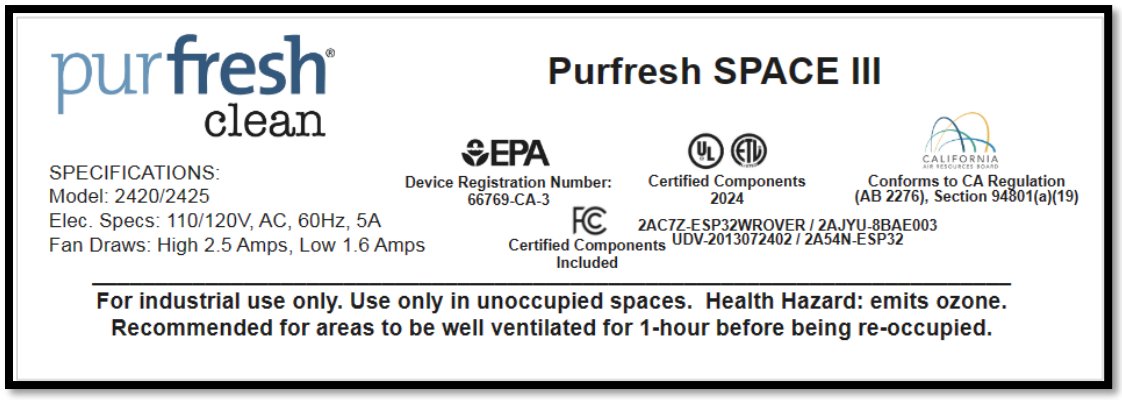
OZONE - O3

USDA, FDA, EPA, CDC, OSHA, CARB
Safety, Approvals, Regulations and Guidelines:

Summary:

- More than 100 years of ozone use worldwide
- United States Food and Drug Administration approved for bottled water in 1982
- EPA allows use of ozone with no reporting or record-keeping
- FDA Expert Panel approved as GRAS (generally recognized as safe) in 1997
- FDA allowed for use with fruits, vegetables, meat, poultry, etc. in June 2001
- Approved under USDA Organic Rule in 2000



(Purfresh Clean Equipment Marks)

Regulatory Details:

EPA Requirements for Ozone Under the FIFRA

Under the FIFRA, EPA requires that all pesticide devices (which includes ozone generators) that are made or distributed in the USA, for which a pesticidal claim is made must carry an Establishment Number. This is a number granted by the EPA upon receipt of a properly completed EPA Form 3540-8 (rev. 5/99), "APPLICATION: ESTABLISHMENT REGISTRATION FOR PESTICIDE AND DEVICE PRODUCERS". Once an Establishment Number has been assigned to a manufacturing facility, that number is required to be placed on devices (ozone generators) produced at that facility. The establishment number confirms that the facility that manufactures ozone generating devices has complied with the registration requirements of the FIFRA.

Purfresh EPA Pesticide Device Establishment Number: 66769-CA-3

EPA Official Registered Approved Device List

CDC Infection Control Sterilization Methods

CDC Approvals and Use Guidelines for Ozone

Ozone has been used for years as a drinking water disinfectant. Ozone is produced when O2 is energized and split into two monatomic (O1) molecules. The monatomic oxygen molecules then collide with O2 molecules to form ozone, which is O3. Thus, ozone consists of O2 with a loosely bonded third oxygen atom that is readily available to attach to, and oxidize, other molecules. This additional oxygen atom makes ozone a powerful oxidant that destroys microorganisms but is highly unstable (i.e., half-life of 22 minutes at room temperature).

A new sterilization process, which uses ozone as the sterilant, was cleared by FDA in August 2003 for processing reusable medical devices. The sterilizer creates its own sterilant internally from USP grade oxygen, steam-quality water and electricity; the sterilant is converted back to oxygen and water vapor at the end of the cycle by a passing through a catalyst before being exhausted into the room. The duration of the sterilization cycle is about 4 h and 15 m, and it occurs at 30-35°C. Microbial efficacy has been demonstrated by achieving a SAL of 10-6 with a variety of microorganisms to include the most resistant microorganism, Geobacillus stearothermophilus.

USDA final rule on ozone dated 12/17/2002, FSIS Directive 7120.1
Safe and suitable ingredients used in the production of meat and poultry.

