

Franke EcO₃lce Antimicrobial Ice Protection

Technical and Certification Summary



March, 2016

PROPRIETARY AND CONFIDENTIAL

Franke EcO₃Ice Antimicrobial Ice Protection

Overview

Section I: Technical Summary presents information to support the Franke EcO_3 lce Antimicrobial Ice Protection and its effectiveness as a preventative method for biofilm growth; to address questions of consumer and worker safety; and to assess its impact on ice machine reliability.

Section II: **Certification Summary** lists the independent testing bodies employed as well as regulatory approvals achieved.

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Executive Summary of Section I

The Technical Summary addresses four key topics, as follows:

1. Efficacy: Summary of Biological Testing

The antimicrobial efficacy of the EcO_3 lce dissolved ozone generator was evaluated in three parts:

- <u>E. Coli Lab Testing</u> was done at an independent microbial lab with two identical machines--one with EcO₃Ice and one without. A "total kill," or 5-log reduction, was achieved after 48 hours of exposure time when ozonated ice was used.
- <u>Biofilm Growth Lab Testing</u> was side-by-side testing of ice machines in a laboratory environment over a 6-month period of operation. In prevention of biofilm build-up, the ozone machine outperformed the one without.
- <u>Biofilm Growth Field Testing</u> was designed to validate laboratory findings in working, commercial kitchens. Nine sites were tested; at all of them, EcO₃Ice showed significant ability to slow down the growth of bacteria, yeast and mold.

2. Competitive Analysis of Core Technology

 EcO_3 lce's novel use of solid synthetic diamonds overcomes the challenges of traditional electrolytic ozone production methods, particularly in the areas of space and energy efficiency; reliability; and efficacy. The EcO_3 lce electrolytic method of producing dissolved ozone "fromwater, in-water" has been optimized to enable compact antimicrobial applications in which purity and resource efficiency are at a premium and off-gassing levels are to be minimized.

3. Water Quality

The EcO_3 lce unit's unique ozone production method is designed to counter the build-up of scale. However, high calcium levels—greater than 150 ppm—may adversely affect the life of the unit (and most other kitchen equipment). As such, it is recommended that EcO_3 lce be supplied with water treated by a conventional filtration device. Studies of ozone's reaction with minerals in water, as well as the by-products of ozonation in potable water, indicate that EcO_3 lce raises no operational or human safety issues stemming from chemical reactions.

4. Human & Materials Exposure

Consumer Exposure: Ozone Ingestion

There are no regulatory standards established by FDA, USDA, or EPA for dissolved ozone ingestion. Based on a review of available data by independent toxicological experts, the limited exposures associated with ingestion of the small amounts of ozone resulting from the EcO₃Ice device are anticipated to be without any significant human health effects.

Worker Exposure to Ozone

We have tested the off-gassing levels of EcO_3 lce units for cubers up to 2000 lbs./day, and any size or number of related ice storage bins, and they are all well below OSHA PEL (Permissible Exposure Limit). EcO_3 lce has been tested to CE and UL standards by a third party.

Ice and Beverage Taste/Odor

Ozone leaves behind none of the chemical trace odors associated with some equipment sanitation methods. Rather, ozone is widely recognized by government agencies to be an effective oxidant used to reduce unpleasant taste and odors in drinking water.

Ice Machine Reliability

Ozone compatibility of ice machines depends on components used in the machine. EcO₃lce produces only a low level of dissolved and gaseous ozone within the ice storage bin. Therefore, It avoids high concentrations of ozone that can have adverse effects on ice machine materials. Materials used in particular ice machine models should be reviewed and tested for ozone compatibility.

Part I: Technical Summary

1. Efficacy: Summary of Biological Testing

1.1 Technology Overview

Ozone is proven and widely accepted for numerous FDA-approved drinking-water and foodrelated applications. Ozone in general has the ability to rapidly kill virtually all of common microorganisms including bacteria, viruses, fungi, algae, yeast, mold, parasites and other known sources of foodborne illness. Properly applied, ozone kills at the same time it eliminates sources of odors.

 EcO_3 lce is a unique technology development that resolves the limitations and safety issues inherent in the use of ozone-generating devices in foodservice. EcO_3 lce is a compact device that attaches to the incoming water line of a commercial ice cube maker and generates dissolved ozone, "from-water, in-water." Ozonated water flows through the water path, and subsequently is frozen into ice. The ozone is present throughout the ice cube, with a higher concentration in the outermost layer. The amount of residual ozone in the ice is well below levels of taste detection.

