CFR - Code of Federal Regulations Title 21

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[Revised as of April 1, 2019]
[CITE: 21CFR173]

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 173SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

Subpart A--Polymer Substances and Polymer Adjuvants for Food Treatment

Sec. 173.5 Acrylate-acrylamide resins.

Acrylate-acrylamide resins may be safely used in food under the following prescribed conditions:

(a) The additive consists of one of the following:

(1) Acrylamide-acrylic acid resin (hydrolyzed polyacrylamide) is produced by the polymerization of acrylamide with partial hydrolysis, or acrylamide and acrylic acid, with the greater part of the polymer being composed of acrylamide units.

(2) Sodium polyacrylate-acrylamide resin is produced by the polymerization and subsequent hydrolysis of acrylonitrile in a sodium silicat solution, with the greater part of the polymer being composed of acrylate units.

(b) The additive contains not more than 0.05 percent of residual monomer calculated as acrylamide.

(c) The additive is used or intended for use as follows:

(1) The additive identified in paragraph (a) (1) of this section is used as a flocculent in the clarification of beet sugar juice and liq liquor or corn starch hydrolyzate in an amount not to exceed 5 parts per million by weight of the juice or 10 parts per million by weight starch hydrolyzate.

(2) The additive identified in paragraph (a)(2) of this section is used to control organic and mineral scale in beet sugar juice and liqu liquor in an amount not to exceed 2.5 parts per million by weight of the juice or liquor.

[42 FR 14526, Mar. 15, 1977, as amended at 46 FR 30494, June 9, 1981]

Sec. 173.10 Modified polyacrylamide resin.

Modified polyacrylamide resin may be safely used in food in accordance with the following prescribed conditions:

(a) The modified polyacrylamide resin is produced by the copolymerization of acrylamide with not more than 5-mole percent [beta]-methacry ltrimethylammonium methyl sulfate.

(b) The modified polyacrylamide resin contains not more than 0.05 percent residual acrylamide.

(c) The modified polyacrylamide resin is used as a flocculent in the clarification of beet or cane sugar juice in an amount not exceeding weight of the juice.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear, in addition to the other information required directions to assure use in compliance with paragraph (c) of this section.

Sec. 173.20 Ion-exchange membranes.

Ion-exchange membranes may be safely used in the processing of food under the following prescribed conditions:

(a) The ion-exchange membrane is prepared by subjecting a polyethylene base conforming to 177.1520 of this chapter to polymerization with polystyrene phase of the base is not less than 16 percent nor more than 30 percent by weight. The base is then modified by reaction with and by subsequent amination with trimethylamine, dimethylamine, diethylenetriamine, or dimethylethanolamine.

(b) The ion-exchange membrane is manufactured so as to comply with the following extraction limitations when subjected to the described p foot samples of membrane weighing approximately 14 grams each are cut into small pieces and refluxed for 4 hours in 150 cubic centimeters Distilled water, 5 percent acetic acid, and 50 percent alcohol. Extraction from each sample will not exceed 0.4 percent by weight of samp

(c) The ion-exchange membrane will be used in the production of grapefruit juice to adjust the ratio of citric acid to total solids of th

Sec. 173.21 Perfluorinated ion exchange membranes.

Substances identified in paragraph (a) of this section may be safely used as ion exchange membranes intended for use in the treatment of food under the following prescribed conditions:

(a) *Identity.* The membrane is a copolymer of ethanesulfonyl fluoride, 2-[1-[difluoro-[(trifluoroethenyl)oxy]methyl]-1,2,2,2-tetrafluoroet with tetrafluoroethylene that has been subsequently treated to hydrolyze the sulfonyl fluoride group to the sulfonic acid. The Chemical A this polymer is ethanesulfonic acid, 2-[1-[difluoro-[(trifluoroethenyl)oxy]methyl]-1,2,2,2-tetrafluoroethoxy]-1,1,2,2,-tetrafluoro-, poly (CAS Reg. No. 31175-20-9).

(b) *Optional adjuvant substances.* The basic polymer identified in paragraph (a) of this section may contain optional adjuvant substances of such basic polymer. These optional adjuvant substances may include substances used in accordance with 174.5 of this chapter.

(c) *Conditions of use.* (1) Perfluorinated ion exchange membranes described in paragraph (a) of this section may be used in contact with a temperatures not exceeding 70deg. (158 deg. F).

(2) Maximum thickness of the copolymer membrane is 0.007 inch (0.017 centimeter).

(3) Perfluorinated ion exchange membranes shall be maintained in a sanitary manner in accordance with current good manufacturing practice adulteration of food.

(4) To assure their safe use, perfluorinated ionomer membranes shall be thoroughly cleaned prior to their first use in accordance with cu practice.

[59 FR 15623, Apr. 4, 1994]

Sec. 173.25 Ion-exchange resins.

Ion-exchange resins may be safely used in the treatment of food under the following prescribed conditions:

(a) The ion-exchange resins are prepared in appropriate physical form, and consist of one or more of the following:

(1) Sulfonated copolymer of styrene and divinylbenzene.

(2) Sulfonated anthracite coal meeting the requirements of ASTM method D388-38, Class I, Group 2, "Standard Specifications for Classifica is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or ava National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.*

(3) Sulfite-modified cross-linked phenol-formaldehyde, with modification resulting in sulfonic acid groups on side chains.

(4) Methacrylic acid-divinylbenzene copolymer.

(5) Cross-linked polystyrene, first chloromethylated then aminated with trimethylamine, dimethylamine, di-ethylenetriamine, or dimethylet

(6) Diethylenetriamine, triethylene-tetramine, or tetraethylenepentamine cross-linked with epichlorohydrin.

(7) Cross-linked phenol-formaldehyde activated with one or both of the following: Triethylene tetramine and tetraethylenepentamine.

(8) Reaction resin of formaldehyde, acetone, and tetraethylenepentamine.

(9) Completely hydrolyzed copolymers of methyl acrylate and divinylbenzene.

(10) Completely hydrolyzed terpolymers of methyl acrylate, divinylbenzene, and acrylonitrile.

(11) Sulfonated terpolymers of styrene, divinylbenzene, and acrylonitrile or methyl acrylate.

(12) Methyl acrylate-divinylbenzene copolymer containing not less than 2 percent by weight of divinylbenzene, aminolyzed with dimethylami

(13) Methyl acrylate-divinylbenzene copolymer containing not less than 3.5 percent by weight of divinylbenzene, aminolyzed with dimethyla

(14) Epichlorohydrin cross-linked with ammonia.

(15) Sulfonated tetrapolymer of styrene, divinylbenzene, acrylonitrile, and methyl acrylate derived from a mixture of monomers containing percent by weight of acrylonitrile and methyl acrylate.

(16) Methyl acrylate-divinylbenzenediethylene glycol divinyl ether terpolymer containing not less than 3.5 percent by weight of divinylbe percent by weight of diethylene glycol divinyl ether, aminolyzed with dimethylaminopropylamine.

(17) Styrene-divinylbenzene cross-linked copolymer, first chloromethylated then aminated with dimethylamine and oxidized with hydrogen pe contains not more than 15 percent by weight of vinyl *N,N*- dimethylbenzylamine-*N*- oxide and not more than 6.5 percent by weight of nitroge

(18) Methyl acrylate-divinylbenzene-diethylene glycol divinyl ether terpolymer containing not less than 7 percent by weight of divinylben percent by weight of diethylene glycol divinyl ether, aminolyzed with dimethylaminopropylamine and quaternized with methyl chloride.

(19) Epichlorohydrin cross-linked with ammonia and then quaternized with methyl chloride to contain not more than 18 percent strong base exchange capacity [Chemical Abstracts Service name: Oxirane (chloromethyl)-, polymer with ammonia, reaction product with chloromethane; C

(20) Regenerated cellulose, cross-linked and alkylated with epichlorohydrin and propylene oxide, then sulfonated whereby the amount of ep oxide employed does not exceed 250 percent by weight of the starting quantity of cellulose.

(b) Ion-exchange resins are used in the purification of foods, including potable water, to remove undesirable ions or to replace less des of the following: bicarbonate, calcium, carbonate, chloride, hydrogen, hydroxyl, magnesium, potassium, sodium, and sulfate except that: T identified in paragraph (a)(12) of this section is used only in accordance with paragraph (b)(1) of this section, the ion-exchange resin (13) of this section is used only in accordance with paragraph (b)(2) of this section, the resin identified in paragraph (a)(16) of this accordance with paragraph (b)(1) or (b)(2) of this section, the ion-exchange resin identified in paragraph (a)(17) of this section is use paragraph (b)(3) of this section, the ion-exchange resin identified in paragraph (a)(18) of this section is used only in accordance with section, and the ion-exchange resin identified in paragraph (a)(20) of this section is used only in accordance with paragraphs (b)(5) and

(1) The ion-exchange resins identified in paragraphs (a) (12) and (16) of this section are used to treat water for use in the manufacture beverages, subject to the following conditions:

(i) The water is subjected to treatment through a mixed bed consisting of one of the resins identified in paragraph (a) (12) or (16) of t strongly acidic cation-exchange resins in the hydrogen form identified in paragraphs (a) (1), (2), and (11) of this section; or

(ii) The water is first subjected to one of the resins identified in paragraph (a) (12) or (16) of this section and is subsequently subje bed of activated carbon or one of the strongly acidic cation-exchange resins in the hydrogen form identified in paragraphs (a) (1), (2),

(iii) The temperature of the water passing through the resin beds identified in paragraphs (b)(1) (i) and (ii) of this section is maintai and the flow rate of the water passing through the beds is not less than 2 gallons per cubic foot per minute.

