The lotus® Professional Cleaning System

Ozone-Based Commercial Cleaning System
Background Information Memorandum

January 2009

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Executive Summary

The lotus® Professional Cleaning System ("lotus®") is a commercial sanitizing and cleaning system manufactured in an Environmental Protection Agency ("EPA") registered site (EPA site registration number – 82126-CHN-001). The lotus® is EPA-regulated and produces liquefied ozone, an approved sanitizer/disinfectant under the US Food and Drug Administration ("FDA") and United States Department of Agriculture ("USDA"), for food and non-food contact surfaces. The system has been proven by third parties using Green Seal Environmental Standards for Industrial Cleaners ("GS-37 Standards") as an effective bathroom cleaner, glass and chrome cleaner and neutral floor cleaner for use in away from home applications.

Numerous studies have proven that ozone is a broad range anti-microbial agent and works faster than chlorine bleach. The lotus® meets Occupational Safety and Health Administration ("OSHA") and NSF International ("NSF") safety requirements and is approved by both NSF and Underwriters Laboratory ("UL"). The FDA has designated liquefied ozone as Generally Recognized as Safe ("GRAS") for food contact.

Backgrounder

Since 2002, Tersano Inc. has been a North American leader in residential and commercial sanitizing systems. Tersano recently launched its commercial product line, the lotus® Professional Cleaning System. The units are built on the same environmentally-friendly technology that saw Tersano's 2006 retail model named as one of Time Magazine's top ten inventions that year.

The lotus® infuses ordinary water with ozone, creating liquefied ozone, a natural sanitizer that destroys bacteria, virus and pathogens safely and effectively on all surfaces, including those used in food preparation. The disinfecting properties of ozone are well documented; the natural element is one of the strongest oxidizing agents known, second only to fluorine. In fact, ozone is a more effective sanitizer than bleach and chlorine.

Many applications can benefit from the use of ozone such as residential, commercial and industrial cleaning. The lotus® system serves in commercial and institutional organizations and is safe and effective as both a cleaning product and a sanitizer.

The benefits of ozone (the sanitizer) have been in the home for many years. Bottled water companies have enjoyed economic and health benefits of being chemical-free using ozone. Not to mention that ozone (the disinfectant) has been the secret of the pharmaceutical industry for years. Municipal water and wastewater plants and more recently the food industry are likewise employers of ozone-based cleaners and whose benefits are enjoyed by communities around the world.

Redefining the "Culture of Clean"

While ozone is widely-used in industrial sanitizing, residential and commercial settings have, until now been the last bastion of "chemical clean", Consumer product companies have spent hundreds of millions of dollars creating the 'culture' of clean. A natural cleaner that is largely odourless, colourless and not easily distinguished from that of water, (except from an atomic perspective), has been in the minds of many, a poor replacement for the powerful fragrances, colours, bubbles and foams and packaging symbolic of chemical cleaners.

However, with the greening of the Western world, increased concerns about the impact of household chemicals on human health, an environmental focus on the manufacturing, storage, use and disposal of chemicals along with tightening household and commercial cleaning budgets, the climate is ripe for the lotus® Professional Cleaning System.

Ozone: Nature's Cleaner

Ozone is a naturally occurring element that is formed when oxygen molecules pass through an electrical field that breaks them apart and reconstitutes them as 0_3; also known as; ozone, tri-oxygen or super-oxygen. Ozone has a short half life after which time the elements revert to their natural state.

Inside the lotus® system, an oxygen concentrator feeds oxygen through an electrical field to create ozone. The ozone is in turn diffused into water via ozone bubbles, which sanitize the water when micro-ozone bubbles come in contact with them, enabling the super-water to transfer the diffused ozone to the surfaces being cleaned and sanitized. Ozone must make contact with subject surfaces in order to be effective.

Ozone generators produce ozone measured in concentration by either (a) weight, basically the percentage of gas in a stream of air or (b) parts per million ("ppm"). One ppm is equal to 2 milligrams per cubic meter (mg/m^3), and 1 percent by weight is equivalent to 10,000 ppm.

