Proposed Registration Decision PRD2022-16

Ozone Generating Device lotus PRO

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Table of Contents

Overview

Proposed registration decision for lotus PRO

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of the ozone generating device lotus PRO, which infuses filtered water with up to 1.7 ppm ozone to create stabilized aqueous ozone for use as a sanitizer and disinfectant on a hard, non-porous surfaces in commercial and industrial areas.

Currently, ozone generators are registered as a molluscide to control zebra mussels in cooling water in power generating stations, see Proposed Registration Decision PRD2008-14, *Hankin Ozone Generator*, and Registration Decision RD2008-12, *Hankin Ozone Generator*.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

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 lotus PRO.

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 individuals 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 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 (for example, children) as well as organisms in the environment.

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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."

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 Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides section of Canada.ca.

Before making a final registration decision on the ozone generating device lotus PRO, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.[3] Health Canada will then publish a Registration Decision[4] on lotus PRO, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada'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 ozone?

Ozone is a gas made of three oxygen atoms (O_3). Ozone can kill bacteria and fungi by causing physical damage to their cell walls, proteins, and DNA. Ozone can be infused into water to create an effective liquid antimicrobial solution.

Health considerations

Can approved uses of ozone and lotus PRO affect human health?

lotus PRO is unlikely to affect human health when it is used according to label directions.

Potential exposure to ozone from stabilized aqueous ozone generated by lotus PRO may occur when dispensing the stabilized aqueous ozone to fill cleaning equipment, such as spray bottles, spray mops or mop buckets, or during application, and postapplication cleaning activities. 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 levels used to assess risks are established to protect the most sensitive human population (in other words, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed.

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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*.

The lotus PRO device generates stabilized aqueous ozone (SAO), which is ozone trapped in filtered water at low levels (maximum of 1.7 ppm). Local off-gassing of SAO results in low levels of airborne ozone.

Publicly available toxicology information was used to assess risks from exposure to ozone and ozonated water. Considering this information and the safe use of ozonated water for various applications, including dermatological use and use as a hand sanitizer (at levels up to 4 ppm) with no reported adverse effects, stabilized aqueous ozone is considered to be non-irritating and not sensitizing to skin. Due to the low levels of ozone in the stabilized aqueous ozone, it is not likely to be toxic by the oral, dermal, and inhalation routes, nor irritating to the eyes or respiratory tract. No short-term toxicity of stabilized aqueous ozone is anticipated from the proposed use.

Residues in water and food

Dietary risks from food and water are acceptable.

There is no direct food use proposed for the lotus PRO device under the *Pest Control Products Act* as stabilized aqueous ozone (SAO) is proposed for use as a surface sanitizer.

Dietary exposure to ozone residues are expected to be negligible due to the low concentration of ozone in the stabilized aqueous ozone, the high reactivity and relatively short half-life of ozone in water, the short (5–15 minute) contact sanitization time, the requirement for lotus PRO and stabilized aqueous ozone to be used in well-ventilated areas, and the fact that all treated surfaces are hard and non-porous in nature and must be thoroughly dried prior to contact with food.

Stabilized aqueous ozone is not for drinking. When the device is used as directed by the label, the likelihood of ozone contaminating surface or groundwater is low and therefore not a health concern. Consequently, health risks from dietary exposure are acceptable.

The use of lotus Pro in commercial food preparation facilities is exempted from the *Pest Control Products Act* under paragraph 3(1)(c) of the *Pest Control Product* Regulations. However it is supported by a letter of acceptance from the Canadian Food Inspection Agency, a letter of no objection from Health Canada's Bureau of Chemical Safety, and provincial letters of acceptance. Therefore, the use will be permitted to appear on the pest control product label.

Risks in residential and other non-occupational environments

Estimated risk for residential and other non-occupational exposure is acceptable.

There are no residential uses for this device; therefore, residential bystanders are not expected to come into contact with the stabilized aqueous ozone or airborne ozone. Therefore, risk due to residential and bystander exposure is acceptable.

Occupational risks from handling lotus PRO

Occupational risks are acceptable when lotus PRO is used according to the directions on the label and operator's manual, which include protective measures.

