airway innervation, accumulation of eosinophils and changes to basement membranes. There is some evidence for attenuation of morphological effects during long-term exposures in rodents, but in some studies the effects on the nasal mucosa and fibrotic changes to the lung have persisted even after exposure has ceased. The strongest epidemiological evidence for the effects of long-term exposures is the association observed between seasonal (summer) ambient ozone levels and decreased lung function growth in children.

Other effects of acute, short- and long-term exposures to ozone in laboratory animals include biochemical alterations in the respiratory tract (e.g. creation of ozone byproducts that mediate toxicity, changes to lung lipids, changes to antioxidant and xenobiotic metabolism and increases in collagen content), changes to lung host defences (e.g. effects on mucocillary clearance, macrophage function and immune responsiveness) and inflammation and lung permeability changes (e.g. production of inflammatory mediator substances, recruitment of macrophages and leukocytes, and disruption of tight junctions between epithelial cells).

No effects on reproductive performance were reported when female CD-1 mice were continuously exposed to ozone from 30 days prior to breeding to gestation day 17, or from 6 days prior to breeding to postnatal day 22 or 26. Neurobehavioural effects (e.g. delayed reflex development, altered behavioural test results and sleep disturbances), cerebellar abnormalities, and depressed growth rates and body weights were observed in offspring of female rats and mice following prenatal or combined prenatal and postnatal exposure to ozone.

Ozone has been reported to be genotoxic in a variety of assays conducted with microorganisms, plants, and mammalian and human cells in vitro. However, mixed results were observed in assays with a variety of laboratory animal species in vivo. The in vivo results may be due to the high reactivity of ozone causing it to be inactivated before it reaches the target tissues in cytogenetic assays and the high toxicity of the compound limiting the exposure concentrations used in the assays.

Less-than-lifetime or lifetime exposures of rats or hamsters to ozone did not induce lung tumours. However, less-than-lifetime exposure of strains of mouse susceptible to the development of lung tumours and lifetime exposure of B6C3F1 mice resulted in increased incidences of alveolar/bronchiolar adenoma and carcinoma. Based on the results of lifetime studies in rats and mice, the United States National Toxicology Program concluded that there was no evidence for the carcinogenicity of ozone in rats, equivocal evidence in male mice and some evidence in female mice. The results of the small number of available epidemiology studies of ozone exposure and cancer are somewhat inconsistent. In 2001, the American Conference of Governmental Industrial Hygienists (ACGIH) concluded that all forms of occupational exposure to ozone were A4, “Not classifiable as a Human Carcinogen.” In 2006, the United States Environmental Protection Agency (USEPA) concluded, “The weight of evidence from recent animal toxicological studies and a very limited number of epidemiological studies do not support ambient ozone as a pulmonary carcinogen.”

3.1.1 PCPA Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to take into account completeness of the data with respect to the exposure of and toxicity to infants and children as well as potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

Since there are no food-related or residential uses of the Hankin Ozone Generator and health risks were assessed qualitatively, the use of a 10-fold factor to account for the completeness of the data with respect to exposure and toxicity to infants and children as well as potential prenatal and postnatal toxicity was not necessary.

3.2 Determination of Acute Reference Dose

There are no food-related uses of the Hankin Ozone Generator, so the determination of an acute reference dose for ozone was not necessary.

3.3 Determination of Acceptable Daily Intake

There are no food-related uses of the Hankin Ozone Generator, so the determination of an acceptable daily intake for ozone was not necessary.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Occupational exposure to ozone from the OWS in the Lennox Generating Station is expected to be primarily via inhalation from leakages or accidental emissions from the system. Any exposures are likely to be acute or short-term as the OWS includes multiple control systems to prevent longer term exposures to elevated levels and the odour threshold of ozone is relatively low (0.0076–0.036 ppm). Acute and short-term exposure to ozone is associated primarily with effects on the respiratory system, including decrements in lung function, respiratory symptoms, inflammation and morphological changes. Since the control systems for the OWS are calibrated to OELs regulated under the *Occupational Health and Safety Act* of Ontario, it is unlikely that workers will be exposed to levels of ozone in air that could adversely affect human health. It was therefore not considered necessary to calculate a margin of exposure for ozone.

