§ 184.1563 Ozone.

(a) Ozone (O₃, CAS Reg. No. 10028–15–6) is an unstable blue 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 ingredient must be of a purity suitable for its intended use in accordance with §170.3(h)(1) of this chapter.

(c) In accordance with §184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:


§ 184.1560 Ox bile extract.

(a) Ox bile extract (CAS Reg. No. 8008–63–7), also known as purified oxgall or sodium choleate, is a yellowish green, soft solid, with a partly sweet, partly bitter, disagreeable taste. It is the purified portion of the bile of an ox obtained by evaporating the alcohol extract of concentrated bile.

(b) Food-grade ox bile extract shall meet the specifications of the U.S. Pharmacopeia (USP), XIV, 1950, p. 410.¹

(c) The ingredient is used as a surfactant as defined in §170.3(o)(29) of this chapter.

(d) The ingredient is used in food in accordance with §184.1(b)(1) at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.002 percent for cheese as defined in §170.3(n)(5) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 184.1583 Bottled water that prior to ozonation meets the microbiological, physical, chemical, and radiological quality standards of §165.110(b)(2) through (b)(5) of this chapter. Not to exceed current good manufacturing practice. Current good manufacturing practice results in a maximum residual level at the time of bottling of 0.4 milligram of ozone per liter of bottled water.

Antimicrobial agent, §170.3(o)(2) of this chapter.

[47 FR 50210, Nov. 5, 1982, as amended at 60 FR 57130, Nov. 13, 1995]

§ 184.1585 Papain.

(a) Papain (CAS Reg. No. 9001–73–4) is a proteolytic enzyme derived from Carica papaya L. Crude latex containing the enzyme is collected from slashed unripe papaya. The food-grade product is obtained by repeated filtration of the crude latex or an aqueous solution of latex or by precipitation from an aqueous solution of latex. The resulting enzyme preparation may be used in a liquid or dry form.


(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing conditions of use:

1. The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

2. The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995, as amended at 78 FR 14666, Mar. 7, 2013]