(iv) The ion-exchange resins identified in paragraph (a) (12) or (16) of this section are exempted from the requirements of paragraph (c) strongly acidic cation-exchange resins referred to in paragraphs (b)(1) (i) and (ii) of this section used in the process meet the require this section, except for the exemption described in paragraph (d) of this section.

(2) The ion-exchange resins identified in paragraphs (a) (13) and (16) of this section are used to treat water and aqueous food only of t Categories I, II, and VI-B in table 1 of 176.170(c) of this chapter: *Provided,* That the temperature of the water or food passing through at 50 deg. C or less and the flow rate of the water or food passing through the beds is not less than 0.5 gallon per cubic foot per minut

(i) The ion-exchange resin identified in paragraph (a)(13) of this section is used to treat water and aqueous food only of the types iden II, and VI-B in Table 1 of 176.170(c) of this chapter: *Provided,* That the temperature of the water or food passing through the resin bed or less and the flow rate of the water or food passing through the bed is not less than 0.5 gallon per cubic foot per minute.

(ii) The ion-exchange resin identified in paragraph (a)(16) of this section is used to treat water and aqueous food only of the types ide II, and VI-B in Table 1 of 176.170(c) of this chapter, *Provided,* that either:

(A) The temperature of the water or food passing through the resin bed is maintained at 50 deg. C or less and the flow rate of the water bed is not less than 0.5 gallon per cubic foot per minute; or

(B) Extracts of the resin will be found to contain no more than 1 milligram/kilogram dimethylaminopropylamine in each of the food simulan percent ethanol, when, following washing and pretreatment of the resin in accordance with 173.25(c)(1), the resin is subjected to the fol simulating the actual temperature and flow rate of use: "The Determination of 3-Dimethylaminopropylamine in Food Simulating Extracts of I February 4, 1998, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 24 examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301 National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.*

(3) The ion-exchange resin identified in paragraph (a)(17) of this section is used only for industrial application to treat bulk quantiti including potable water, or for treatment of municipal water supplies, subject to the condition that the temperature of the food or water bed is maintained at 25 deg. C or less and the flow rate of the food or water passing through the bed is not less than 2 gallons per cubi

(4) The ion-exchange resin identified in paragraph (a)(18) of this section is used to treat aqueous sugar solutions subject to the condit the sugar solution passing through the resin bed is maintained at 82 deg. C (179.6 deg. F) or less and the flow rate of the sugar solutio not less than 46.8 liters per cubic meter (0.35 gallon per cubic foot) of resin bed volume per minute.

(5) The ion-exchange resin identified in paragraph (a)(20) of this section is limited to use in aqueous process streams for the isolation concentrates and isolates under the following conditions:

(i) For resins that comply with the requirements in paragraph (d)(2)(i) of this section, the pH range for the resin shall be no less than the temperatures of water and food passing through the resin bed shall not exceed 25 deg. C.

(ii) For resins that comply with the requirements in paragraph (d)(2)(ii) of this section, the pH range for the resin shall be no less th and the temperatures of water and food passing through the resin shall not exceed 50 deg. C.

(c) To insure safe use of ion-exchange resins, each ion-exchange resin will be:

(1) Subjected to pre-use treatment by the manufacturer and/or the user in accordance with the manufacturer's directions prescribed on the accompanying the resins, to guarantee a food-grade purity of ion-exchange resins, in accordance with good manufacturing practice.

(2) Accompanied by label or labeling to include directions for use consistent with the intended functional purpose of the resin.

(3) Used in compliance with the label or labeling required by paragraph (c)(2) of this section.

(4) Found to result in no more than 1 part per million of organic extractives obtained with each of the named solvents, distilled water, percent acetic acid when, having been washed and otherwise treated in accordance with the manufacturer's directions for preparing them fo exchange resin is subjected to the following test: Using a separate ion-exchange column for each solvent, prepare columns using 50 millil ion-exchange resin that is to be tested. While maintaining the highest temperature that will be encountered in use pass through these bed milliliters per hour the three test solvents distilled water, 15 percent (by volume) ethyl alcohol, and 5 percent (by weight) acetic acid effluent from each solvent is discarded, then the next 2 liters are used to determine organic extractives. The 2-liter sample is carefull weight at 105 deg. C; this is total extractives. This residue is fired in a muffle furnace at 850 deg. C to constant weight; this is ash. ash equals the organic extractives. If the organic extractives are greater than 1 part per million of the solvent used, a blank should be correction should be made by subtracting the total extractives obtained with the blank from the total extractives obtained in the resin t to be made as follows:

Distilled water (de-ionized water is distilled).

15 percent ethyl alcohol made by mixing 15 volumes of absolute ethyl alcohol A.C.S. reagent grade, with 85 volumes of distilled de-ionize

5 percent acetic acid made by mixing 5 parts by weight of A.C.S. reagent grade glacial acetic acid with 95 parts by weight of distilled d

In addition to the organic extractives limitation prescribed in this paragraph, the ion-exchange resin identified in paragraph (a)(17) of extracted with each of the named solvents, distilled water, 50 percent alcohol, and 5 percent acetic acid, will be found to result in not million of nitrogen extractives (calculated as nitrogen) when the resin in the free-base form is subjected to the following test immediat separate 1-inch diameter glass ion-exchange column for each solvent, prepare each column using 100 milliliters of ready to use ion-exchan tested. With the bottom outlet closed, fill each ion-exchange column with one of the three solvents at a temperature of 25 deg. C until t with the top of the resin bed. Seal each column at the top and bottom and store in a vertical position at a temperature of 25 deg. C. Aft each column, drain the solvent into a collection vessel, and analyze each drained solvent and a solvent blank for nitrogen by a standard

(d)(1) The ion-exchange resins identified in paragraphs (a)(1), (a)(2), (a)(11), and (a)(15) of this section are exempted from the acetic of paragraph (c)(4) of this section.

(2) The ion-exchange resin identified in paragraph (a)(20) of this section shall comply either with:

(i) The extraction requirement in paragraph (c)(4) of this section by using dilute sulfuric acid, pH 3.5 as a substitute for acetic acid;

(ii) The extraction requirement in paragraph (c)(4) of this section by using reagent grade hydrochloric acid, diluted to pH 2, as a subst resin shall be found to result in no more than 25 parts per million of organic extractives obtained with each of the following solvents: alcohol; and hydrochloric acid, pH 2. Blanks should be run for each of the solvents, and corrections should be made by subtracting the to with the blank from the total extractives obtained in the resin test.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of 180.22 of this chapter.

[42 FR 14526, Mar. 15, 1977, as amended at 46 FR 40181, Aug. 7, 1981; 46 FR 57033, Nov. 20, 1981; 49 FR 28830, July 17, 1984; 56 FR 16268 Feb. 20, 1997; 64 FR 14609, Mar. 26, 1999; 64 FR 56173, Oct. 18, 1999; 78 FR 14665, Mar. 7, 2013; 81 FR 5592, Feb. 3, 2016]

Sec. 173.40 Molecular sieve resins.

Molecular sieve resins may be safely used in the processing of food under the following prescribed conditions:

(a) The molecular sieve resins consist of purified dextran having an average molecular weight of 40,000, cross-linked with epichlorohydri dextran to 10 parts of epichlorohydrin, to give a stable three dimensional structure. The resins have a pore size of 2.0 to 3.0 millilite (expressed in terms of water regain), and a particle size of 10 to 300 microns.

(b) The molecular sieve resins are thoroughly washed with potable water prior to their first use in contact with food.

(c) Molecular sieve resins are used as the gel filtration media in the final purification of partially delactosed whey. The gel bed shall manner in accordance with good manufacturing practice so as to prevent microbial build-up on the bed and adulteration of the product.

Sec. 173.45 Polymaleic acid and its sodium salt.

Polymaleic acid (CAS Reg. No. 26099-09-2) and its sodium salt (CAS Reg. No. 70247-90-4) may be safely used in food in accordance with the conditions:

(a) The additives have a weight-average molecular weight in the range of 540 to 850 and a number-average molecular weight in the range of the acid. Molecular weights shall be determined by a method entitled "Determination of Molecular Weight Distribution of Poly(Maleic) Acid by Ciba-Geigy, Inc., Seven Skyline Dr., Hawthorne, NY 10532-2188, which is incorporated by reference in accordance with 5 U.S.C. 552(a) a available from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, Park, MD 20740, 240-402-1200, or are available for inspection at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability call 202-741-6030, or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.*

(b) The additives may be used, individually or together, in the processing of beet sugar juice and liquor or of cane sugar juice and liqu

(c) The additives are to be used so that the amount of either or both additives does not exceed 4 parts per million (calculated as the ac cane sugar juice or liquor process stream.

[51 FR 5315, Feb. 13, 1986, as amended at 61 FR 386, Jan. 5, 1996; 78 FR 14665, Mar. 7, 2013; 81 FR 5592, Feb. 3, 2016]

Sec. 173.50 Polyvinylpolypyrrolidone.

The food additive polyvinylpolypyrrolidone may be safely used in accordance with the following prescribed conditions:

(a) The additive is a homopolymer of purified vinylpyrrolidone catalytically produced under conditions producing polymerization and cross insoluble polymer is produced.

(b) The food additive is so processed that when the finished polymer is refluxed for 3 hours with water, 5 percent acetic acid, and 50 pe 50 parts per million of extractables is obtained with each solvent.

(c) It is used or intended for use as a clarifying agent in beverages and vinegar, followed by removal with filtration.

Sec. 173.55 Polyvinylpyrrolidone.

