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## CFR - Code of Federal Regulations Title 21

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TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER B - FOOD FOR HUMAN CONSUMPTION (CONTINUED)  
PART 173 -- SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

Subpart D - Specific Usage Additives

Sec. 173.368 Ozone.

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 § 170.3(o) (2) of this chapter.

(c) The additive meets the specifications for ozone in the Food Chemicals Codex, 7th ed. (2010), pp. 754-755, 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. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(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.

[66 FR 33830, June 26, 2001; 67 FR 271, Jan. 3, 2002, as amended at 78 FR 14665, Mar. 7, 2013; 78 FR 71467, Nov. 29, 2013]

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