

§ 173.370

21 CFR Ch. I (4–1–09 Edition)

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, 5100 Paint Branch Pkwy., College Park, MD 20740, and 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/code_of_federal_regulations/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]

§ 173.370 Peroxyacids.

Peroxyacids may be safely used in accordance with the following prescribed conditions:

(a) The additive is a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid.

(b)(1) The additive is used as an antimicrobial agent on meat carcasses, parts, trim, and organs in accordance with current industry practice where the maximum concentration of peroxyacids is 220 parts per million (ppm) as peroxyacetic acid, and the maximum concentration of hydrogen peroxide is 75 ppm.

(2) The additive is used as an antimicrobial agent on poultry carcasses, poultry parts, and organs in accordance with current industry standards of good manufacturing practice (unless precluded by the U.S. Department of Agriculture's standards of identity in 9 CFR part 381, subpart P) where the maximum concentration of peroxyacids is 220 parts per million (ppm) as peroxyacetic acid, the maximum concentration of hydrogen peroxide is 110 ppm, and the maximum concentration of 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) is 13 ppm.

(c) The concentrations of peroxyacids and hydrogen peroxide in the additive are determined by a method entitled "Hydrogen Peroxide and Peracid (as Peracetic Acid) Content," July 26, 2000, developed by Ecolab, Inc., St. Paul, MN, which is incorporated by reference. The concentration of 1-hydroxyethylidene-1,1-diphosphonic acid is determined by a method entitled "Determination of 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) Peroxyacid/Peroxide-Containing Solutions," August 21, 2001, developed by Ecolab, Inc., St. Paul, MN, which is incorporated by reference. The Director of the Office of the Federal Register approves these incorporations by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of these methods from the Division of Petition Review, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 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/code_of_federal_regulations/ibr_locations.html.

[65 FR 70660, Nov. 27, 2000, as amended at 66 FR 48208, Sept. 19, 2001; 67 FR 61784, Oct. 2, 2002]

§ 173.375 Cetylpyridinium chloride.

Cetylpyridinium chloride (CAS Reg. No. 123-03-05) may be safely used in

food in accordance with the following conditions:

(a) The additive meets the specifications of the United States Pharmacopeia (USP)/National Formulary (NF) described in USP 30/NF 25, May 1, 2007, pp. 1700–1701, 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, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 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>.

(b) The additive is used in food as an antimicrobial agent as defined in §170.3(o)(2) of this chapter to treat the surface of raw poultry carcasses. The solution in which the additive is used to treat raw poultry carcasses shall also contain propylene glycol (CAS Reg. No. 57-55-6) complying with §184.1666 of this chapter, at a concentration of 1.5 times that of cetylpyridinium chloride.

(c) The additive is used as follows:

(1) As a fine mist spray of an ambient temperature aqueous solution applied to raw poultry carcasses prior to immersion in a chiller, at a level not to exceed 0.3 gram cetylpyridinium chloride per pound of raw poultry carcass, provided that the additive is used in systems that collect and recycle solution that is not carried out of the system with the treated poultry carcasses; or

(2) As a liquid aqueous solution applied to raw poultry carcasses either prior to or after chilling at an amount not to exceed 5 gallons of solution per carcass, provided that the additive is used in systems that recapture at least 99 percent of the solution that is applied to the poultry carcasses. The concentration of cetylpyridinium chloride in the solution applied to the carcasses shall not exceed 0.8 percent by weight.

When application of the additive is not followed by immersion in a chiller, the treatment will be followed by a potable water rinse of the carcass.

[72 FR 67576, Nov. 29, 2007]

§ 173.385 Sodium methyl sulfate.

Sodium methyl sulfate may be present in pectin in accordance with the following conditions.

(a) It is present as the result of methylation of pectin by sulfuric acid and methyl alcohol and subsequent treatment with sodium bicarbonate.

(b) It does not exceed 0.1 percent by weight of the pectin.

§ 173.395 Trifluoromethane sulfonic acid.

Trifluoromethane sulfonic acid has the empirical formula $\text{CF}_3\text{SO}_3\text{H}$ (CAS Reg. No. 1493-13-6). The catalyst (Trifluoromethane sulfonic acid) may safely be used in the production of cocoa butter substitute from palm oil (1-palmitoyl-2-oleoyl-3-stearin) (see §184.1259 of this chapter) in accordance with the following conditions:

(a) The catalyst meets the following specifications:

Appearance, Clear liquid.
Color, Colorless to amber.
Neutralization equivalent, 147-151.
Water, 1 percent maximum.
Fluoride ion, 0.03 percent maximum.
Heavy metals (as Pb), 30 parts per million maximum.
Arsenic (as As), 3 parts per million maximum.

(b) It is used at levels not to exceed 0.2 percent of the reaction mixture to catalyze the directed esterification.

(c) The esterification reaction is quenched with steam and water and the catalyst is removed with the aqueous phase. Final traces of catalyst are removed by washing batches of the product three times with an aqueous solution of 0.5 percent sodium bicarbonate.

(d) No residual catalyst may remain in the product at a detection limit of 0.2 part per million fluoride as determined by the method described in "Official Methods of Analysis of the Association of Official Analytical Chemists," sections 25.049-25.055, 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from