The food additive polyvinylpyrroli-done may be safely used in accordance with the following prescribed conditions:

(a) The additive is a polymer of purified vinylpyrrolidone catalytically produced, having an average molecular weight of 40,000 and a max percent, calculated as the monomer, except that the polyvinylpyrrolidone used in beer is that having an average molecular weight of 360,0 unsaturation of 1 percent, calculated as the monomer.

(b) The additive is used or intended for use in foods as follows:

Food	Limitations
Beer	As a clarifying agent, at a residual level not to exceed 10 parts per million.
Flavor concentrates in tablet form	As a tableting adjuvent in an amount not to exceed good manufacturing practice.
Nonnutritive sweeteners in concentrated liquid form	As a stabilizer, bodying agent, and dispersant, in an amount not to exceed good ma
Nonnutritive sweeteners in tablet form	As a tableting adjuvant in an amount not to exceed good manufacturing practice.
Vitamin and mineral concentrates in liquid form	As a stabilizer, bodying agent, and dispersant, in an amount not to exceed good ma
Vitamin and mineral concentrates in tablet form	As a tableting adjuvant in an amount not to exceed good manufacturing practice.
Vinegar	As a clarifying agent, at a residual level not to exceed 40 parts per million.
Wine	As a clarifying agent, at a residual level not to exceed 60 parts per million.

Sec. 173.60 Dimethylamine-epichlorohydrin copolymer.

Dimethylamine-epichlorohydrin copolymer (CAS Reg. No. 25988-97-0) may be safely used in food in accordance with the following prescribed

(a) The food additive is produced by copolymerization of dimethylamine and epichlorohydrin in which not more than 5 mole-percent of dimet an equimolar amount of ethylenediamine, and in which the mole ratio of total amine to epichlorohydrin is approximately 1:1.

(b) The additive meets the following specifications:

(1) The nitrogen content of the copolymer is 9.4 to 10.8 weight percent on a dry basis.

(2) A 50-percent-by-weight aqueous solution of the copolymer has a minimum viscosity of 175 centipoises at 25 deg. C as determined by LVT viscometer using a No. 2 spindle at 60 RPM (or by another equivalent method).

(3) The additive contains not more than 1,000 parts per million of 1,3-dichloro-2-propanol and not more than 10 parts per million epichlo epichlorohydrin and 1,3-dichloro-2-propanol content is determined by an analytical method entitled "The Determination of Epichlorohydrin in Dimethylamine-Epichlorohydrin Copolymer," which is incorporated by reference. Copies are available from the Center for Food Safety and 200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Rec For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.*

(4) Heavy metals (as Pb), 2 parts per million maximum.

(5) Arsenic (as As), 2 parts per million maximum.

(c) The food additive is used as a decolorizing agent and/or flocculant in the clarification of refinery sugar liquors and juices. It is defecation/clarification stage of sugar liquor refining at a concentration not to exceed 150 parts per million of copolymer by weight of

(d) To assure safe use of the additive, the label and labeling of the additive shall bear, in addition to other information required by t to assure use in compliance with paragraph (c) of this section.

[48 FR 37614, Aug. 19, 1983, as amended at 54 FR 24897, June 12, 1989]

Sec. 173.65 Divinylbenzene copolymer.

Divinylbenzene copolymer may be used for the removal of organic substances from aqueous foods under the following prescribed conditions:

(a) The copolymer is prepared in appropriate physical form and is derived by the polymerization of a grade of divinylbenzene which compri percent divinylbenzene, 15 to 20 weight-percent ethylvinylbenzene, and no more than 4 weight-percent nonpolymerizable impurities.

(b) In accordance with the manufacturer's directions, the copolymer described in paragraph (a) of this section is subjected to pre-use ex soluble alcohol until the level of divinylbenzene in the extract is less than 50 parts per billion as determined by a method titled, "The Divinylbenzene in Alcohol Extracts of Amberlite XAD-4," which is incorporated by reference. Copies of this method are available from the Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the Na Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.* The copolymer is then treated with water according to recommendation to remove the extraction solvent to guarantee a food-grade purity of the resin at the time of use, in accordance with curr practice.

(c) The temperature of the aqueous food stream contacting the polymer is maintained at 79.4 deg. C (175 deg. F) or less.

(d) The copolymer may be used in contact with food only of Types I, II, and VI-B (excluding carbonated beverages) described in table 1 of this chapter.

[50 FR 61, Jan. 2, 1985]

Sec. 173.70 Chloromethylated aminated styrene-divinylbenzene resin.

Chloromethylated aminated styrene-divinylbenzene copolymer (CAS Reg. No. 60177-39-1) may be safely used in food in accordance with the fo conditions:

(a) The additive is an aqueous dispersion of styrene-divinylbenzene copolymers, first chloromethylated then aminated with trimethylamine, size of not more than 2.0 microns.

(b) The additive shall contain no more than 3.0 percent nonvolatile, soluble extractives when tested as follows: One hundred grams of the 17,000 r/min for 2 hours. The resulting clear supernatant is removed from the compacted solids and concentrated to approximately 10 grams gram sample is again centrifuged at 17,000 r/min for 2 hours to remove any residual insoluble material. The supernatant from the second c removed from any compacted solids and dried to constant residual weight using a steam bath. The percent nonvolatile solubles is obtained the dried residue by the weight of the solids in the original resin dispersion.

(c) The additive is used as a decolorizing and clarification agent for treatment of refinery sugar liquors and juices at levels not to ex solids per million parts of sugar solids.

[50 FR 29209, July 18, 1985]

Sec. 173.73 Sodium polyacrylate.

Sodium polyacrylate (CAS Reg. No. 9003-04-7) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is produced by the polymerization of acrylic acid and subsequent hydrolysis of the polyacrylic acid with an aqueous sodi determined by a method entitled "Determination of Weight Average and Number Average Molecular Weight of Sodium Polyacrylate," which is in accordance with 5 U.S.C. 552(a), the additive has--

(1) A weight average molecular weight of 2,000 to 2,300; and

(2) A weight average molecular weight to number average molecular weight ratio of not more than 1.3. Copies of the method are available f Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspectio 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/federalregister/codeoffederalregulations/ibrlocations.html.*

(b) The additive is used to control mineral scale during the evaporation of beet sugar juice or cane sugar juice in the production of sug exceed 3.6 parts per million by weight of the raw juice.

[53 FR 39456, Oct. 7, 1988; 53 FR 49823, Dec. 9, 1988]

Sec. 173.75 Sorbitan monooleate.

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

(a) The additive is produced by the esterification of sorbitol with commercial oleic acid.

(b) It meets the following specifications:

(1) Saponification number, 145-160.

(2) Hydroxyl number, 193-210.

(c) The additive is used or intended for use as follows:

(1) As an emulsifier in polymer dispersions that are used in the clarification of cane or beet sugar juice or liquor in an amount not to in the final polymer dispersion.

(2) The additive is used in an amount not to exceed 0.70 part per million in sugar juice and 1.4 parts per million in sugar liquor.

[51 FR 11720, Apr. 7, 1986]

Subpart B--Enzyme Preparations and Microorganisms

Sec. 173.110 Amyloglucosidase derived from Rhizopus niveus.

Amyloglucosidase enzyme product, consisting of enzyme derived from *Rhizopus niveus,* and diatomaceous silica as a carrier, may be safely u with the following conditions:

(a) *Rhizopus niveus* is classified as follows: Class, Phycomycetes; order, Mucorales; family, Mucoraceae; genus, *Rhizopus;* species, *niveus*

(b) The strain of *Rhizopus niveus* is nonpathogenic and nontoxic in man or other animals.

(c) The enzyme is produced by a process which completely removes the organism *Rhizopus niveus* from the amyloglucosidase.

(d) The additive is used or intended for use for degrading gelatinized starch into constituent sugars, in the production of distilled spi

(e) The additive is used at a level not to exceed 0.1 percent by weight of the gelatinized starch.

Sec. 173.115 Alpha-acetolactate decarboxylase ([alpha]-ALDC) enzyme preparation derived from a recombinant Bacillus subtilis.

The food additive alpha-acetolactate decarboxylase ([alpha]-ALDC) enzyme preparation, may be safely used in accordance with the following

(a) The food additive is the enzyme preparation derived from a modified *Bacillus subtilis* strain that contains the gene coding for [alpha

(b)(1) The manufacturer produces the additive from a pure culture fermentation of a strain of *Bacillus subtilis* that is nonpathogenic and other animals.

(2) The manufacturer may stabilize the enzyme preparation with glutaraldehyde or with other suitable approved food additives or generally substances.

(3) The enzyme preparation must meet the general and additional requirements for enzyme preparations in the *Food Chemicals Codex,* 4th ed. is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance w CFR part 51. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20055, or may be examined Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/ibrl*

(c) The additive is used in an amount not in excess of the minimum required to produce its intended effect as a processing aid in the pro beverages and distilled liquors.

[66 FR 27022, May 16, 2001]

Sec. 173.120 Carbohydrase and cellulase derived from Aspergillus niger.

Carbohydrase and cellulase enzyme preparation derived from *Aspergillus niger* may be safely used in food in accordance with the following

(a) *Aspergillus niger* is classified as follows: Class, Deuteromycetes; order, Moniliales; family, Moniliaceae; genus, *Aspergillus;* specie

(b) The strain of *Aspergillus niger* is nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that completely removes the organism *Aspergillus niger* from the carbohydrase and cellulase enzy

(d) The additive is used or intended for use as follows:

(1) For removal of visceral mass (bellies) in clam processing.

(2) As an aid in the removal of the shell from the edible tissue in shrimp processing.

(e) The additive is used in an amount not in excess of the minimum required to produce its intended effect.

Sec. 173.130 Carbohydrase derived from Rhizopus oryzae.