Following a brief "ozination" cycle, the lotus® generates approximately 2.5 – 3.0 ppm ozone dropping to approximately 1.0 ppm after fifteen minutes, after which time the sanitizing benefits have expired as the water continues to revert to safe, ordinary water. The ozinated water does however; continue to retain sufficient ozone to clean for 60 minutes.

Ozone's 125 Year History as a Sanitizer and Disinfectant

Ozone has a safe history in commercial applications stretching more than 125 years. In 1881, Dr. Kellogg, noted American medical pioneer, observed ozone's use as a disinfectant for diphtheria and eleven years later the world's first water treatment plant using ozone was installed in Holland.

More than a century later, sanitizing and disinfecting with ozone remains environmentally acceptable. Using ozone eliminates the need for handling, storage, recordkeeping and disposal of toxic chemicals that are covered by increasingly stringent government regulations. Ozone has a high germicidal effectiveness against a wide range of pathogenic organisms including bacteria, protozoa, and viruses.

Iotus® : Proven Antimicrobial

The difference between the terms sanitizer and disinfectant are largely regulatory. Both are highly effective killers of bacteria, viruses and pathogens. Under EPA protocol, sanitizers eliminate 99.99% germs, whereas disinfectants are able to kill 99.999% of the same elements in the same test. In addition, disinfectants can kill live spores.

A recent article published in the Association for Professionals in Infection Control and Epidemiology found that ozone was able to inactivate more than $3\log_{10}$ colony-forming units of most bacteria including Acinetobacter baumannii, Clostridium difficile ("C. difficile") and methicillin-resistant Staphylococcus aureus ("MRSA") in both laboratory and simulated field conditions.

The study concluded that ozone generation can provide a valuable decontamination tool for the removal of bacteria in many institutions and communal settings including hospitals and other health care institutions.[1]

The Benefits of Liquefied Ozone

Liquefied ozone, is a significantly faster disinfectant, requiring lesser concentrations than ozone diffused in air. For example 20ppm of ozone in air takes 20 minutes to disinfect and 93ppm of ozone in air takes 30 seconds to disinfect. By contrast, 0.25ppm of ozone in water takes 96 seconds to disinfect while 0.81ppm of ozone in water takes 30 seconds.[2]

Ozone Concentration	Diffusion Media	Time Required to Disinfect
20ppm	Air	20 minutes
93ppm	Air	30 seconds
0.25ppm	Water	96 seconds
0.81ppm	Water	30 seconds

The Iotus® Regulatory and Approval Framework

As previously explained the Iotus® is an EPA regulated device that produces liquefied ozone, a sanitizer recognized by the FDA and proven disinfectant. Classified as a commercial germicide (disinfectant), for both food contact and non-food contact surfaces, the Iotus® is regulated and/or monitored by the US Food and Drug Administration ("FDA"), the US Environmental Protection Agency ("EPA"), the US

[1] Ozone gas is an effective and practical antibacterial agent. Manju, S. and Hudson, J. Am J Infect Control 2008: 36:559-63.
[2] Source: Tersano Research.

Department of Agriculture ("USDA") and the US Department of Labor's Occupational Health and Safety Administration ("OSHA").

(i) EPA and the lotus®

In the United States, liquid chemical germicides ("disinfectants") are regulated by EPA and FDA. In commercial applications, EPA regulates germicides that are used on environmental surfaces whereas FDA is more focused on high-level sterilants for surfaces for medical and food contact. Commercial disinfectants are also regulated in interstate commerce by the Antimicrobials Division, Office of Pesticide Programs, EPA, under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") of 1947.

Under FIFRA, any substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, including microorganisms but excluding those in or on living man or animals must be registered before sale or distribution. To obtain an EPA registration number, a manufacturer must submit specific data regarding the safety and the effectiveness of each product.