3.4.2 Dermal Absorption

Although there is limited evidence for the reaction of ozone with components of the skin, the high reactivity of the compound means that it is unlikely to be significantly absorbed across the skin or accumulate in the body. Therefore, a dermal absorption study was not considered necessary to complete the health hazard assessment.

3.4.3 Mixer, Loader and Applicator Exposure and Risk Assessment

In the event that a leak or accidental emission from the OWS results in either a high (0.10 ppm) or very high (0.30 ppm) level of ozone in air, a series of ozone in air analyzers will trigger warning lights, audible alarms, automatic exhaust fans and ventilators, and for a very high level of ozone, the automatic shutdown of the ozone generator via a programmable logic controller. The high and very high ozone trigger levels for the analyzers within the generating station are calibrated to OELs for ozone, which restrict the amount and duration of workers' exposure to hazardous substances. Current OELs for ozone include a time weighted average exposure value of 0.1 ppm and a short-term exposure value of 0.3 ppm. The time weighted average exposure value is the average of the airborne concentrations of ozone determined from air samples of the airborne concentrations to which a worker is exposed in a workday or workweek. The short-term exposure value is the maximum airborne concentration of ozone to which a worker is exposed in any 15-minute period calculated from a single sample or time weighted average of samples. In addition, the piping included in the OWS is designed in accordance with American Society for Mechanical Engineers piping codes and Compressed Gas Association guidelines and standards, and is inspected and registered with the Technical Standards and Safety Authority. Finally, a set of operating instructions has been prepared for the OWS, which includes specific instructions for technicians on how to respond to high and very high ozone alarms to limit worker exposure. Therefore, there is a very low potential for occupational exposure to elevated levels of ozone in air and as such, a quantitative assessment of occupational exposure to ozone in air was not considered necessary.

The OWS is designed such that a concentration of 0.5–0.6 ppm ozone is attained in the inlet well resulting in a residual of 0.1–0.2 ppm at any point in the service water system. The operating instructions for the OWS indicate that should the ozone concentration exceed 0.01 ppm in the condenser cooling system water outfall (a discharge point for ozonated water), corrective action must be taken, including reducing ozone production and if necessary, shutting down the system. This level is included in the effluent requirements specified in an OME Certificate of Approval. While the Certificate of Approval did not include effluent requirements for all ozonated water discharge points associated with the OWS, effluent quality is monitored weekly at these discharge points. Finally, the low residual used in the service water system and the high reactivity of ozone in water mean that workers in the generating station are unlikely to be exposed to elevated levels of ozone from the water in the OWS. As a result, a quantitative assessment of occupational exposure to ozone in water was not necessary.

3.4.4 Bystander Exposure and Risk Assessment

The main potential source of ozone emissions to ambient air is the outlet stack of the ozone destruct unit located 5 m above the ground and 30 m from the nearest receptor. This should ensure adequate time for mixing, dilution and breakdown of any ozone emissions prior to any potential transportation to areas where bystanders could be exposed. The outlet stack of the ozone destruct unit has an ozone in-air analyzer that is linked through the programmable logic controller to warning lights, alarms and automatic ventilation and shutdown processes. The high ozone level alarm trigger for the analyzer on the outlet stack of the ozone destruct unit (0.08 ppm) is calibrated to the Ontario *Environmental Protection Act* ambient air quality criteria for ozone. The current ambient air quality criteria for ozone is 0.08 ppm for a one-hour period. Ambient air quality criteria are acceptable effects-based levels in air, with variable averaging times appropriate for the effect. In the case of ozone, the effect for the ambient air quality criteria is based on human health. In addition, a Certificate of Approval issued for the OWS by the OME involved an assessment of all air emissions and compliance with OME air standards/guidelines. Consequently, it is unlikely that bystanders could be exposed to elevated levels of ozone in air from the OWS and as such, a quantitative bystander exposure assessment was not considered necessary.

3.4.5 Food Residue Exposure Assessment

There are no food-related uses of the Hankin Ozone Generator, so a quantitative assessment of residues in food is not necessary.