Carbohydrase from *Rhizopus oryzae* may be safely used in the production of dextrose from starch in accordance with the following prescribe

(a) *Rhizopus oryzae* is classified as follows: Class, Phycomycetes; order, Mucorales; family, Mucoraceae; genus, *Rhizopus;* species, *Rhizop*

(b) The strain of *Rhizopus oryzae* is nonpathogenic and nontoxic.

(c) The carbohydrase is produced under controlled conditions to maintain nonpathogenicity and nontoxicity, including the absence of aflat

(d) The carbohydrase is produced by a process which completely removes the organism *Rhizopus oryzae* from the carbohydrase product.

(e) The carbohydrase is maintained under refrigeration from production to use and is labeled to include the necessity of refrigerated sto

Sec. 173.135 Catalase derived from Micrococcus lysodeikticus.

Bacterial catalase derived from *Micrococcus lysodeikticus* by a pure culture fermentation process may be safely used in destroying and rem in the manufacture of cheese, in accordance with the following conditions.

(a) The organism *Micrococcus lysodeikticus* from which the bacterial catalase is to be derived is demonstrated to be nontoxic and nonpatho

(b) The organism *Micrococcus lysodeikticus* is removed from the bacterial catalase prior to use of the bacterial catalase.

(c) The bacterial catalase is used in an amount not in excess of the minimum required to produce its intended effect.

Sec. 173.140 Esterase-lipase derived from Mucor miehei.

Esterase-lipase enzyme, consisting of enzyme derived from *Mucor miehei* var. *Cooney et Emerson* by a pure culture fermentation process, wit as a carrier, may be safely used in food in accordance with the following conditions:

(a) *Mucor miehei* var. *Cooney et Emerson* is classified as follows: Class, Phycomycetes; subclass, Zygomycetes; order, Mucorales; family, M species, *miehei;* variety *Cooney et Emerson.*

(b) The strain of *Mucor miehei* var. *Cooney et Emerson* is nonpathogenic and nontoxic in man or other animals.

(c) The enzyme is produced by a process which completely removes the organism *Mucor miehei* var. *Cooney et Emerson* from the esterase-lipas

(d) The enzyme is used as a flavor enhancer as defined in 170.3(o)(12).

(e) The enzyme is used at levels not to exceed current good manufacturing practice in the following food categories: cheeses as defined i chapter; fat and oils as defined in 170.(3)(n)(12) of this chapter; and milk products as defined in 170.(3)(n)(31) of this chapter. Use o

limited to nonstandarized foods and those foods for which the relevant standards of identity permit such use.

(f) The enzyme is used in the minimum amount required to produce its limited technical effect.

[47 FR 28090, June 29, 1982; 48 FR 2748, Jan. 21, 1983]

Sec. 173.145 Alpha-Galactosidase derived from Mortierella vinaceae var. raffinoseutilizer.

The food additive alpha-galactosidase and parent mycelial microorganism *Mortierella vinaceae* var. *raffinoseutilizer* may be safely used in following conditions:

(a) The food additive is the enzyme alpha-galactosidase and the mycelia of the microorganism *Mortierella vinaceae* var. *raffinoseutilizer*

(b) The nonpathogenic microorganism matches American Type Culture Collection (ATCC) No. 20034, [1] and is classified as follows:

Class: Phycomycetes.

Order: Mucorales.

Family: Mortierellaceae.

Genus: *Mortierella.*

Species: *vinaceae.*

Variety: *raffinoseutilizer.*

(c) The additive is used or intended for use in the production of sugar (sucrose) from sugar beets by addition as mycelial pellets to the yield of sucrose, followed by removal of the spent mycelial pellets by filtration.

(d) The enzyme removal is such that there are no enzyme or mycelial residues remaining in the finished sucrose.

[1]Available from: American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 20852.

[42 FR 14526, Mar. 15, 1977, as amended at 54 FR 24897, June 12, 1989]

Sec. 173.150 Milk-clotting enzymes, microbial.

Milk-clotting enzyme produced by pure-culture fermentation process may be safely used in the production of cheese in accordance with the conditions:

(a) Milk-clotting enzyme is derived from one of the following organisms by a pure-culture fermentation process:

(1) *Endothia parasitica* classified as follows: Class, Ascomycetes; order, Sphaeriales; family, Diaporthacesae; genus, *Endothia;* species,

(2) *Bacillus cereus* classified as follows: Class, Schizomycetes; order, Eubacteriales; family, Bacillaceae; genus, *Bacillus;* species, *cer* Frankland).

(3) *Mucor pusillus* Lindt classified as follows: Class, Phycomycetes; subclass, Zygomycetes; order, Mucorales; family, Mucoraceae; genus, variety, *Lindt.*

(4) *Mucor miehei Cooney et Emerson* classified as follows: Class, Phycomycetes; subclass, Zygomycetes; order, Mucorales; family, Mucoracea *miehei;* variety, *Cooney et Emerson.*

(5) *Aspergillus oryzae* modified by recombinant deoxyribonucleic (DNA) techniques to contain the gene coding for aspartic proteinase from *Cooney et Emerson* as defined in paragraph (a)(4) of this section, and classified as follows: Class, Blastodeuteromycetes (Hyphomycetes); (Moniliales); genus, *Aspergillus* ; species *oryzae.*

(b) The strains of organism identified in paragraph (a) of this section are nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that completely removes the generating organism from the milk-clotting enzyme product.

(d) The additive is used in an amount not in excess of the minimum required to produce its intended effect in the production of those che permitted by standards of identity established pursuant to section 401 of the Act.

[42 FR 14526, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 62 FR 59284, Nov. 3, 1997]

Sec. 173.160 Candida guilliermondii.

The food additive *Candida guilliermondii* may be safely used as the organism for fermentation production of citric acid in accordance with

(a) The food additive is the enzyme system of the viable organism *Candida guilliermondii* and its concomitant metabolites produced during

(b)(1) The nonpathogenic and nontoxicogenic organism descending from strain, American Type Culture Collection (ATCC) No. 20474, [1] is clas

Class: Deuteromycetes.

Order: Moniliales.

Family: Cryptococcaceae.

Genus: *Candida.*

Species: *guilliermondii.*

Variety: *guilliermondii.*

(2) The toxonomic characteristics of the reference culture strain ATCC No. 20474 agree in the essentials with the standard description fo variety *guilliermondii* listed in "The Yeasts--A Toxonomic Study;" 2d Ed. (1970), by Jacomina Lodder, which is incorporated by reference. the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or ava National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.*

(c)(1) The additive is used or intended for use as a pure culture in the fermentation process for the production of citric acid using an carbohydrate substrate.

(2) The organism *Candida guilliermondii* is made nonviable and is completely removed from the citric acid during the recovery and purifica

(d) The additive is so used that the citric acid produced conforms to the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet addr Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-60 *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

[1]Available from: American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 20852.

[42 FR 14526, Mar. 15, 1977, as amended at 47 FR 11838, Mar. 19, 1982; 49 FR 10106, Mar. 19, 1984; 54 FR 24897, June 12, 1989; 78 FR 7146

Sec. 173.165 Candida lipolytica.

The food additive *Candida lipolytica* may be safely used as the organism for fermentation production of citric acid in accordance with the

(a) The food additive is the enzyme system of the organism *Candida lipolytica* and its concimitant metabolites produced during the ferment

(b)(1) The nonpathogenic organism is classified as follows:

Class: Deuteromycetes.

Order: Moniliales.

Family: Cryptococcaceae.

Genus: *Candida*.

Species: *lipolytica*.

(2) The taxonomic characteristics of the culture agree in essential with the standard description for *Candida lipolytica* variety *lipolyti* Toxonomic Study," 2d Ed. (1970), by Jacomina Lodder, which is incorporated by reference. Copies are available from the Center for Food Sa (HFS-200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives an (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.*

(c) The additive is used or intended for use as a pure culture in the fermentation process for the production of citric acid from purifie

(d) The additive is so used that the citric acid produced conforms to the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet addr Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-60 *http://www.archives.gov/federal-register/cfr/ibr-locations.html.* The additive meets the following ultraviolet absorbance limits when subj procedure described in this paragraph:

Ultraviolet absorbance per centimeter path length

280 to 289 millimicrons
290 to 299 millimicrons
300 to 359 millimicrons
360 to 400 millimicrons

Analytical Procedure for Citric Acid

general instructions

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance t scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware including stoppers ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all gl isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of citric acid sample to assure absence of any extraneous material arising from inadequate packaging. Because some of the polynuclear hydrocarbons sought in th to photo-oxidation, the entire procedure is to be carried out under subdued light.

apparatus

1. Aluminum foil, oil free.

2. Separatory funnels, 500-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

3. Chromatographic tubes: (a) 80-millimeter ID * 900-millimeter length equipped with tetrafluoroethylene polymer stopcock and course frit ID * 300-millimeter length equipped with tetrafluoroethylene polymer stopcock.

4. Rotary vacuum evaporator, Buchi or equivalent.

5. Spectrophotometer--Spectral range 250-400 nanometers with spectral slit width of 2 nanometers or less; under instrument operating cond measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, +/-0.01 at 0.4 absorbance.

Wavelength repeatability, +/-0.2 nanometer.

Wavelength accuracy, +/-1.0 nanometer.

The spectrophotometer is equipped with matched 1 centimeter path length quartz microcuvettes with 0.5-milliliter volume capacity.

6. Vacuum oven, minimum inside dimensions: 200 mm * 200 mm * 300 mm deep.

reagents and materials

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The benzene, hexane and 1,2-dichloroethane designated in the list following this paragraph shall pass the following test:

The specified quantity of solvent is added to a 250-milliliter round bottom flask containing 0.5 milliliter of purified *n-* hexadecane and evaporator at 45 deg. C to constant volume. Six milliliters of purified isooctane are added to this residue and evaporated under the same minutes. Determine the absorbance of the residue compared to purified *n-* hexadecane as reference. The absorbance of the solution of the s exceed 0.03 per centimeter path length between 280 and 299 nanometers and 0.01 per centimeter path length between 300 and 400 nanometers.