The resulting, low-level ozone effectively reduces microbes on surfaces in both the ice machine (water lines, reservoir, evaporator, etc.) and the ice holding bin (bin surfaces, drain, etc). The process significantly retards biofilm growth within the ice machine and extends the required time between routine cleanings.

Ozone is well preserved in ice and dissipates very gradually in the ice bin over a period of several days. The ice gradually melts and the resulting water drains from the bin. The "ice melt" contributes to the ozone's ability to reduce microbes and their growth on surfaces as well as on the drain fixture and line.

The antimicrobial efficacy of the EcO₃lce dissolved ozone generator was evaluated in three phases:

- Part I of the study (E. coli Lab Testing) was designed to determine the level of dissolved ozone concentration needed to be effective against bacteria and still remain within defined safe limits.
- Part II of the study (Biofilm Growth Lab Testing) was comprised of side-by-side testing of ice machines in a laboratory environment over a 6-month period of operation.
- Part III of the study (Biofilm Growth Field Testing) was designed to validate laboratory findings in working, commercial kitchens.

1.2 E. coli Lab Testing

In Part I of the biological testing, a side-by-side comparison of the effect of ozone on E. coli in an ice machine bin was conducted. Two identical ice machines were set up on site at the microbiology lab, one equipped with the EcO_3Ice unit and one without.



Figure 1: Coupon and lab set-up of ice machines.

Duplicate stainless steel coupons of 4.0" X 4.0" were inoculated with 1.0 X 10⁷ E. coli and placed in the ice cube machine. The coupons were tested at three different time intervals to determine the log reduction of the E. coli. Ice production was limited to 4 hours to provide a manageable but realistic layer of ice cubes over the coupons. Proper care was taken to remove the coupons to prevent any incidental removal of the E. coli bacterium.

The log reductions were determined for both machines after 2, 4, and 48 hours. At the end of each exposure time, four coupons from 'Experiment Ice Maker' and four coupons from 'Control Ice Maker' were retrieved and the approximate number of surviving bacteria was determined. Once the target bacteria were extracted from the challenged surface of the coupons, the resulting solutions were plated on both TSA and VRB agar and were incubated at 32.5±2.5°C for 22 to 24 hours. A "total kill," or 5-log reduction in bacterial counts was achieved after 48 hours of exposure time.

Time	Bacterial Kill with Ozone	Bacterial Kill without Ozone
2 hr	Log reduction 1.8	Log reduction <0.4
4 hr	Log reduction 2.8	Log reduction 0.6
48 hr	Log reduction 5.0	Log reduction 1.6

Results of Bacteria Kill

1.3 Biofilm Growth Lab Testing

In Part II of the biological testing, a side-by-side comparison of two identical ice machines was made in the product development lab. Each ice machine was equipped with a conventional water filter and was connected to the municipal water supply. One ice machine was outfitted with an in-line EcO₃ lce dissolved ozone generator and the other was not.

A grid was drawn on the floor of both ice bins to ensure that swabbing over the subsequent months was distributed appropriately over the bottom of the ice bin and that both machines were swabbed in the same location in the same time period. The ice bin of each machine was emptied every day during the week. Every two weeks a microbial swab was taken from five locations of each machine plus a control. The floor of each ice machine was swabbed at the same location in the grid and the swab sticks were collected and processed at the outside lab. At the lab the swabs were plated on both TSA and VRB agar and incubated at 35.5 deg. C for 22 to 24 hours.

The results for the EcO_3 lce ozonated ice machine indicated an improved cleanliness compared to the ice machine without the EcO_3 lce unit. Specifically, testing found a reduction of microbial growth in the ozonated ice machine. These data led directly into Part III of the testing, a field study to confirm these findings in a "real world" setting.

1.4 Biofilm Growth Field Testing

In Part III of the biological testing, a field study was conducted on nine randomly selected restaurants and fast food chains within the greater Boston area. Establishments that made dough and bread were included. The ice machines were cleaned prior to installing the IST unit. A swab test was taken before and after cleaning to establish a baseline.

Each ice machine in the restaurant was swabbed in four locations:

- 1- Ice bin (red bar in graphs below)
- 2- Ice thickness gauge (yellow bar)
- 3- Ice tray (blue bar)
- 4- Water reservoir (tan bar)

The standard plate count for each location was recorded. The machines were operating as they were prior to the installation of the device. Samples of the four locations within the ice machine were collected once every two weeks. The overall results show that the installation of the EcO_3 loc dissolved ozone unit clearly retarded bacteria growth.