Since the OWS is designed to maintain an ozone residual of 0.1–0.2 ppm in the service water system of the Lennox Generating Station, it is very unlikely that elevated levels of ozone could occur in drinking or recreational water as a result of the operation of the OWS. As outlined above, the operating instructions for the OWS indicate that should ozone levels above those specified in an OME Certificate of Approval be detected in the condenser cooling system water outfall from the OWS, corrective action must be taken. Based on a past performance report for the generating station, effluents were in compliance with an OME Certificate of Approval. Although there are currently no Canadian drinking water, recreational water or water quality guidelines for ozone, given that concentrations used in drinking water treatment can be in the

range of 2–5 ppm and ozone has a high reactivity and relatively short half-life in water, ozonated discharge water from the generating station is unlikely to adversely impact the quality of drinking or recreational water derived from Lake Ontario. Therefore, a quantitative assessment of residues in drinking water is not necessary.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Ozone is used to treat process water to control zebra mussel fouling at the Lennox Generating Station, operated by Ontario Power Generation. Excess ozone is expelled during the treatment; however, some remains dissolved in process water and is discharged into Lake Ontario. Once in the aquatic environment, ozone will chemically degrade and will readily react with other compounds in water, including organic, dissolved and particulate matter; therefore, ozone will dissipate rapidly.

4.2 Effects on Non-Target Species

The primary concern with the discharge of ozonated process water into Lake Ontario is the potential effects on non-target aquatic organisms. A qualitative risk assessment was conducted by considering the treatment concentration of ozone, the highly reactive nature of ozone, and toxicity of treatment water to aquatic organisms.

4.2.1 Effects on Terrestrial Organisms

Ozone use at the Lennox Generating Station does not result in any significant discharge of ozone to the terrestrial environment. Therefore, there is negligible risk to terrestrial animals from the use of ozone in this manner.

4.2.2 Effects on Aquatic Organisms

Aquatic organisms are exposed to ozone through the discharge of treated process water. Ontario Power Generation has carried out quarterly testing on rainbow trout and *Daphnia* using grab samples from the ozone-treated water. In addition, Ontario Power Generation has conducted flow-through testing on rainbow trout exposed to diverted process water. All results have been reviewed and considered acceptable. The results indicated that there were no lethal or sublethal effects on aquatic organisms tested. Therefore, risk to aquatic organisms is expected to be negligible.

5.0 Value

5.1 Effectiveness Against Pests

Data from a comprehensive operational trial within the Lennox Generating Station was provided for the Hankin Ozone Generator. The study analyzed the planktonic veligers (zebra mussel larvae) and counted the number of mussels that attached to the surfaces of bioboxes at various

sampling points within the cooling water system before and after the ozone treatment over a five-week period. The number of zebra mussels that established themselves on the pipe surface upstream from the ozone treatment correlated to the number of veligers entering the pipes. At the conclusion of the five-week operational trial, there was a 98% reduction in the total number of established zebra mussels following the 0.5 ppm continuous ozone treatment compared to the untreated control.

5.1.1 Acceptable Efficacy Claims

The submitted data established that the Hankin Ozone Generator is effective at controlling fouling from zebra mussels in the Lennox Generating Station service water intake pipes when applied continuously at 0.5 ppm ozone.

5.2 Economics

No information provided.

5.3 Sustainability

5.3.1 Survey of Alternatives

The availability of the Hankin Ozone Generator within the Lennox Generating Station will provide a new active ingredient for the control of zebra mussel fouling within the station's service water intake pipes. The main advantage of ozone as an active ingredient is that it does not create unwanted byproducts, such as the trihalomethanes that may be generated during treatment with chlorine or bromine-based biocides. Physical removal of zebra mussels, such as scraping, is an alternative to chemical methods such as ozone treatment. However, frequent scraping of the pipes is inconvenient, costly, and may damage the pipes themselves. There are several biocides currently registered for zebra mussel control, based on quaternary ammonium compounds or oxidizing bromine/chlorine chemistries, that would provide chemical alternatives to the ozone treatment. However, some of these are only for recirculating cooling waters and not once-through systems. These products are summarized in Appendix I, Table 1.

5.3.2 Compatibility With Current Management Practices Including Integrated Pest Management

The Hankin Ozone Generator should be compatible with the service water intake operations of the Lennox Generating Station. Ontario Power Generation has provided an extensive array of studies examining adverse effects, such as corrosion of the metal pipes and brittleness of gaskets and seals, on the materials with which the dissolved ozone will come in contact. Ozone is a corrosive chemical, but the former treatment (i.e. halogen-based biocides) was also corrosive. The ozone treatment at 0.5 ppm was found to be acceptable and did not cause increased corrosion or gasket brittleness compared to the former chlorine treatment used at the Lennox Generating Station.