Workers using lotus PRO can come into direct contact with stabilized aqueous ozone on the skin while filling cleaning equipment, or during the sanitization process, and postapplication clean-up to remove SAO from treated surfaces. Workers can be exposed through direct skin contact with stabilized aqueous ozone or by inhalation of airborne ozone during handling and spraying of stabilized aqueous ozone and from spray drift. Minimal eye exposure to splashes or spray drift is also possible.

Provincial occupational exposure limits for airborne ozone include an average limit of 0.1 ppm and a short-term exposure limit of 0.3 ppm.

The design of the device with engineering and other design controls limit exposure of ozone to levels below regulated occupational exposure limits. Therefore, occupational risks are acceptable when the directions for use and precautionary statements on the label and operating manual are observed.

Health risks to occupational bystanders

Occupational bystander risks are not of health concern when lotus PRO is used according to directions on the label and operator's manual.

Occupational bystander exposure is expected to be low as generated SAO and airborne ozone from local off-gassing of SAO are not likely to exceed natural background levels of ozone. Therefore, risk due to occupation bystander exposure is acceptable.

Environmental considerations

As the use of lotus PRO and stabilized aqueous ozone is proposed for indoor use an environmental assessment was not required.

Value considerations

What is the value of the lotus PRO?

The lotus PRO generates stabilized aqueous ozone (SAO) from filtered tap water, which can be used to kill potentially harmful bacteria and fungi on hard non-porous surfaces.

The registration of the lotus PRO device will give commercial facilities the ability to create aqueous ozone, an effective hard surface sanitizer, on demand. Aqueous ozone produced by the lotus PRO is effective in killing bacteria and fungi.

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 lotus PRO to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

Standard precautionary statements appear on the end-use product label to avoid contact with eye and breathing spray mist.

To limit occupational and bystander exposure, the end-use product label and operating manual require a drift statement and direction for use statement that lotus PRO and stabilized aqueous ozone are to be used only in well-ventilated areas.

To mitigate dietary exposure to residues of the stabilized aqueous ozone, the end-use product label and operating manual require a statement to avoid contamination of food during application and storage.

The maximum concentration of ozone in in the stabilized aqueous ozone is included on the label.

Next steps

Before making a final registration decision on the ozone generating device, lotus PRO, Health Canada's PMRA will consider any comments received from the public in response to this consultation document. Health Canada 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). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other information

When Health Canada makes its registration decision, it will publish a Registration Decision on the ozone generating device, lotus PRO (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. For more information, please contact the PMRA's Pest Management Information Service.

Science evaluation

lotus PRO, ozone generating device

1.0 The active ingredient, its properties and uses

A chemical assessment was not required for this application.

1.1 Directions for use

Ozone is the common name for the inorganic molecule O_3. The lotus PRO device uses electricity to convert O_2 from the air into O_3. Ozone is highly reactive, and quickly converts back to O_2. When ozone is dissolved in water, its stability is influenced by water temperature and the presence of other dissolved minerals and organic matter. To maintain an effective concentration of ozone in aqueous form, the lotus PRO pre-filters the water before it is infused with the ozone. This pre-filtration, and the use of cold water rather than warm water, results in the creation of SAO.

The lotus PRO device and its replaceable water filter cartridge must be connected directly to a cold-water supply line with access to a drain. To operate the device, the user flips the "Flow" switch to "on". The device will begin infusing the filtered cold water with ozone to a concentration of 1.7ppm. Once this concentration is reached (indicated by a green "system ready" light), the user can dispense the SAO from the device into spray bottles or buckets for use on hard non-porous surfaces. The device tracks the volume of SAO dispensed and will notify users when the filter cartridge needs to be changed.

Five minutes of wet contact time will reduce bacteria by 99.99%, and 15 minutes of wet contact time will reduce fungi by 99.9%. The SAO will maintain this level of efficacy for up to 4 hours after it is produced, if it is dispensed into and stored in low ozone demand containers. SAO should be used as-is, undiluted, and without adding any chemicals or cleaning products.

1.2 Mode of action

Ozone is a broad spectrum, non-specific antimicrobial. In gas form and when dissolved in water, ozone destroys bacterial and fungal cells by causing the oxidation of membrane phospholipids and lipoproteins. As well as causing cell lysis, ozone interferes with microbial enzyme activities and causes DNA damage by disrupting bonds between base pairs.