Under the same legislation, any establishment that produces or imports pesticides into the United States must register and file production reports with the EPA. Production in an unregistered establishment is a violation of the law. Germicide producing establishments and their production amounts are closely tracked by the EPA.

This regulation yields the traditional registration process with which purchasers and users of traditional commercial disinfectants are familiar – chemical companies with both (a) an EPA establishment number and (b) an EPA registration number.

Uniqueness of Ozone-Generators under EPA Regulation

Ozone-generating systems are unique in the opinion of the EPA. Unlike chemical, biochemical and microbial pesticide substances, EPA does not require the registration of devices that generate ozone. The EPA does however regulate devices that make claims that they kill, inactivate, entrail or suppress growth of fungi, bacteria or viruses in various sites. These devices may be regulated or unregulated, by the EPA, however, the device is not registered by EPA and therefore does not receive an EPA registration number.

Why The lotus® does not have an EPA Registration Number

Based on correspondence with EPA's Antimicrobial Division, the lotus® system is regulated under FIFRA but cannot be registered under FIFRA and therefore does not have an EPA registration number. However, the device is subject to strict EPA regulations with regard to labeling, production, record keeping, packaging and import/export requirements. Furthermore the lotus® system devices must be produced in an EPA-registered establishment and has received an EPA establishment number.

EPA Testing

The lotus® is subject to the same rigorous testing and process that EPA registered chemicals face in determining and assessing their sanitizing and disinfecting claims. In addition, to make claims of disinfectant and sanitizing, EPA still requires manufacturers to test formulations by using accepted methods for microbicidal activity, stability, and toxicity to animals and humans. Manufacturers submit these data to EPA with proposed labeling.

(ii) FDA and the lotus®

Ozone as an Antimicrobial Agent

In 2001 the FDA approved the use of ozone as an antimicrobial agent in the gas or liquid phases for direct contact with foods. On June 26, 2001 the U.S. FDA approved the use of ozone as an antimicrobial agent in the gas or liquid phases for direct contact with foods. Ozone has been approved for use under "Good Manufacturing Practices", meaning "exposure of foods to sufficient ozone (concentrations and times of exposure) to accomplish its intended purpose." This means determining the minimum exposure to ozone necessary to provide desired antimicrobial benefits on specific foodstuffs and also determining at what (presumably higher) level ozone causes damage to the foodstuffs and/or result in off-gassing of ozone sufficient to violate OSHA's PEL or STEL and/or EPA's environmental limits.

The lotus® in Food Preparation Areas

Liquefied ozone produced by the lotus® is an effective tool in sanitizing food preparation surfaces. A unique feature of the lotus® is the ability of ozinated water to disinfect surfaces in the close presence of food without concerns of chemicals ingestion among consumers. The ability to sanitize food preparation surfaces without manually applying, drying, wiping or similar contact limits cross contamination. The environmentally-friendly lotus® uses minimal energy, no chemicals and creates an effective sanitizing and solution at minimal cost. The lotus® is rapidly becoming a product of choice for foodservice sanitizing.

Ozone as a GRAS Substance

In June 2001, the FDA granted ozone disinfection Generally Recognized as Safe (GRAS) classification. GRAS substances are those that are intentionally added to food, or food additives. Food additives are subject to pre-market review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. For example, substances whose use meets the definition of a pesticide, a dietary ingredient of a dietary supplement, a color additive, a new animal drug, or a substance approved for such use prior to September 6, 1958, are excluded from the definition of food additive. Sections 201(s) and 409 were enacted in 1958 as part of the Food Additives Amendment to the Act. While it is impracticable to list all ingredients whose use is

generally recognized as safe, FDA published a partial list of food ingredients whose use is generally recognized as safe to aid the industry's understanding of what did not require approval.