5.3.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Ozone is a powerful oxidizing agent with a broad-spectrum, non-specific mode of action. Ozone has also been used for many years in a variety of applications, such as drinking water treatment, without significant resistance issues arising. Therefore, it is not expected that the development of resistance to ozone during treatment with the Hankin Ozone Generator at the Lennox Generating Station poses a problem.

5.3.4 Contribution to Risk Reduction and Sustainability

The Hankin Ozone Generator was chosen by Ontario Power Generation to replace halogen-based biocides as part of a specific chlorine reduction program. The ozone treatment does not produce the unwanted trihalomethane byproducts that may occur with halogen-based biocides.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, ozone was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of ozone were also considered, including transformation products formed in the environment, contaminants and formulants in the technical product. The end-use product, ozone, and its transformation products were evaluated against the following Track 1 criteria: persistence in soil $\geq$ 182 days; persistence in water $\geq$ 182 days; persistence in sediment $\geq$ 365 days; persistence in air $\geq$2 days; bioaccumulation log $K_{ow} \geq 5$ or bioconcentration factor $\geq$ 5000 (or bioaccumulation factor $\geq$ 5000). In order for ozone or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met. The technical product and end-use product, including formulants, were assessed against the contaminants identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern, Part 3—Contaminants of Health or Environmental Concern.* The PMRA has reached the following conclusions.

- Ozone or its transformation products do not meet TSMP Track 1 criteria as they are non-persistent and non-bioaccumulative.

- Technical grade ozone does not contain any contaminants or formulants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

Therefore, the use of ozone is not expected to result in the entry of Track 1 substances into the environment.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, formulants and contaminants in the technical and end-use products are assessed against the formulants and contaminants identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. This list of formulants and contaminants of health and environmental concern are identified using existing policies and regulations, including the following: the federal Toxic Substances Management Policy; the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol); and the PMRA Formulants Policy as described in Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*. The *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* is maintained and used as described in the Notice of Intent NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*.

The *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* consists of three parts:

- Part 1: Formulants of Health or Environmental Concern
- Part 2: Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions
- Part 3: Contaminants of Health or Environmental Concern

The contaminants to which Part 3 applies meet the federal Toxic Substances Management Policy criteria as Track 1 substances, and are considered in Section 6.1. The following assessment refers to the formulants and contaminants in Parts 1 and 2 of the list.

Technical grade ozone is generated by the end-use product, Hankin Ozone Generator; the ozone itself is used to treat process water. Therefore, the generated ozone does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*

7.0 Summary

7.1 Human Health and Safety

The available published information for ozone is adequate to qualitatively define the majority of toxic effects that may result from human exposure to ozone through use of the Hankin Ozone Generator. Ozone is highly acutely toxic in rats by the inhalation route of exposure. Associations between acute exposure to ambient ozone levels and effects on the respiratory system, including reduced lung function, increased respiratory symptoms, inflammation and other effects, have been reported in epidemiological field studies. No evidence of eye irritation was observed in studies with rabbits and dogs. No information on skin irritation or sensitization potential was identified, but it is likely that ozone could induce skin irritation. However, concentrations that would severely affect the respiratory tract would be reached prior to skin irritation occurring. Concentrations causing respiratory effects and airway hyper-responsiveness to a variety of allergens have been induced in a variety of animal species by acute and short-term exposures to ozone. Short- and longer-term exposures to ozone have also induced other effects on the respiratory tract, including morphological changes, altered pulmonary function, biochemical changes, effects on lung host defences and inflammation and permeability changes. Although no effects on reproductive performance were reported for female mice exposed to ozone prior to and during breeding, neurobehavioural effects, brain abnormalities and depressed growth rates and body weights were observed in offspring of female rats exposed to ozone prenatally and postnatally. Ozone is genotoxic in microorganisms and cells in vitro, but mixed results were obtained with in vivo cytogenetic assays in laboratory animals. Based on reviews of the results of bioassays involving lifetime and less-than-lifetime exposure to ozone in rodents, the ACGIH concluded that occupational exposure to ozone was “not classifiable as a human carcinogen” and the USEPA determined that the weight of evidence did not support the pulmonary carcinogenicity of ambient ozone.