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

A review of publicly available toxicology information on ozonated water was conducted in support of SAO and lotus PRO. For details on the previously reviewed scientific information in support of ozone, see PRD2008-14, *Hankin Ozone Generator*. Since SAO consists of ozone sequestered within filtered water and local off-gassing of SAO results in low levels of airborne ozone, a toxicology review on ozonated water was considered appropriate to qualitatively characterize the risks from exposure. In addition, existing provincial regulatory occupational exposure limits for ozone were considered.

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.

Inhalation of ozone can cause dryness of the mouth, coughing, and irritation of the nose, throat, and chest. It may cause labored breathing, headaches, and fatigue. Absorption through intact skin is not expected. Ozone can be an irritant to the eyes, causing minor inflammation. Although highly concentrated ozone is harmful to humans, ozonated water is less toxic as there is less concern of inhalation as a route of exposure, and ozone auto-decomposes rapidly to oxygen, leaving no residues.

In a cytotoxicity study of ozonated liquids on skin cells, ozonated water (4ppm; up to 15-minute exposure time) showed no cytotoxic effects on a normal thickness stratum corneum of cultured epidermis as compared to other hand disinfectants as test substances (in other words, 1% chlorhexidine, 1% chlorhexidine ethanol, 0.2% benzalkonium chloride, 83% ethanol, and 0.5% povidone-iodine) that destroyed or damaged the stratum corneum. In addition, ozonated water did not cause morphological changes to keratinocytes below the stratum corneum when compared to the other test substances that produced condensed nuclei and vacuolar cells. However, in a “sensitive skin” model (immature stratum corneum and other layers), ozonated water resulted in fewer vacuolar cells than those produced by the other test substances. Compared with control (deionised distilled water) having a 100% cell survival rate after a 15-minute application, ozonated water demonstrated ≥ 92.4% cell survival, while the other test substances showed decreased cell survival rates (< 20%) after a 15-minute application.

In a clinical crossover trial on thirty nursing student volunteers to assess hand decontamination with ozonated water (0.8 ppm or 4 ppm) and alcohol-based hand rub (ABHR), no subjects reported burning or dryness with ozonated water, but 20% of them reported burning or dryness with ABHR use.

There is limited information available on the dermal effects from repeated long-term exposure to ozonated water, and conclusive evidence is lacking on its long-term safety on human skin. However, there is lack of reported adverse effects from large-scale use of ozonated water for hand hygiene and from several described uses in the field of dentistry, clinical applications, and various industrial uses to indicate the high safety profile of ozonated water when used topically.

Considering the available toxicology information and the history of safe use of ozonated water for various applications, including its reported dermatological use and use as a hand sanitizer (up to 4 ppm) with no reported adverse effects, SAO is not likely to be a dermal irritant or sensitizer. Due to the low levels of ozone in SAO, it is not likely to be toxic by the oral, dermal, and inhalation routes, nor irritating to the eyes or respiratory tract. No short-term toxicity of stabilized aqueous ozone is anticipated from the proposed use.

3.2 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 that the low levels of ozone present in the SAO will be significantly absorbed across the skin or accumulate in the body.

3.3 Occupational, residential and bystander exposure and risk assessment

3.3.1 Use description

lotus PRO consists of a filter cartridge unit and a dispensing unit. The device is installed over a sink or floor drain at a height of 122 cm (48″) (from the bottom of the dispenser to the floor), and is connected directly to a cold water supply line, with a minimum required water flow of 4 L/min. Cold water flows through a filter cartridge and then into the dispenser, where it is infused with ozone to form SAO. The device dispenses SAO on-demand, and the user dispenses the SAO through a hose directly into spray bottles, buckets, or other containers for use as a surface sanitizer/disinfectant. SAO can be used for up to 4 hours after dispensing. lotus PRO is programmed to produce SAO with a maximum concentration of 1.7 ppm ozone. The device can produce up to 11.5 L of SAO per minute.

The device is to be protected by a ground-fault circuit-interrupter (GFCI) and plugged into 120 V power outlet (220 V where applicable).

