

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

§ 173.400

the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined 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.

[43 FR 54237, Nov. 11, 1978, as amended at 49 FR 10106, Mar. 19, 1984; 54 FR 24897, June 12, 1989; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005]

§ 173.400 Dimethyldialkylammonium chloride.

Dimethyldialkylammonium chloride may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is produced by one of the following methods:

(1) Ammonolysis of natural tallow fatty acids to form amines that are subsequently reacted with methyl chloride to form the quaternary ammonium compounds consisting primarily of dimethyldioctadecylammonium chloride and dimethyldihexadecylammonium chloride. The additive may contain residues of isopropyl alcohol not in excess of 18 percent by weight when used as a processing solvent.

(2) Ammonolysis of natural tallow fatty acids to form amines that are then reacted with 2-ethylhexanal, reduced, methylated, and subsequently reacted with methyl chloride to form the quaternary ammonium compound known as dimethyl(2-ethylhexyl) hydrogenated tallow ammonium chloride and consisting primarily of dimethyl(2-ethylhexyl)octadecylammonium chloride and dimethyl(2-ethylhexyl)hexadecylammonium chloride.

(b) The food additive described in paragraph (a)(1) of this section contains not more than a total of 2 percent by weight of free amine and amine hydrochloride. The food additive described in paragraph (a)(2) of this section contains not more than 3 percent by weight, each, of free amine and amine hydrochloride as determined by A.O.C.S. method Te 3a-64, "Acid Value and Free Amine Value of Fatty Quaternary Ammonium Chlorides," 2d printing including additions and revisions

21 CFR Ch. I (4-1-09 Edition)

1990, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and from the American Oil Chemists' Society, P.O. Box 5037, Station A, Champaign, IL 61820, or available for inspection 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.

(c) The food additive is used as a decolorizing agent in the clarification of refinery sugar liquors under the following limitations:

(1) The food additive described in paragraph (a)(1) of this section is added only at the defecation/clarification stage of sugar liquor refining in an amount not to exceed 700 parts per million by weight of sugar solids.

(2) The food additive described in paragraph (a)(2) of this section is used under the following conditions:

(i) The additive is adsorbed onto a support column composed of suitable polymers that are regulated for contact with aqueous food. Excess non-adsorbed additive shall be rinsed away with potable water prior to passage of sugar liquor through the column.

(ii) The residue of the additive in the decolorized sugar liquor prior to crystallization shall not exceed 1 part per million of sugar as determined by a method entitled "Colorimetric Determination of Residual Quaternary Ammonium Compounds (Arquad HTL8) in Sugar and Sugar Solutions," June 13, 1990, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection 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/