Workers at the Lennox Generating Station and bystanders within the vicinity of the generating station are not expected to be exposed to levels of ozone that could result in an unacceptable risk when the Hankin Ozone Generator is used according to the operating instructions for the OWS. The multiple systems in the generating station for limiting occupational exposures and environmental emissions combined with the precautionary statements on the label for the Hankin Ozone Generator are adequate to protect workers and bystanders.

7.2 Environmental Risk

Ozone is used to control zebra mussels in process water and on equipment at the Lennox Generating Station, operated by Ontario Power Generation. Ozone is released into the environment through discharged water; however, ozone is highly reactive and is expected to dissipate rapidly and will react with organic, dissolved and particulate matter in the water. In addition, no toxic effects to aquatic organisms were observed through testing. Therefore, the risk to non-target aquatic organisms is considered negligible.

7.3 Value

The data submitted to register the Hankin Ozone Generator were adequate to demonstrate its efficacy for the control of zebra mussel fouling within the service water intake pipes of the Lennox Generating Station when continuously dosed at 0.5 ppm ozone. The Hankin Ozone Generator has been amply demonstrated to be compatible with the service water operations at the Lennox Generating Station, with no significant adverse effects, such as corrosion of the pipes or breakdown of the gaskets and sealants within the intake pipe infrastructure. The Hankin Ozone Generator offers an alternative to treatment with halogen-based biocides, which may produce unwanted byproducts such as trihalomethanes.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing full registration for the use of the Hankin Ozone Generator to control fouling from zebra mussels. An evaluation of current scientific data from the applicant, scientific reports and information from other regulatory agencies has resulted in the determination that, under the proposed conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

ACGIH	American Conference of Governmental Industrial Hygienists
K_{ow}	*n*-octanol–water partition coefficient
m	metre(s)
OEL	occupational exposure limit
OME	Ontario Ministry of the Environment
OWS	ozonated water system
PCPA	*Pest Control Products Act*
PMRA	Pest Management Regulatory Agency
ppm	parts per million
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I Tables and Figures

Table 1 Alternative Biocides for Zebra Mussel Control in Service Water Intake Pipes

End-Use Product	Reg. No.	Active Ingredients	Registered Uses
EC6224A	22333	N-Alkyl-(5% C12, 60% C14, 30% C16, 5%C18) dimethyl benzyl ammonium chlorides; and N-Alkyl-(68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides	Control of zebra mussels and bacteria and fungal slime in industrial recirculating cooling water systems
ACTI-BROM 7342	23463	Sodium bromide + sodium hypochlorite OR chlorine gas	Zebra mussel control at industrial, utility or municipal plant intake streams
DREWBROM™ PRECURSOR BIOCIDE	23624	Sodium bromide + sodium hypochlorite OR chlorine gas	Bactericide, slimicide, algicide and mollusc control agent in commercial and industrial recirculating cooling water systems, influent water systems such as flow-through filters, heat exchange water systems, industrial water scrubbing water systems, brewery pasteurizing systems and air washers
SPECTRUS CT1300	25666	N-alkyl(C12-40%,C14-50%,C16-10%)dimethyl benzyl ammonium chloride	Control of Mollusca and bacterial and algal slimes in evaporative condensers, heat exchange water systems, commercial and industrial cooling towers, influent systems such as flow-through filters and lagoons, industrial water-scrubbing systems and brewery pasteurizers. Control of zebra mussels and algal and bacterial slimes in once-through cooling systems.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

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PMRA 1381701 2000, Continuous Ozonation of Service Water at Lennox G.S. - Overview of System Location and Operation, DACO: 5.2
PMRA 1381703 2000, Continuous Ozonation of Service Water at Lennox G.S. - Overview of Off-Gas Destruct Unit, DACO: 5.2
PMRA 1595843 2006, Certificate of Approval for Industrial Sewage Works No.2624-6 MASFH, DACO: M9.9

2.0 Impact on the Environment

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3.0 Value

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B. ADDITIONAL INFORMATION CONSIDERED

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