



# OZONE - O3

## USDA, FDA, EPA, CDC, OSHA

### Approvals, Recommendations 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

The image shows a product label for the Purfresh SPACE III ozone generator. It features the Purfresh clean logo on the left. In the center, it says 'Purfresh SPACE III'. Below this, there are three certification logos: EPA (EPA logo), Intertek (ETL US logo), and California Resources Board (California Resources Board logo). To the left of the EPA logo, it says 'SPECIFICATIONS: Model: 2420, Elec. Specs: 110/120V, AC, 60Hz, 5A, Fan Draws: High 2.5 Amps, Low 1.6 Amps'. Below the EPA logo, it says 'Device Registration Number: 66769-CA-3'. Below the Intertek logo, it says 'Intertek 4607646 CONFORMS TO UL STD. 507 CERTIFIED TO CSA STD. C22.2NO.113'. Below the California Resources Board logo, it says 'Conforms to CA Regulation (AB 2276), Section 94801(a)(19)'. At the bottom of the label, there is a warning: 'For industrial use only. Use only in unoccupied spaces. Health Hazard: emits ozone. Recommended for areas to be well ventilated for 1-hour before being re-occupied.'

#### 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 O<sub>2</sub> is energized and split into two monatomic (O<sub>1</sub>) molecules. The monatomic oxygen molecules then collide with O<sub>2</sub> molecules to form ozone, which is O<sub>3</sub>. Thus, ozone consists of O<sub>2</sub> 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<sup>-6</sup> 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

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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 O<sub>3</sub> 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](#)