FSIS Directive 7120.1 States: Ozone for use on all meat and poultry products. Ozone can be used in accordance with current industry standards of good manufacturing practice. No other guidelines are given on levels or dosages of ozone. Reference 21 CFR 173.368

USDA CFR 173.368

Ozone (CAS Reg. No. 10028-15-6) may be safely used in the treatment, storage, and processing of foods, including meat and poultry (unless such use is precluded by standards of identity in 9 CFR part 319), in accordance with the following prescribed conditions: (a) The additive is an unstable, colorless gas with a pungent, characteristic odor, which occurs freely in nature. It is produced commercially by passing electrical discharges or ionizing radiation through air or oxygen. (b) The additive is used as an antimicrobial agent as defined in CFR 170.3(o)(2) of this chapter. (c) The additive meets the specifications for ozone in the Food Chemicals Codex, 4th ed. (1996), p. 277, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20055, or may be examined at the Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. (d) The additive is used in contact with food, including meat and poultry (unless such use is precluded by standards of identity in 9 CFR part 319 or 9 CFR part 381, subpart P), in the gaseous or aqueous phase in accordance with current industry standards of good manufacturing practice. (e) When used on raw agricultural commodities, the use is consistent with section 201(q)(1)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) and not applied for use under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act.

USDA Guidance on Ingredients and sources of radiation used to reduce microorganisms on carcasses, ground beef, and beef trimmings:

Ozone is classified a Secondary direct food additive/processing aid allowable for all meat and poultry products.

FDA Federal Register Vol. 66 No.123 June 26, 2001

The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ozone in gaseous and aqueous phases as an antimicrobial agent on food, including meat and poultry. This action is in response to a petition filed by the Electric Power Research Institute, Agriculture and Food Technology Alliance.

OSHA Ozone Regulations

OSHA guidelines for O3 in the workplace are based on time-weighted averages. Ozone levels should never exceed the following average: 0.10 ppm (parts per million) for 8 hours per day exposure. For more detailed information on safe ozone levels, see the bullet points below.

The OSHA website cites several ACGIH (American Conference of Governmental Industrial Hygienists) guidelines for ozone in the workplace:

0.2 ppm for no more than 2 hours exposure
0.1 ppm for 8 hours per day exposure doing light work
0.08 ppm for 8 hours per day exposure doing moderate work
0.05 ppm for 8 hours per day exposure doing heavy work

More information:
OSHA Guidelines for Ozone

CARB - California's Air Cleaner Regulation (AB 2276) Overview and Exemptions:

In 2008 CARB adopted regulation AB 2276 to limit the amount of ozone emitted from indoor air cleaning devices in order to protect public health. All air cleaning devices sold in California, including over the internet, must adhere to regulation requirements. **All Purfresh SPACE model units comply with AB 2276 regulations sections 94800, 94803, and 94801.**

§ 94800. Applicability

Except as provided in **Section 94803**, this article shall apply to any person who manufactures, sells, supplies, offers for sale, or introduces into commerce in the state of California indoor air cleaning devices, including both medical and non-medical devices.

§ 94803. Exclusions and Exemptions

(a) Industrial use: The provisions of this article do not apply to indoor air cleaning devices manufactured, advertised, marketed, labeled, and used solely for industrial use as defined in Section 94801(a)(19) above, provided the devices display an advisory that states: For "**industrial use"** only. Use only in unoccupied spaces. Health hazard: emits ozone." This advisory must be clearly visible and placed near the power

switch or electrical connection on the device. A graphic illustrating that people should not be present during use of the device is also required to be placed next to the text. The advisory also must be prominently displayed in all owner's, operations, and installation manuals for the device(s) and on all marketing materials, including websites. Information about potential adverse health effects associated with exposure to ozone must be included in all owners, operations, and installation manuals for the device(s). The owner's or operations manual must include a recommendation that any enclosed space in which ozone-producing air cleaners are used should be well-ventilated for at least one hour before being re-occupied. Manufacturers, distributors, sellers, and retailers of ozone generating air cleaning devices must be able to demonstrate that devices are manufactured, marketed, advertised, and labeled solely for an exempted purpose(s).

§ 94801. Definitions. Section (a)(19)(A-F) "Industrial use"

(19) "Industrial use" or "industrial application" means the use of an ozone-producing air cleaning device in the following manner:

- (A)destruction of microbes on produce in an agricultural processing plant, refrigerated transport truck, or related facility, provided no people are physically present.
- (B) chemical oxidation and disinfection in the electronics, pharmaceutical, biotechnology and chemical industries, provided no people are physically present.
- (C) odor and smoke control in the hotel industry, for intermittent and temporary use, carried out by trained personnel, and provided no people are physically present.
- (D) mold, odor, fire and smoke damage remediation services, carried out by trained personnel, and provided no people are physically present.
- (E) odor control in the motor vehicle reconditioning and detailing industry, carried out by trained personnel, and provided no people are physically present.
- (F) odor control in mausoleums, carried out by trained personnel, and provided no people are physically present.

California's Air Cleaner Full Regulation (AB 2276)

https://ww2.arb.ca.gov/resources/documents/indoor-air-cleaning-devices-regulation