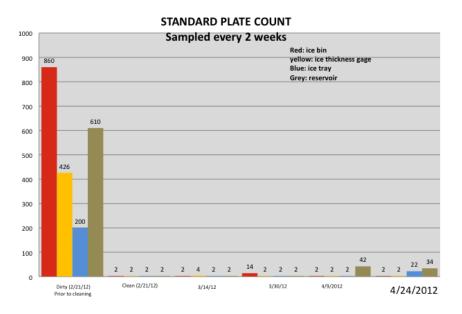


Figure 2: Standard Plate Count over 5-week period.

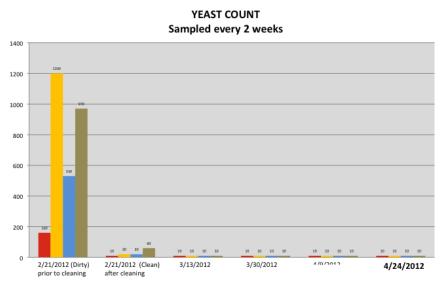


Figure 3: Yeast Count in field locations that bake bread.

The preliminary results of the expanded testing to evaluate the effect of the EcO₃lce unit on 'mold' & 'yeast' indicate a positive effect as well.

1.5 Conclusions

Test results demonstrate that the amount of dissolved ozone in water supplying the ice machine was sufficient to reduce the "bio-burden" while ensuring that ozone gas inside the unit was kept below OSHA permissible exposure limits at all times.

Testing also demonstrates that the Franke EcO_3 lce device is an effective and practical method for controlling and reducing biofilm formation, as well as effectively reducing pathogens in the ice machines.

2. Competitive Analysis of Core Technology

The Franke EcO₃ lce electrolytic method of producing dissolved ozone "from-water, in-water" has been optimized to enable compact applications in which purity and resource efficiency are at a premium and off-gassing levels must be minimized. This method effectively reduces and retards bacteria and other microorganisms within the ice bin, while keeping ozone gas levels far below OSHA PEL (permissible exposure limits) standards.

The EcO₃lce unit's solid, boron-doped diamond technology enables greater efficiency, reliability and greater antimicrobial power as compared to coated synthetic diamond electrodes used in electrolytic ozone production.

2.1 Space and Resource Efficiency

Through the use of diamond electrodes, a higher current density is possible for more efficient ozone production and a more compact ozone cell—two to four times smaller than those using coated electrodes. Alternative ozone technologies, namely "corona discharge," have not been suited to confined spaces and require more complex systems.

2.2 Reliability

The solid synthetic diamond technology used in EcO₃Ice doesn't suffer the safety and stability issues known to plague lead oxide electrodes, and are found to be more efficient than platinum coated electrodes.

- Lead oxide electrodes can require complex systems, may experience low current efficiencies, and may pose a safety risk, especially in applications where the purified water is eventually consumed.
- Other metals used to coat electrodes, such as platinum, have been found to be less efficient than solid diamond, and may require larger electrodes or increased power requirements.
- Coated electrodes are subject to hydrogen "embrittlement" of the metal substrate. This issue can plague coated electrodes when they are used as a cathode. De-lamination, where the coatings break off, can negatively impact reliability and effectiveness of coated electrodes.
- Symmetric electrode construction enables a patent-pending reverse polarity scheme that helps to reduce scale.

2.3 Antimicrobial Power

EcO₃Ice solid diamond electrodes can be driven at a higher current density which allows much greater efficiency at producing ozone.

- Smaller aperture spacing means greater dissolution of ozone and less off-gassing.
- The use of symmetric electrodes means more continuous ozone production, even in hard water.

3. Water Quality Considerations

3.1 Reliability

As noted, EcO_3 lce's unique ozone production method is designed to counter the build-up of scale. However, high calcium levels—greater than 150 ppm—may adversely affect the life of the EcO_3 lce (and most other kitchen equipment). As such, we recommend that EcO_3 lce be supplied with water treated by a conventional filtration device.

3.2 Reaction with Minerals in Water

Ozone is a strong oxidizing agent. It does react with cations in the water forming oxides. Manganese oxide and iron oxide can coagulate and precipitate out of the water. Sodium, potassium, and calcium oxides stay in solution; however, they do not freeze in the ice machine and they are purged from the ice machine after each freeze cycle. They are not expected to cause any issues in the ice.

3.3 Hazardous By-Products

There are no known hazardous, disinfection by-products generated by ozone treatment of potable water other than bromate, which is produced from water containing bromide. Some studies have shown that bromate is formed at ozone exposure (CT) 0.4 ppm. The level of ozone exposure in the EcO_3 lce unit is well below this level.