Methyl alcohol, A.C.S. reagent grade. Use 100 milliliters for the test described in the preceding paragraph. If necessary, methyl alcohol distillation through a Virgreaux column discarding the first and last ten percent of the distillate or otherwise.

Benzene, spectrograde (*Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent*). Use 80 milliliters for the test. If nece purified by distillation or otherwise.

Isooctane (*2,2,4-trimethylpentane*). Use 100 milliliters for the test. If necessary, isooctane may be purified by passage through a colum distillation or otherwise.

Hexane, spectrograde (*Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent*). Use 100 milliliters for the test. If nece purified by distillation or otherwise.

1,2-Dichloroethane, spectrograde (*Matheson, Coleman and Bell, East Rutherford, N.J., or equivalent*). Use 100 milliliters for the test. I dichloroethane may be purified by distillation or otherwise.

eluting mixtures

1. *10 percent 1,2-dichloroethane in hexane.* Prepare by mixing the purified solvents in the volume ratio of 1 part of 1,2-dichloroethane t

2. *40 percent benzene in hexane.* Prepare by mixing the purified solvents in the volume ratio of 4 parts of benzene to 6 parts of hexane.

n-Hexadecane, 99 percent olefin-free. Determine the absorbance compared to isooctane as reference. The absorbance per centimeter path len the range of 280-400 nanometers. If necessary, *n-* hexadecane may be purified by percolation through activated silica gel, distillation or

Silica gel, 28-200 mesh (*Grade 12, Davison Chemical Co., Baltimore, MD, or equivalent*). Activate as follows: Slurry 900 grams of silica purified water in a 3-liter beaker. Cool the mixture and pour into a 80 * 900 chromatographic column with coarse fritted disc. Drain the additional 6 liters of purified water and wash with 3,600 milliliters of purified methyl alcohol at a relatively slow rate. Drain all of the silica gel to an aluminum foil-lined drying dish. Place foil over the top of the dish. Activate in a vacuum oven at low vacuum (appro Mercury or 27 inches of Mercury below atmospheric pressure) at 173deg. to 177 deg. C for at least 20 hours. Cool under vacuum and store i

Sodium sulfate, anhydrous, A.C.S. reagent grade. This reagent should be washed with purified isooctane. Check the purity of this reagent this chapter.

Water, purified. All water used must meet the specifications of the following test:

Extract 600 milliliters of water with 50 milliliters of purified isooctane. Add 1 milliliter of purified *n*- hexadecane to the isooctane e resulting solution to 1 milliliter. The absorbance of this residue shall not exceed 0.02 per centimeter path length between 300-400 nanom centimeter path length between 280-299 nanometers. If necessary, water may be purified by distillation, extraction with purified organic absorbent (e.g., activated carbon) followed by filtration of the absorbent or otherwise.

procedure

Separate portions of 200 milliliters of purified water are taken through the procedure for use as control blanks. Each citric acid sample Weigh 200 grams of anhydrous citric acid into a 500 milliliter flask and dissolve in 200 milliliters of pure water. Heat the solution to 500 milliliter separatory funnel. Rinse the flask with 50 milliliters of isooctane and add the isooctane to the separatory funnel. Gently (caution: vigorous shaking will cause emulsions) with periodic release of the pressure caused by shaking.

Allow the phases to separate for at least 5 minutes. Draw off the lower aqueous layer into a second 500-milliliter separatory funnel and second aliquot of 50 milliliters of isooctane. After separation of the layers, draw off and discard the water layer. Combine both isoocta containing the first extract. Rinse the funnel which contained the second extract with 10 milliliters of isooctane and add this portion t extract.

A chromatographic column containing 5.5 grams of silica gel and 3 grams of anhydrous sodium sulfate is prepared for each citric acid samp column with a small glass wool plug. Rinse the inside of the column with 10 milliliters of purified isooctane. Drain the isooctane from t activated silica gel into the column. Tap the column approximately 20 times on a semisoft, clean surface to settle the silica gel. Carefu anhydrous sodium sulfate onto the top of the silica gel in the column.

Carefully drain the isooctane extract of the citric acid solution into the column in a series of additions while the isooctane is drainin elution rate of approximately 3 milliliters per minute. Rinse the separatory funnel with 10 milliliters of isooctane after the last porti applied to the column and add this rinse to the column. After all of the extract has been applied to the column and the solvent layer rea bed, rinse the column with 25 milliliters of isooctane followed by 10 milliliters of a 10-percent dichloroethane in hexane solution. For the column until the solvent layer reaches the top of the sodium sulfate bed. Discard the rinse solvents. Place a 250-milliliter round bo milliliter of purified *n*- hexadecane under the column. Elute the polynuclear aromatic hydrocarbons from the column with 30 milliliters of hexane solution. Drain the eluate until the 40-percent benzene in the hexane solvent reaches the top of the sodium sulfate bed.

Evaporate the 40-percent benzene in hexane eluate on the rotary vacuum evaporator at 45 deg. C until only the *n*- hexadecane residue of 0. the *n*- hexadecane residue twice with the following wash step: Add 6 milliliters of purified isooctane and remove the solvents by vacuum e constant volume, i.e., 0.5 milliliter. Cool the *n*- hexadecane residue and transfer the solution to an 0.5-milliliter microcuvette. Determ solution compared to purified *n*- hexadecane as reference. Correct the absorbance values for any absorbance derived from the control reage absorbance does not exceed the limits prescribed, the samples meet the ultraviolet absorbance specifications.

The reagent blank is prepared by using 200 milliliters of purified water in place of the citric acid solution and carrying the water samp The typical control reagent blank should not exceed 0.03 absorbance per centimeter path length between 280 and 299 nanometers, 0.02 absor length between 300 and 359 nanometers, and 0.01 absorbance per centimeter path length between 360 and 400 nanometers.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11838, Mar. 19, 1982; 49 FR 10106, Mar. 19, 1984; 54 FR 24897, June 12, 1989; 78 FR 7146

Sec. 173.170 Aminoglycoside 3'-phosphotransferase II.

The food additive aminoglycoside 3'-phosphotransferase II may be safely used in the development of genetically modified cotton, oilseed r accordance with the following prescribed conditions:

(a) The food additive is the enzyme aminoglycoside 3'-phosphotransferase II (CAS Reg. No. 58943-39-8) which catalyzes the phosphorylation antibiotics, including kanamycin, neomycin, and gentamicin.

(b) Aminoglycoside 3'-phosphotransferase II is encoded by the *kan* ^{r} gene originally isolated from transposon Tn5 of the bacterium *Escheri*

(c) The level of the additive does not exceed the amount reasonably required for selection of plant cells carrying the *kan* ^{r} gene along w interest.

[59 FR 26711, May 23, 1994]

Subpart C--Solvents, Lubricants, Release Agents and Related Substances

Sec. 173.210 Acetone.

A tolerance of 30 parts per million is established for acetone in spice oleoresins when present therein as a residue from the extraction

Sec. 173.220 1,3-Butylene glycol.

1,3-Butylene glycol (1,3-butanediol) may be safely used in food in accordance with the following prescribed conditions:

(a) The substance meets the following specifications:

(1) 1,3-Butylene glycol content: Not less than 99 percent.

(2) Specific gravity at 20/20 deg. C: 1.004 to 1.006.

(3) Distillation range: 200deg. -215 deg. C.

(b) It is used in the minimum amount required to perform its intended effect.

(c) It is used as a solvent for natural and synthetic flavoring substances except where standards of identity issued under section 401 of

Sec. 173.228 Ethyl acetate.

Ethyl acetate (CAS Reg. No. 141-78-6) may be safely used in food in accordance with the following conditions:

(a) The additive meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 343-344, which is incorporated by reference. T 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 Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at th Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: *http://www.archives.gov/ locations.html.*

(b) The additive is used in accordance with current good manufacturing practice as a solvent in the decaffeination of coffee and tea.

[47 FR 146, Jan. 5, 1982, as amended at 49 FR 28548, July 13, 1984; 78 FR 71466, Nov. 29, 2013]

Sec. 173.230 Ethylene dichloride.

A tolerance of 30 parts per million is established for ethylene dichloride in spice oleoresins when present therein as a residue from the *Provided, however,* That if residues of other chlorinated solvents are also present the total of all residues of such solvents shall not e

Sec. 173.240 Isopropyl alcohol.

Isopropyl alcohol may be present in the following foods under the conditions specified:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 50 parts per million.

(b) In lemon oil as a residue in production of the oil, at a level not to exceed 6 parts per million.

(c) In hops extract as a residue from the extraction of hops at a level not to exceed 2.0 percent by weight: *Provided,* That,

(1) The hops extract is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops extract specifies the presence of the isopropyl alcohol and provides for the use of the hops extract only as pr of this section.

Sec. 173.250 Methyl alcohol residues.

Methyl alcohol may be present in the following foods under the conditions specified:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 50 parts per million.

(b) In hops extract as a residue from the extraction of hops, at a level not to exceed 2.2 percent by weight; *Provided,* That:

(1) The hops extract is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops extract specifies the presence of methyl alcohol and provides for the use of the hops extract only as prescribe this section.

Sec. 173.255 Methylene chloride.

Methylene chloride may be present in food under the following conditions:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 30 parts per million; *Provided,* That, if resi solvents are also present, the total of all residues of such solvents shall not exceed 30 parts per million.