For sanitizing, the label instructs that the surface for disinfection be pre-cleaned by applying SAO and wiping with a microfiber cloth (or paper towel) to remove visible dirt. SAO is then re-applied and the treated surface is to remain wet for 5–15 minutes, then cleaned with a microfiber cloth (or paper towel), and the surface left to air dry.

3.3.2 Occupational exposure and risk assessment

3.3.2.1 Mixer, loader, and applicator exposure and risk assessment

When lotus PRO is used according to label directions, occupational exposure to SAO and airborne ozone is characterized as short- or intermediate-term in duration.

Occupational exposure to SAO will occur primarily via the dermal route when filling cleaning equipment (spray bottle, mop bottle, mop bucket, etc.) and during sanitizing. Ocular exposure to SAO is possible from splashes while filling cleaning equipment or from spray drift while applying. However, due to the low ozone content, ocular irritation is expected to be minimal. Occupational exposure to airborne ozone from local off-gassing of SAO will occur primarily via the inhalation route when filling sanitizing equipment, during sanitization, or postapplication clean-up, or due to spray drift. Airborne ozone may be present immediately after dispensing due to limited local off-gassing of SAO. However, based on laboratory ozone emission measurements, these concentrations are not expected to increase significantly above background levels, or above established occupational exposure limits, following the first minute after dispensing.

To further reduce inhalation exposure to airborne ozone, the label and operating manual will require a statement that the lotus PRO and SAO be used in a well-ventilated area. No personal protective equipment is proposed for using lotus PRO or SAO. It is expected that workers in a commercial/industrial facility follow occupational health and safety standards or standard industrial hygiene practices.

Due to the low levels of ozone in the SAO, the high reactivity and relatively short half-life of ozone in water, and the limited use pattern, the potential for occupational exposure to SAO or off-gassed airborne ozone is low. Moreover, the design of the device system, which includes engineering and design controls, limits worker exposure to ozone to acceptable occupational exposure levels.

Precautionary statements on the lotus PRO label and operation manual aimed at mitigating exposure are adequate to protect individuals from risk due to occupational exposure. Overall, occupational risks for workers are acceptable when label and operating manual directions are followed.

3.3.2.2 Postapplication exposure and risk assessment

Post-application activities involve wiping the treated wet surface 5–15 minutes after the application of SAO with a clean microfiber cloth (or paper towel), and letting the surface air-dry. Postapplication exposure can be characterized as short-term in duration, with the primary routes of exposure by the dermal and inhalation routes. Based on provided information, postapplication ozone levels are expected to be comparable to pre-application background measurements.

Precautionary statements on the end-use product label and operating manual aimed at mitigating exposure are adequate to protect workers from risk due to postapplication exposure. Consequently, the risks to workers due to post-application exposure are acceptable.

3.3.3 Residential and bystander exposure and risk assessment

There are no residential uses for the device; therefore, residential exposure is not expected to occur.

lotus PRO is proposed for use in commercial/industrial facilities. Occupational bystander exposure is expected to be low as airborne ozone from local off-gassing of SAO are not likely to exceed natural background levels of ozone. Health risk to occupational bystanders are acceptable when the directions for use and precautionary statements on the label and operating manual are observed.

3.4 Dietary exposure and risk assessment

3.4.1 Food

There are no direct food uses under the *Pest Control Products Act* as SAO is proposed for use as a surface sanitizer. Dietary exposure to ozone residues are expected to be negligible due to the low ozone levels in SAO, high reactivity and relatively short half-life of ozone in water, a short (5–15 min) contact sanitization time, restricting the use of lotus PRO and SAO to well-ventilated areas, and the fact that treated surfaces are hard and non-porous in nature and must be thoroughly dried prior to contact with food. Moreover, the label will require a precautionary statement to prevent contamination of food with SAO during application and storage.

The use of lotus Pro in commercial food preparation facilities is exempted from the *Pest Control Products Act* under paragraph 3(1)(c) of the *Pest Control Product* Regulations. However, it is supported by a letter of acceptance from the Canadian Food Inspection Agency, a letter of no objection from Health Canada's Bureau of Chemical Safety, and provincial letters of acceptance. Therefore, the use will be permitted to appear on the pest control product label.