4. Human & Materials Impact

4.1 Consumer Exposure: Ozone Ingestion

Based on a review of available data by independent toxicological experts, the limited exposures associated with ingestion of the small amounts of ozone resulting from the EcO₃Ice device are anticipated to be without any significant human health effects.

Ozone is presently used in both food and water applications. The USDA National Organic Program allows ozone to be used as an ingredient in or on processed products labeled as "organic" or "made with organic ingredients" per 7 CFR section 205.605. Under FDA 21 CFR Section 184.1563, the presence of ozone in bottled water is permitted when limited to 0.4 ppm ozone per liter of bottle water. By comparison, we estimate that at the time EcO₃Ice ozonated ice is served, ozone levels have dropped dramatically to approximately 0.05ppm or less. At this residual concentration, the taste and odor of ozone is not anticipated to be detectable. The device may in fact remove odors, which may have otherwise been resident in the inlet water and ice.

4.2 Worker Ozone Exposure

EPA and OSHA regulatory requirements exist for only for gaseous ozone. The off-gassing levels of the EcO₃lce unit are well below OSHA PEL limits. This stands in contrast to the off-gassing risk inherent in technologies which inject ozone into the water via large bubbles.

4.3 Ice and Beverage Taste/Odor

Ozone leaves behind none of the chemical trace odors associated with other equipment sanitation methods. Rather, ozone is recognized to be an effective oxidant used to reduce unpleasant taste and odors in drinking water. The EPA Guidance Manual, *Alternative Disinfectants and Oxidants*, refers to ozone treatment for removal of unpleasant taste and odor.

4.4 Ozone Exposure: Ice Machine Reliability

Our method of producing ozone from-water in-water gradually releases ozone in a dissolved, liquid form within the ice storage bin, preventing high concentrations of ozone that can have adverse effects on ice machine materials. Users who have concerns about specific materials used in particular ice machine models should consult Franke.

5. Application

The first release of the EcO₃Ice dissolved-ozone unit is optimized for cubers up to 2000 lbs/day, and any size or number of related ice storage bins.

The EcO_3 lce unit is designed to accept a water supply with a flow rate of 0.5 to 1.5 gpm (1.9-5.7 lpm); a maximum temperature of 100 deg. F. (38 deg C.); and a maximum pressure of 125 Psi (8.61 bar). Support for flake and nugget ice is under discussion, though no development program is underway at present.

Part II: Certification Summary

1. Bacteriological Testing

Lapuck Laboratories, certified and registered by the FDA and USDA, has executed all bacteriological testing.

2. Device Safety Certification

TUV/ SUD - Mass has been selected as the Safety Certification Agency for all components supplied by EOI. (See certificate herein.)

3. EMI Certification

Retlif Test Labs has been selected as the Emissions and Immunity Testing lab. (See certificate herein.)

Because the EcO_3 lce unit utilizes high frequency switching internally, the device must be certified not to cause or be sensitive to EMI. The Retlif testing certifies the device to this requirement; the resulting reports are kept on file as part of the manufacturer's self-certification and application of both FCC and CE marks.

4. Material Safety Certification

EcO₃Ice was tested to NSF 2 by Intertek Testing Services, NA Inc. Specifically, Intertek performed NSF/ANSI 2-2010: Food Equipment Materials, Section 4.1-Toxicological Review and FDA Extraction Testing at its microbiological laboratory in Columbus, Ohio.

 EcO_3 lce ozone cell samples were evaluated for their concentration of non-volatiles and extraction of heavy metals. Test sample evaluations were conducted at the Columbus labe between May 18, 2012 and June 18, 2012. The ozone cell complies with the FDA's extraction requirements for polymers that are used at room temperature.

5. Non-U.S. Certification

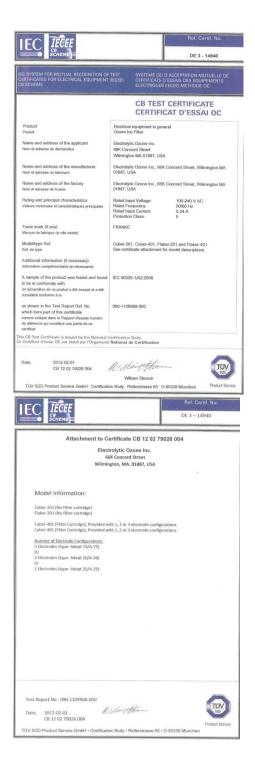
Reports from the various above-named sources prove compliance to the European Directives required for this device and allow us to certify to the CE mark as well as US and Canadian safety standards.