(b) In hops extract as a residue from the extraction of hops, at a level not to exceed 2.2 percent, *Provided,* That:

(1) The hops extract is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops extract identifies the presence of the methylene chloride and provides for the use of the hops extract only as (1) of this section.

(c) In coffee as a residue from its use as a solvent in the extraction of caffeine from green coffee beans, at a level not to exceed 10 p percent) in decaffeinated roasted coffee and in decaffeinated soluble coffee extract (instant coffee).

Sec. 173.270 Hexane.

Hexane may be present in the following foods under the conditions specified:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 25 parts per million.

(b) In hops extract as a residue from the extraction of hops, at a level not to exceed 2.2 percent by weight; *Provided,* That:

(1) The hops extract is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops extract specifies the presence of the hexane and provides for the use of the hops extract only as prescribed by section.

Sec. 173.275 Hydrogenated sperm oil.

The food additive hydrogenated sperm oil may be safely used in accordance with the following prescribed conditions:

(a) The sperm oil is derived from rendering the fatty tissue of the sperm whale or is prepared by synthesis of fatty acids and fatty alco whale. The sperm oil obtained by rendering is refined. The oil is hydrogenated.

(b) It is used alone or as a component of a release agent or lubricant in bakery pans.

(c) The amount used does not exceed that reasonably required to accomplish the intended lubricating effect.

Sec. 173.280 Solvent extraction process for citric acid.

A solvent extraction process for recovery of citric acid from conventional *Aspergillus niger* fermentation liquor may be safely used to pr in accordance with the following conditions:

(a) The solvent used in the process consists of a mixture of *n*- octyl alcohol meeting the requirements of 172.864 of this chapter, synthe hydrocarbons meeting the requirements of 172.882 of this chapter, and tridodecyl amine.

(b) The component substances are used solely as a solvent mixture and in a manner that does not result in formation of products not prese produced citric acid.

(c) The citric acid so produced meets the polynuclear aromatic hydrocarbon specifications of 173.165 and the specifications of the Food C (2010), pp. 226-227, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation b 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., Roc address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of thi 202-741-6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

(d) Residues of *n*- octyl alcohol and synthetic isoparaffinic petroleum hydrocarbons are removed in accordance with good manufacturing pra manufacturing practice results in residues not exceeding 16 parts per million (ppm) *n*- octyl alcohol and 0.47 ppm synthetic isoparaffinic citric acid.

(e) Tridodecyl amine may be present as a residue in citric acid at a level not to exceed 100 parts per billion.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10106, Mar. 19, 1984; 78 FR 71466, Nov. 29, 2013]

Sec. 173.290 Trichloroethylene.

Tolerances are established for residues of trichloroethylene resulting from its use as a solvent in the manufacture of foods as follows:

Decaffeinated ground coffee	25 parts per million.
Decaffeinated soluble (instant) coffee extract	10 parts per million.
Spice oleoresins	30 parts per million (provided that if residues of other chlorinated solvents are also present, the total solvents in spice oleoresins shall not exceed 30 parts per million).

Subpart D--Specific Usage Additives

Sec. 173.300 Chlorine dioxide.

Chlorine dioxide (CAS Reg. No. 10049-04-4) may be safely used in food in accordance with the following prescribed conditions:

(a)(1) The additive is generated by one of the following methods:

(i) Treating an aqueous solution of sodium chlorite with either chlorine gas or a mixture of sodium hypochlorite and hydrochloric acid.

(ii) Treating an aqueous solution of sodium chlorate with hydrogen peroxide in the presence of sulfuric acid.

(iii) Treating an aqueous solution of sodium chlorite by electrolysis.

(2) The generator effluent contains at least 90 percent (by weight) of chlorine dioxide with respect to all chlorine species as determine the "Standard Methods for the Examination of Water and Wastewater," 20th ed., 1998, or an equivalent method. Method 4500-ClO2 E ("Amperom incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Office of Food Additive Sa

Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or the American Public Health A Washington, DC 20001-3750. You may inspect a copy at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this materi 6030, or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.*

(b)(1) The additive may be used as an antimicrobial agent in water used in poultry processing in an amount not to exceed 3 parts per mill dioxide as determined by Method 4500-ClO2 E, referenced in paragraph (a)(2) of this section, or an equivalent method.

(2) The additive may be used as an antimicrobial agent in water used to wash fruits and vegetables that are not raw agricultural commodit exceed 3 ppm residual chlorine dioxide as determined by Method 4500-ClO2 E, referenced in paragraph (a)(2) of this section, or an equival fruits and vegetables with chlorine dioxide shall be followed by a potable water rinse or by blanching, cooking, or canning.

[60 FR 11900, Mar. 3, 1995. Redesignated at 61 FR 14245, Apr. 1, 1996, as amended at 61 FR 14480, Apr. 2, 1996; 63 FR 38747, July 20, 199 2000; 70 FR 7396, Feb. 14, 2005; 81 FR 5592, Feb. 3, 2016]

Sec. 173.310 Boiler water additives.

Boiler water additives may be safely used in the preparation of steam that will contact food, under the following conditions:

(a) The amount of additive is not in excess of that required for its functional purpose, and the amount of steam in contact with food doe to produce the intended effect in or on the food.

(b) The compounds are prepared from substances identified in paragraphs (c) and (d) of this section, and are subject to the limitations,

(c) List of substances:

Substances	Limitations
Acrylamide-sodium acrylate resin	Contains not more than 0.05 percent by weight of acrylamic
Acrylic acid/2-acrylamido-2-methyl propane sulfonic acid copolymer having a minimum weight average molecular weight of 9,900 and a minimum number average molecular weight of 5,700 as determined by a method entitled "Determination of Weight Average and Number Average Molecular Weight of 60/40 AA/AMPS"	Total not to exceed 20 parts per million (active) in boile
Ammonium alginate	
Cobalt sulfate (as catalyst)	
1-hydroxyethylidene-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4) and its sodium and potassium salts	
Lignosulfonic acid	
Monobutyl ethers of polyethylene-polypropylene glycol produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol	Minimum mol. wt. 1,500.
Poly(acrylic acid-co-hypophosphite), sodium salt (CAS Reg. No. 71050-62-9), produced from a 4:1 to a 16:1 mixture by weight of acrylic acid and sodium hypophosphite	Total not to exceed 1.5 parts per million in boiler feed w not more than 0.5 percent by weight of acrylic acid monome
Polyethylene glycol	As defined in 172.820 of this chapter.
Polymaleic acid [CAS Reg. No. 26099-09-2], and/or its sodium salt. [CAS Reg. No. 30915-61-8 or CAS Reg. No. 70247-90-4]	Total not to exceed 1 part per million in boiler feed wate
Polyoxypropylene glycol	Minimum mol. wt. 1,000.
Potassium carbonate	
Potassium tripolyphosphate	
Sodium acetate	
Sodium alginate	
Sodium aluminate	
Sodium carbonate	
Sodium carboxymethylcellulose	Contains not less than 95 percent sodium carboxymethylcell basis, with maximum substitution of 0.9 carboxymethylcellu anhydroglucose unit, and with a minimum viscosity of 15 ce weight aqueous solution at 25 deg. C; by the "Viscosity of prescribed in the Food Chemicals Codex, pp. 1128-1129.
Sodium glucoheptonate	Less than 1 part per million cyanide in the sodium glucohe
Sodium hexametaphosphate	
Sodium humate	
Sodium hydroxide	
Sodium lignosulfonate	
Sodium metabisulfite	
Sodium metasilicate	
Sodium nitrate	
Sodium phosphate (mono-, di-, tri-)	
Sodium polyacrylate	
Sodium polymethacrylate	
Sodium silicate	
Sodium sulfate	
Sodium sulfite (neutral or alkaline)	
Sodium tripolyphosphate	
Sorbitol anhydride esters: A mixture consisting of sorbitan monostearate as defined in 172.842 of this chapter; polysorbate 60 ((polyoxyethylene (20) sorbitan monostearate)) as defined in 172.836 of this chapter; and polysorbate 20 ((polyoxyethylene (20) sorbitan monolaurate)), meeting the specifications of the Food Chemicals Codex, pp. 825-827.	The mixture is used as an anticorrosive agent in steam boi with each component not to exceed 15 milligrams per kilogr
Tannin (including quebracho extract)	
Tetrasodium EDTA	
Tetrasodium pyrophosphate	

(d) Substances used alone or in combination with substances in paragraph (c) of this section:

Substances	Limitations
Cyclohexylamine	Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk p
Diethylaminoethanol	Not to exceed 15 parts per million in steam, and excluding use of such steam in contact with milk and milk p
Hydrazine	Zero in steam.
Morpholine	Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk p
Octadecylamine	Not to exceed 3 parts per million in steam, and excluding use of such steam in contact with milk and milk pr
Trisodium nitrilotriacetate	Not to exceed 5 parts per million in boiler feedwater; not to be used where steam will be in contact with mi

(e) To assure safe use of the additive, in addition to the other information required by the Act, the label or labeling shall bear:

(1) The common or chemical name or names of the additive or additives.

(2) Adequate directions for use to assure compliance with all the provisions of this section.

(f) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Feder 552(a) and 1 CFR part 51. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, T MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this materi 6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

(1) FDA Main Library, 10903 New Hampshire Ave., Silver Spring, MD 20993:

(i) "Determination of Weight Average and Number Average Molecular Weight of 60/40 AA/AMPS" (October 23, 1987).

(ii) [Reserved]

(2) United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*):

(i) Food Chemicals Codex, 7th ed. (2010), pp. 1128-1129.

(ii) Food Chemicals Codex, 7th ed. (2010), pp. 825-827.