Data For Food Service Health Inspectors

lotus® produces an FDA approved food surface and food contact sanitizer designated as GRAS. Liquid produced by the lotus® may safely be used by foodservice operators to sanitize and clean food contact surfaces (tables, cutting boards, knives, etc.) as long as it is applied within 15 minutes of being produced by the lotus® device. To eliminate Salmonella and e coli it is recommend having a dwell time of 30 seconds. The liquefied ozone produced by the lotus® device will leave no residue. Surfaces or food sanitized using lotus® do not need to be rinsed. Liquid produced by the lotus® device has no volatile organic compounds and all zeros for health, flammability and reactivity. See MSDS at www.tersanoprofessional.com.

Data for County Health inspectors

Lotus® produces liquefied ozone which is both a cleaner and sanitizer. Cleaning capabilities last for 50 minutes after production by the device. It exceeds GS-37 cleaning standards as a glass/chrome cleaner, bathroom cleaner and all-purpose neutral cleaner.

Liquid produced by the lotus® device has no volatile organic compounds and all zeros for health, flammability and reactivity. See MSDS at www.tersanoprofessional.com.

lotus® is an effective sanitizer 50% stronger and 3,000 times faster than chlorine bleach. Safely use lotus® wherever you currently use bleach to clean and disinfect.

Liquefied ozone produced by lotus® is effective on MRSA, Norovirus, C. difficile and many other bacteria and viruses when applied within 15 minutes of production by the lotus® device. lotus® exceeds the EPA required thresholds on a number of organisms. (See appendix “A”). It is this threshold that must be exceeded and submitted to the EPA for a germicide to be considered for use in healthcare environments.

(iii) US Department of Labor’s OSHA and lotus®

OSHA develops workplace standards to help ensure safe and healthful working conditions in places of employment. EPA and OSHA standards allow workers to be exposed to a weighted average of 0.1 ppm ozone over eight hours, or 0.3 ppm for 15 minutes. The lotus® system generates UL tested emission from the lotus® system and determined that lotus® emit about 1-2ppm into the air. This is well within the safe range according to the OSHA.

(iv) GS-37 Standards

Green Seal, a non-profit organization devoted to environmental standard setting, product certification, and public education, which promotes environmentally responsible products. Green Seal produces GS-37, Standards for Institutional and Industrial Cleaners. Under GS-37, industrial and institutional cleaners are those cleaners intended for routine cleaning of offices, institutions, warehouses, and industrial facilities. The standard also includes consideration of vulnerable populations in institutional settings such as schools, day-care facilities, nursing homes, and other facilities. The lotus® system exceeds GS-37 Standards. See UMASS TURI study at www.tersanorofessional.com for third party validation.

(v) NSF and UL

The lotus® is pending approval form NSF International and Underwriters Laboratory, trusted international sources for product compliance. United Laboratories have tested the lotus® for risk of electrical shock as well as ozone emissions.

The lotus® and Performance

Sanitizing

The lotus® kills all bacteria, virus, fungus and mold spores, protozoa, fungal pathogens, yeasts, cysts and algae. For a full listing of the specific conditions that the lotus® kills see Appendix A.

Cleaning

When it comes to cleaning, the lotus® Professional Cleaning System is top of its class. The Surface Solutions Laboratory (“SSL”) at the Toxics Use Reduction Institution (“TURI”) a state agency based at the University of Massachusetts who provide surface cleaning testing. The lotus® system was evaluated in comparison to two chemical commercial/institutional disinfectants, Pleascent Neutra Shine and Compass, using GS-37 Standards. It was determined the lotus® was an effective bathroom, glass and chrome cleaner and neutral cleaner.

Deodorizer

As tested by Microbiotest to EPA protocol on odor control, lotus charged water was found to reduce up to 99% of odor causing bacteria on cotton fabric.