3.4.2 Drinking water

Generated SAO is not for drinking, and the proposed use of the device will not result in ozone contaminating surface or groundwater. Moreover, ozone in aqueous solution auto-decomposes rapidly in the environment to produce oxygen and leaves no harmful residues.

Consequently, the health risks from residues of ozone and generated SAO in drinking water are acceptable.

3.4.3 Acute and chronic dietary risks for sensitive subpopulations

When the end-use product is applied as directed by the label, the health risk is acceptable for the general population, including infants and children, and domestic animals.

3.5 Aggregate exposure and risk

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. A major consideration is the likelihood of co-occurrence of exposures. Additionally, only exposures from routes that share common toxicological endpoints can be aggregated.

Based on available information, there is reasonable certainty that no harm will result from aggregate exposure of residues of ozone, SAO or by-products generated by the lotus PRO device to the general Canadian population, including infants and children, when the end-use product is used as labelled. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information.

3.6 Cumulative assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. Accordingly, an assessment of potential common mechanisms of toxicity with other pesticides was undertaken. One other ozone-generating device is registered in Canada for pesticidal use, however no dietary or residential exposure is anticipated from its use to control zebra mussels in cooling water in power generating stations. Furthermore, given the proposed use pattern of lotus PRO is not likely to result in ozone levels in excess of natural background levels, that generated SAO is expected to auto-decompose rapidly to produce oxygen, and that dietary or residential exposure to SAO is not expected under the proposed conditions of use, there is no requirement for a cumulative risk assessment at this time.

3.7 Maximum residue limits

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether dietary risks are acceptable from the consumption of foods treated with the pesticide when used according to the supported label directions. If acceptable, this means food containing that amount of residue is safe to eat, and maximum residue limits (MRLs) may be proposed. MRLs are the maximum amount of pesticide residue legally permitted to remain in/on food sold in Canada and are specified under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act.*

SAO generated by lotus PRO device is not proposed for use on food. Consequently, the specification of MRLs, under the *Pest Control Products Act*, will not be required for ozone or SAO.

3.8 Health Incident Reports

As of 27 July 2022, one human incident affecting three people involving an ozone-generating device and three human incidents involving devices had been submitted to the PMRA. These incidents either involved other device types (for example, bug zapping device) and/or exposure scenarios (for example, exposure to ozone-generating air purifying devices in a home) that were not considered relevant to the use pattern of the proposed ozone sanitizing device.

4.0 Impact on the environment

An environmental assessment was not required for this application.

5.0 Value

Bacteria and fungi are omnipresent in our indoor environments. Some species of bacteria and fungi found on hard surfaces can contaminate industrial processes, contributing to economic losses, or can negatively impact human health. In commercial and industrial settings, routine cleaning and sanitizing/disinfection of surfaces is performed to lower this microbial bioburden, and help reduce the spread of microorganisms through human or fomite transfer.

Numerous sanitizers, containing a variety of active ingredients, are registered by the PMRA to kill bacteria and fungi on hard non-porous surfaces in commercial settings. This device has unique value, as it allows users to generate an effective sanitizer/disinfectant on site and on-demand.

The registrant submitted data from multiple laboratory studies to support their efficacy claims. Reports for a number of quantitative suspension tests were submitted which evaluated the efficacy of the SAO at a range of concentrations and contact times against *Escherichia coli*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Enterococcus hirae*. These tests were modified from standard methods (AOAC 960.09 and EN1276:2019) to accommodate the use of a test substance freshly generated from an on-demand device.

As primary support of the approved use pattern, coupon-based tests were conducted according to a modified version of BS EN 13697:2015. Stainless steel coupons were used as the representative hard surface material. Four different bacterial species (*P. aeruginosa, S. aureus, E. coli*, and *E. hirae*) were challenged with SAO generated by the lotus PRO device, at a measured concentration of 1.0 ppm. A 5 minute contact time reduced the number of all four bacteria species by more than 4-log (99.99%). Two fungal species (*Candida albicans* and *Aspergillus niger*) were also tested in the same manner. A 15 minute contact time with the 1.0 ppm aqueous ozone reduced the number of both fungal species by more than 3-log (99.9%).