[42 FR 14526, Mar. 15, 1977, as amended at 45 FR 73922, Nov. 7, 1980; 45 FR 85726, Dec. 30, 1980; 48 FR 7439, Feb. 22, 1983; 49 FR 5748, Mar. 19, 1984; 50 FR 49536, Dec. 3, 1985; 53 FR 15199, Apr. 28, 1988; 54 FR 31012, July 26, 1989; 55 FR 12172, Apr. 2, 1990; 61 FR 14245, Jan. 12, 1999; 64 FR 29227, June 1, 1999; 78 FR 71466, Nov. 29, 2013]

Sec. 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables.

Chemicals may be safely used to wash or to assist in the peeling of fruits and vegetables in accordance with the following conditions:

(a) The chemicals consist of one or more of the following:

(1) Substances generally recognized as safe in food or covered by prior sanctions for use in washing fruits and vegetables.

(2) Substances identified in this subparagraph and subject to such limitations as are provided:

Substances	
A mixture of alkylene oxide adducts of alkyl alcohols and phosphate esters of alkylene oxide adducts of alkyl alcohols consisting of: [alpha]-alkyl (C12-C18)-omega-hydroxy-poly (oxyethylene) (7.5-8.5 moles)/poly (oxypropylene) block copolymer having an average molecular weight of 810; [alpha]-alkyl (C12-C18)-omega-hydroxy-poly (oxyethylene) (3.3-3.7 moles) polymer having an average molecular weight of 380, and subsequently esterified with 1.25 moles phosphoric anhydride; and [alpha]-alkyl (C10-C12)-omega-hydroxypoly (oxyethylene) (11.9-12.9 moles)/poly (oxypropylene) copolymer, having an average molecular weight of 810, and subsequently esterified with 1.25 moles phosphoric anhydride	May exc pee the veg
Aliphatic acid mixture consisting of valeric, caproic, enanthic, caprylic, and pelargonic acids	May exc pee the veg
Polyacrylamide	Not mil Cor per
Potassium bromide	May fru May to of
Sodium n-alkylbenzene-sulfonate (alkyl group predominantly C12 and C13 and not less than 95 percent C10 to C16)	Not was was lye veg
Sodium dodecylbenzene-sulfonate (alkyl group predominantly C12 and not less than 95% C10 to C16)	Do.
Sodium 2 ethyl-hexyl sulfate	Do.
Sodium hypochlorite	May to of
Sodium mono- and dimethyl naphthalene sulfonates (mol. wt. 245-260)	Not was was lye veg

(3) Sodium mono- and dimethyl naphthalene sulfonates (mol. wt. 245-260) may be used in the steam/scald vacuum peeling of tomatoes at a le percent in the condensate or scald water.

(4) Substances identified in this paragraph (a)(4) for use in flume water for washing sugar beets prior to the slicing operation and subj are provided for the level of the substances in the flume water:

Substance
[alpha]-Alkyl-omega-hydroxypoly-(oxyethylene) produced by condensation of 1 mole of C11-C486315 straight chain randomly substituted secon alcohols with an average of 9 moles of ethylene oxide
Linear undecylbenzenesulfonic acid
Dialkanolamide produced by condensing 1 mole of methyl laurate with 1.05 moles of diethanolamine
Triethanolamine
Ethylene glycol monobutyl ether
Oleic acid conforming with 172.860 of this chapter
Tetrapotassium pyrophosphate
Monoethanolamine
Ethylene dichloride
Tetrasodium ethylenediaminetetraacetate

(5) Substances identified in this paragraph (a)(5) for use on fruits and vegetables that are not raw agricultural commodities and subject provided:

Substances	Limitations
Hydrogen peroxide	Used in combination with acetic acid to form peroxyacetic acid. Not to exceed 59 ppm in v
1-Hydroxyethylidene-1,1-diphosphonic acid	May be used only with peroxyacetic acid. Not to exceed 4.8 ppm in wash water.
Peroxyacetic acid	Prepared by reacting acetic acid with hydrogen peroxide. Not to exceed 80 ppm in wash wat

(b) The chemicals are used in amounts not in excess of the minimum required to accomplish their intended effect.

(c) The use of the chemicals listed under paragraphs (a)(1), (a)(2), and (a)(4) is followed by rinsing with potable water to remove, to t of the chemicals.

(d) To assure safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the act, the name of th its composition.

(2) The label or labeling of the additive container shall bear adequate use directions to assure use in compliance with all provisions of

[42 FR 14526, Mar. 15, 1977, as amended at 42 FR 29856, June 10, 1977; 42 FR 32229, June 24, 1977; 43 FR 54926, Nov. 24, 1978; 61 FR 4637 FR 7069, Feb. 12, 1998; 64 FR 38564, July 19, 1999]

Sec. 173.320 Chemicals for controlling microorganisms in cane-sugar and beet-sugar mills.

Agents for controlling microorganisms in cane-sugar and beet-sugar mills may be safely used in accordance with the following conditions:

(a) They are used in the control of microorganisms in cane-sugar and/or beet-sugar mills as specified in paragraph (b) of this section.

(b) They are applied to the sugar mill grinding, crusher, and/or diffuser systems in one of the combinations listed in paragraph (b) (1), section or as a single agent listed in paragraph (b) (4) or (6) of this section. Quantities of the individual additives in parts per mill of the weight of the raw cane or raw beets.

(1) Combination for cane-sugar mills:

	Parts pe
Disodium cyanodithioimidocarbonate	
Ethylenediamine	
Potassium N-methyldithiocarbamate	

(2) Combination for cane-sugar mills:

	Parts p
Disodium ethylenebisdithiocarbamate	
Sodium dimethyldithiocarbamate	

(3) Combinations for cane-sugar mills and beet-sugar mills:

	Parts
(i) Disodium ethylenebisdithiocarbamate	
Ethylenediamine	
Sodium dimethyldithiocarbamate	
(ii) Disodium cyanodithioimidocarbonate	
Potassium N-methyldithiocarbamate	

(4) Single additive for cane-sugar mills and beet-sugar mills.

2,2-Dibromo-3-nitrilopropionamide (CAS Reg. No. 10222-01-2). Limitations: Byproduct molasses, bagasse, and pulp containing residues of 2,2-dibromo-3-nitrilopropionamide are not authorized for use in animal feed

(5) Combination for cane-sugar mills:

	P
n-Dodecyl dimethyl benzyl ammonium chloride	
n-Dodecyl dimethyl ethylbenzyl ammonium chloride	
n-Hexadecyl dimethyl benzyl ammonium chloride	
n-Octadecyl dimethyl benzyl ammonium chloride	
n-Tetradecyl dimethyl benzyl ammonium chloride	
n-Tetradecyl dimethyl ethylbenzyl ammonium chloride	

Limitations. Byproduct molasses, bagasse, and pulp containing residues of these quaternary ammonium salts are not authorized for use in a

(6) Single additive for beet-sugar mills:

	Parts p
Glutaraldehyde (CAS Reg. No. 111-30-8)	Not more than 250.

(c) To assure safe use of the additives, their label and labeling shall conform to that registered with the Environmental Protection Agen

[42 FR 14526, Mar. 15, 1977, as amended at 47 FR 35756, Aug. 17, 1982; 50 FR 3891, Jan. 29, 1985; 57 FR 8065, Mar. 6, 1992]

Sec. 173.322 Chemicals used in delinting cottonseed.

Chemicals may be safely used to assist in the delinting of cottonseed in accordance with the following conditions:

(a) The chemicals consist of one or more of the following:

(1) Substances generally recognized as safe for direct addition to food.

(2) Substances identified in this paragraph and subject to such limitations as are provided:

Substances	**Limitations**
alpha-Alkyl-omega-hydroxypoly-(oxyethylene) produced by condensation of a linear primary alcohol containing an average chain length of 10 carbons with poly(oxyethylene) having an average of 5 ethylene oxide units	May be used at an application rate not to exceed 0.3 percent to enhance delinting of cottonseeds intended for the product Byproducts including lint, hulls, and meal may be used in a
An alkanomide produced by condensation of coconut oil fatty acids and diethanolamine, CAS Reg. No. 068603-42-9	May be used at an application rate not to exceed 0.2 percent to enhance delinting of cottonseeds intended for the product Byproducts including lint, hulls, and meal may be used in a

[47 FR 8346, Feb. 26, 1982]

Sec. 173.325 Acidified sodium chlorite solutions.

Acidified sodium chlorite solutions may be safely used in accordance with the following prescribed conditions:

(a) The additive is produced by mixing an aqueous solution of sodium chlorite (CAS Reg. No. 7758-19-2) with any generally recognized as s

(b)(1) The additive is used as an antimicrobial agent in poultry processing water in accordance with current industry practice under the

(i) As a component of a carcass spray or dip solution prior to immersion of the intact carcass in a prechiller or chiller tank;

(ii) In a prechiller or chiller solution for application to the intact carcass;

(iii) As a component of a spray or dip solution for application to poultry carcass parts;

(iv) In a prechiller or chiller solution for application to poultry carcass parts; or

(v) As a component of a post-chill carcass spray or dip solution when applied to poultry meat, organs, or related parts or trim.

(2) When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1, in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

(3) When used in a prechiller or chiller solution, the additive is used at levels that result in sodium chlorite concentrations between 5 combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.8 to 3.2.

(c) The additive is used as an antimicrobial agent in accordance with current industry practice in the processing of red meat, red meat p component of a spray or in the processing of red meat parts and organs as a component of a dip. Applied as a dip or spray, the additive i in sodium chlorite concentrations between 500 and 1,200 ppm in combination with any GRAS acid at levels sufficient to achieve a solution

(d)(1) The additive is used as an antimicrobial agent in water and ice that are used to rinse, wash, thaw, transport, or store seafood in industry standards of good manufacturing practice. The additive is produced by mixing an aqueous solution of sodium chlorite with any GRA the range of 2.5 to 2.9 and diluting this solution with water to achieve an actual use concentration of 40 to 50 parts per million (ppm) that is intended to be consumed raw shall be subjected to a potable water rinse prior to consumption.