Contact:

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APPENDIX A[i]

The lotus® kills bacteria, virus, fungus and mold spores, protozoa, fungal pathogens, yeasts, cysts and algae

(i) Bacteria

- Achromobacter butyri NCI-9404
- Aeromonas harveyi NC-2
- Aeromonas salmonicida NC-1102
- Bacillus anthracis
- Bacillus cereus
- B. coagulans
- Bacillus globigii
- Bacillus licheniformis
- Bacillus megatherium sp.
- Bacillus paratyphosus
- B. prodigiosus
- Bacillus subtilis
- B. stearothermophilus
- Clostridium botulinum
- C. sporogenes
- C. difficile
- Clostridium tetoni
- Cryptosporidium
- Coliphage
- Corynebacterium diphthriae
- Eberthella typhosa
- Endamoeba histolica
- Escherichia coli
- Flavorbacterium SP A-3
- Leptospira canicola
- Listeria
- Micrococcus candidus
- Micrococcus caseolyticus KM-15
- Micrococcus spharaeroides
- MRSA
- Mycobacterium leprae
- Mycobacterium tuberculosis
- Neisseria catarrhalis
- Parvo
- Phytomonas tumefaciens
- Proteus vulgaris
- Pseudomonas aeruginosa
- Pseudomonas fluorscens (bioflims)
- Pseudomonas putida
- Salmonella choleraesuis
- Salmonella enteritidis
- Salmonella typhimurium
- Salmonella typhosa
- Salmonella paratyphi
- Sarcina lutea
- Seratia marcescens
- Shigella dysenteriae
- Shigella flexnaria
- Shigella paradysenteriae
- Spirllum rubrum
- Staphylococcus albus
- Staphylococcus aureus
- Streptococcus 'C'
- Streptococcus faecalis
- Streptococcus hemolyticus
- Streptococcus lactis
- Streptococcus salivarius
- Streptococcus viridans
- Torula rubra
- Vibrio alginolyticus & angwillarum
- Vibrio clolarae
- Vibrio comma
- Virrio ichthyodermis NC-407
- V. parahaemolyticus

(ii) Virus

- Adenovirus (type 7a)
- Bacteriophage (E.coli)
- Coxackie A9, B3, & B5
- Cryptosporidium
- Echovirus 1, 5, 12, &29
- Encephalomyocarditis
- Hepatitis A
- Hepatitis B
- HIV
- GD V11 Virus
- Onfectious hepatitis
- Influenza
- Legionella pneumophila
- Polio virus 1, 2 & 3
- Rotavirus
- Tobacco mosaic
- Vesicular Stomatitis

(iii) Fungus & Mold Spores

- Aspergillus candidus
- Aspergillus flavus (yellowish-green)

- Aspergillus glaucus (bluish-green)
- Aspergillus niger (black)
- Aspergillus terreus, saitoi & oryzac
- Botrytis allii
- Colletotrichum lagenarium
- Fusarium oxysporum
- Grotrichum
- Mucor recomosus A & B (white-gray)
- Mucor piriformis
- Oospora lactis (white)
- Penicillium cyclopium
- P. chrysogenum & citrinum
- Penicillium digitatum (olive)
- Penicillium glaucum
- Penicillium expansum (olive)
- Penicillium egyptiacum
- Penicillium roqueforti (green)
- Rhizopus nigricans (black)
- Rhizopus stolonifer

(iv) Protozoa

- Paramecium
- Nematode eggs
- Chlorella vulgaris (Algae)
- All Pathogenic and Non-pathogenic forms of Protozoa

(v) Fungal Pathogens

- Alternaria solani
- Botrytis cinerea
- Fusarium oxysporum
- Monilinia fruiticola
- Monilinia laxa
- Pythium ultimum
- Phytophthora erythroseptica
- Phytophthora parasitica
- Rhizoctonia solani
- Rhizopus stolonifera
- Sclerotium rolfsii
- Sclerotinia sclerotiorum

(vi) Yeast

- Baker's yeast
- Candida albicans-all forms
- Common yeast cake
- saccharomyces cerevisiae
- saccharomyces ellipsoideus
- saccharomyces sp.

(vii) Cysts

- Cryptosporidium parvum
- Giardia lamblia
- Giardia muris

(vii) Algae

- Chlorella vulgaris
- Thamnidium
- Trichoderma viride
- Verticillium albo-atrum
- Verticillium dahliae

[i] As demonstrated through independent testing.
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