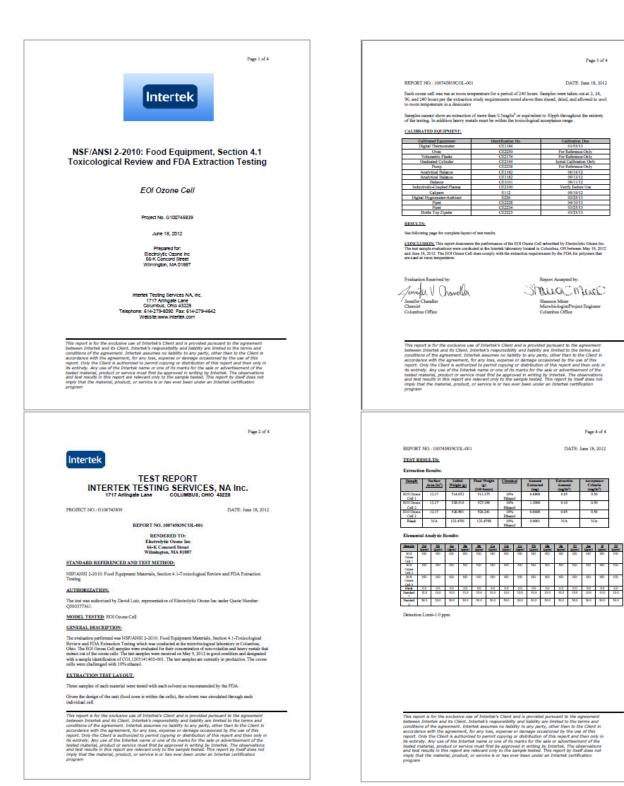
6. Certificate Exhibits

(Attached, below.)

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Date of Issue:	December, 2011	Date of Issue:	December, 2011
Issued By:	Retiif Testing Laboratories 101 New Boston Road Goffstown, NH 03045	Issued By:	Retilf Testing Laboratories 101 New Boston Road Goffstown, NH 03045
Issued To:	Electrolytic Ozone, Inc. 66-K Concord Road Wilmington, MA 01887	Issued To:	Electrolytic Ozone, Inc. 66-K Concord Road Wilmington, MA 01887
Reference:	Retlif Report Number R-5529N-1	Reference:	Retlif Report Number R-5529N-1
below listed standards was Retlif Testing Laboratories	hereby acknowledges that compliance testing in accordance with the performed on a representialive sample of the equipment listed below. Unter acknowledges that the test sample listed below was found to be in dards. This certificate is hereby issued to the above named grantee and in identified below.	below listed standards was Retlif Testing Laboratories fi	hereby acknowledges that compliance testing in accordance with I performed on a representative sample of the equipment listed belo tarter acknowledges that the test sample listed below was found belo tartes. This certificate is hereby issued to the above named grantee a titidentitid below.
Manufacturer:	Electrolytic Ozone, Inc. 66-K Concord Road Wilmington, MA 01887	Manufacturer:	Electrolytic Ozone, Inc. 66-K Concord Road Wilmington, MA 01887
Equipment Tested:	Ice Machine Filter	Equipment Tested:	Ice Machine Filter
Model Number:	A1979	Model Number:	A1979
Serial Number:	SCM0221011	Serial Number:	SCM0221011
Brand Name:	EOI	Brand Name:	EOI
Product Type:	Household Appliance, Category II	Product Type:	Household Appliance, Category II
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CERTIFIC	
No. U8 12 02 79026 0	
Holder of Certificate:	Electrolytic Ozone Inc. 66// Concord Street Wainington MA 01887 USA
Production Facility(ies):	79026
Certification Mark:	10.0
Product:	Electrical equipment in general Ozone Ice Filter
Model(s):	Cuber-201, Cuber-401, Flaker-201 and Flaker-401 See certificate attachment for model descriptions
Parameters:	Rated input Voltage: 100-240 V AC Rated Frequency: 50000 Hz Rated rput Current: 0.24 A Protection Class: II
Tested according to:	CANICSA-E335-1 2003 UL 60335-1 2004 EN 60335-1 A2 2006
The product was voluntarily test properties. It can be marked will not be altered in any way. This p most closely resembles that dee Fundamentals of product certific	and according to the relevant safety requirements and mentioned in the certification mark shown above. The certification mark must product certification system operated by TUV SUO America Inc. scribed by TSOREC calub 6.7, contomity assessment - calon, System 3. See also notes to order.
Test report no.:	090-1100968-000
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