Ozone in aqueous solution decays quickly. The filtration cartridges used with the lotus PRO system are designed to remove impurities from the water, increasing the stability of the ozone in solution, thus forming “stabilized” aqueous ozone. The long-term stability of the aqueous ozone is dependent on the function of the filter cartridge. Filters of this nature lose their effectiveness

with use. The SAO-24 cartridges can dispense a maximum of 3000L. The lotus PRO device tracks the dispensed volume, and gives a warning at 2800L. At 3000L, the unit will not allow further SAO generation until the filter cartridge is changed. Data was submitted, demonstrating the measured ozone concentration in the SAO dispensed from a cartridge near the end of its useful life is the same as the measured ozone concentration in the SAO dispensed from a fresh cartridge.

The rate of decay in ozone concentration over time, after dispensing from the device, was measured. The SAO can maintain its potency and effectiveness as a sanitizer/disinfectant for 4 hours after dispensing. Laboratory data was provided, which tracked the decrease in ozone concentration after creation and storage in low ozone demand secondary containers. The ozone concentration drops slightly faster in SAO generated using cartridges at the end of their useable life. It takes approximately 7 hours for the concentration of ozone in SAO generated using fresh cartridges to drop from 1.7 ppm to 1.0 ppm. The same decrease in concentration takes 4 hours when the SAO was generated using cartridges which had filtered the maximum 3000 L volume permitted by the device programming.

SAO generated by the lotus PRO should be used at full strength. No additional cleaning products or chemicals should be used. Heavily soiled surfaces should be pre-cleaned before the final 5 or 15 minute wet contact time. When used according to the directions on the label, SAO works as an effective sanitizer/disinfectant of hard non-porous surfaces.

6.0 Pest control product policy considerations

6.1 Toxic Substances Management Policy considerations

The *Toxic Substances Management Policy* (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, in other words, those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, ozone and its transformation was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that ozone and generated SAO do not meet all of the TSMP Track 1 criteria.

[5] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use product are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.[6]

The list is used as described in the PMRA Science Policy Note SPN2020-01[7] and is based on existing policies and regulations, including the *Toxic Substance Management Policy* and *Formulants Policy*,[8] and taking into consideration the *Ozone-Depleting Substances and Halocarbon Alternatives Regulations* under the *Canadian Environmental Protection Act, 1999,* (substances designated under the *Montreal Protocol*).

The PMRA has reached the following conclusions:

- lotus PRO does not contain any formulants or generate contaminants identified in the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

8.0 Proposed regulatory decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use the ozone generating device lotus PRO, which infuses filtered water with up to 1.7 ppm ozone to create stabilized aqueous ozone for use as a sanitizer and disinfect on a hard non-porous surface in commercial and industrial areas.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

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6 SI/2005-114, last amended on June 24, 2020. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

7 PMRA's Science Policy Note SPN2020-01, *Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under paragraph 43(5)(b) of the *New Pest Control Products Act.*

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

List of abbreviations

CFIA	Canadian Food Inspection Agency
cm	centimetre
L	litre
min	minute
MRL	maximum residue limit
O_3	ozone
PMRA	Pest Management Regulatory Agency
ppm	parts per million
SAO	stabilized aqueous ozone
TSMP	Toxic Substances Management Policy

References

A. List of studies/Information submitted by registrant

1.0 Chemistry

NA

2.0 Human and animal health

PMRA document number	Reference
3251605	2021, Mode of Action, DACO: 10.2.1
3251606	2021, Description of Pest Problem, DACO: 10.2.2
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3251616	G. Gupta, B. Mansi, 2012, Ozone therapy in periodontics, J. Med. And Life Vol 5(1): 59-67 DACO: 10.2.1,10.6
3251618	2016, Letter from Alberta Health Services, DACO: 10.6
3251619	2017, Letter from New Brunswick, DACO: 10.6
3251620	2016, Letter from Newfoundland, DACO: 10.6
3251621	2017, Letter from Prince Edward Island, DACO: 10.6
3251622	2016, Letter from Quebec, DACO: 10.6
3251623	2017, Letter from Saskatchewan, DACO: 10.6
3251624	2018, CE Declaration, DACO: 10.6
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PMRA document number	Reference
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3.0 Environment

NA

4.0 Value

PMRA document number	Reference
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B. Additional information considered

i) Published information

Human and animal health

PMRA document number	Reference
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