(2) The additive is used as a single application in processing facilities as an antimicrobial agent to reduce pathogenic bacteria due to the harvesting, handling, heading, evisceration, butchering, storing, holding, packing, or packaging of finfish and crustaceans; or follo finfish; in accordance with current industry standards of good manufacturing practice. Applied as a dip or spray, the additive is used at sodium chlorite concentration of 1,200 ppm, in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treated prior to consumption.

(e) The additive is used as an antimicrobial agent on raw agricultural commodities in the preparing, packing, or holding of the food for consistent with section 201(q)(1)(B)(i) of the act, and not applied for use under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1) accordance with current industry standards of good manufacturing practice. Applied as a dip or a spray, the additive is used at levels th concentrations of 500 to 1200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2 agricultural commodities with acidified sodium chlorite solutions shall be followed by a potable water rinse, or by blanching, cooking, o

(f) The additive is used as an antimicrobial agent on processed, comminuted or formed meat food products (unless precluded by standards o 319) prior to packaging of the food for commercial purposes, in accordance with current industry standards of good manufacturing practice the additive is used at levels that result in sodium chlorite concentrations of 500 to 1200 ppm, in combination with any GRAS acid at lev pH of 2.5 to 2.9.

(g) The additive is used as an antimicrobial agent in the water applied to processed fruits and processed root, tuber, bulb, legume, frui groundcherry, pepino, pepper, tomatillo, and tomato), and cucurbit vegetables in accordance with current industry standards of good manuf component of a spray or dip solution, provided that such application be followed by a potable water rinse and a 24-hour holding period pr for processed leafy vegetables (i.e., vegetables other than root, tuber, bulb, legume, fruiting, and cucurbit vegetables) and vegetables family, application must be by dip treatment only, and must be preceded by a potable water rinse and followed by a potable water rinse an prior to consumption. When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

(h) The concentration of sodium chlorite is determined by a method entitled "Determination of Sodium Chlorite: 50 ppm to 1500 ppm Concent developed by Alcide Corp., Redmond, WA, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies a of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College P or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.*

[61 FR 17829, Apr. 23, 1996, as amended at 63 FR 11119, Mar. 6, 1998; 64 FR 44123, Aug. 13, 1999; 64 FR 49982, Sept. 15, 1999; 65 FR 1776 16312, Mar. 28, 2000; 66 FR 22922, May 7, 2001; 66 FR 31841, June 13, 2001; 67 FR 15720, Apr. 3, 2002; 69 FR 78304, Dec. 30, 2004; 78 FR 5592, Feb. 3, 2016]

Sec. 173.340 Defoaming agents.

Defoaming agents may be safely used in processing foods, in accordance with the following conditions:

(a) They consist of one or more of the following:

(1) Substances generally recognized by qualified experts as safe in food or covered by prior sanctions for the use prescribed by this sec

(2) Substances listed in this paragraph (a)(2) of this section, subject to any limitations imposed:

Substances	Limitations
Dimethylpolysiloxane (substantially free from hydrolyzable chloride and alkoxy groups; no more than 18 percent loss in weight after heating 4 hours at 200 deg. C; viscosity 300 to 1,050 centistokes at 25 deg. C; refractive index 1.400-1.404 at 25 deg. C)	10 parts per million in food, or at such level in a concentrated food that when pre labels, the food in its ready-for-consumption state will have not more than 10 part follows: Zero in milk; 110 parts per million in dry gelatin dessert mixes labeled f 16 parts per million is present in the ready-to-serve dessert; 250 parts per millio cooking purposes, whereby no more than 10 parts per million is present in the cooke
Formaldehyde	As a preservative in defoaming agents containing dimethylpolysiloxane, in an amount of the dimethylpolysiloxane content.
[alpha]-Hydro-omega-hydroxy-poly (oxyethylene)/poly(oxypropylene) (minimum 15 moles)/poly(oxyethylene) block copolymer (CAS Reg. No. 9003-11-6) as defined in 172.808(a)(3) of this chapter	For use as prescribed in 172.808(b)(3) of this chapter.
Polyacrylic acid, sodium salt	As a stabilizer and thickener in defoaming agents containing dimethylpolysiloxane i required to accomplish the intended effect.
Polyethylene glycol	As defined in 172.820 of this chapter.
Polyoxyethylene 40 monostearate	As defined in U.S.P. XVI.
Polysorbate 60	As defined in 172.836 of this chapter.
Polysorbate 65	As defined in 172.838 of this chapter.
Propylene glycol alginate	As defined in 172.858 of this chapter.
Silicon dioxide	As defined in 172.480 of this chapter.
Sorbitan monostearate	As defined in 172.842 of this chapter.
White mineral oil: Conforming with 172.878 of this chapter	As a component of defoaming agents for use in wash water for sliced potatoes at a l percent of the wash water.

(3) Substances listed in this paragraph (a)(3), provided they are components of defoaming agents limited to use in processing beet sugar any limitations imposed:

Substances	
Aluminum stearate	As defined in 172.
Butyl stearate	
BHA	As an antioxidant, by weight of defoa
BHT	Do.
Calcium stearate	As defined in 172.
Fatty acids	As defined in 172.
Formaldehyde	As a preservative.
Hydroxylated lecithin	As defined in 172.
Isopropyl alcohol	
Magnesium stearate	As defined in 172.
Mineral oil: Conforming with 172.878 of this chapter	Not more than 150 as hydrocarbons.
Odorless light petroleum hydrocarbons: Conforming with 172.884 of this chapter	
Petrolatum: Conforming with 172.880 of this chapter	

Petroleum wax: Conforming with 172.886 of this chapter	
Petroleum wax, synthetic	
Polyethylene glycol (400)dioleate: Conforming with 172.820(a)(2) of this chapter and providing the oleic acid used in the production of this substance complies with 172.860 or 172.862 of this chapter	As an emulsifier r weight of defoame
Synthetic isoparaffinic petroleum hydrocarbons: Conforming with 172.882 of this chapter	
Oleic acid derived from tall oil fatty acids	Complying with 17
Oxystearin	As defined in 172.
Polyoxyethylene (600) dioleate	
Polyoxyethylene (600) monoricinoleate	
Polypropylene glycol	Molecular weight r
Polysorbate 80	As defined in 172.
Potassium stearate	As defined in 172.
Propylene glycol mono- and diesters of fats and fatty acids	As defined in 172.
Soybean oil fatty acids, hydroxylated	
Tallow, hydrogenated, oxidized or sulfated	
Tallow alcohol, hydrogenated	

(4) The substances listed in this paragraph (a)(4), provided they are components of defoaming agents limited to use in processing beet su limitations imposed:

Substances	Limitations
n-Butoxypoly(oxyethylene)-poly(oxypropylene)glycol	Viscosity range, 4,850-5,350 Saybolt Universal Seconds (SUS) at 37.8 deg. C (100 deg. F). The viscosity range is "Viscosity Determination of n-butoxypoly(oxyethylene)-poly(oxypropylene) glycol" dated April 26, 1995, developed Box 670, Bound Brook, NJ 08805, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR p material incorporated by reference are available from the Office of Food Additive Safety (HFS-200), Center for Fo Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, and may be examined at the Food Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the Na Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.
Monoester of alpha-hydro-omega-hydroxy-poly(oxyethylene) poly(oxypropylene) poly(oxyethylene) (15 mole minimum) blocked copolymer derived from low erucic acid rapeseed oil	

(b) They are added in an amount not in excess of that reasonably required to inhibit foaming.

[42 FR 14526, Mar. 15, 1977, as amended at 43 FR 2872, Jan. 20, 1978; 46 FR 30493, June 9, 1981; 46 FR 57476, Nov. 24, 1981; 60 FR 54036, Jan. 9, 1996; 63 FR 29134, May 28, 1998; 81 FR 5592, Feb. 3, 2016]

Sec. 173.342 Chlorofluorocarbon 113 and perfluorohexane.

A mixture of 99 percent chlorofluorocarbon 113 (1,1,2-trichloro-1,2,2-trifluoroethane) (CAS Reg. No. 76-13-1, also known as fluorocarbon 1 percent perfluorohexane (CAS Reg. No. 355-42-0) may be safely used in accordance with the following prescribed conditions:

(a) The additive chlorofluorocarbon 113 has a purity of not less than 99.99 percent.

(b) The additive mixture is intended for use to quickly cool or crust-freeze chickens sealed in intact bags composed of substances regula 178, and 179.45 of this chapter and conforming to any limitations or specifications in such regulations.

[55 FR 8913, Mar. 9, 1990]

Sec. 173.345 Chloropentafluoroethane.

The food additive chloropentafluoroethane may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a purity of not less than 99.97 percent, and contains not more than 200 parts per million saturated fluoro comp million unsaturated fluoro compounds as impurities.

(b) The additive is used or intended for use alone or with one or more of the following substances: Carbon dioxide, nitrous oxide, propan complying with 173.360, as an aerating agent for foamed or sprayed food products, with any propellant effect being incidental and no more to achieve the aerating function, except that use is not permitted for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive

(1) The label of the food additive container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, chloropentafluoroethane.

(ii) The percentage of the additive present in the case of a mixture.

(iii) The designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

[42 FR 14526, Mar. 15, 1977, as amended at 43 FR 11317, Mar. 17, 1978; 43 FR 14644, Apr. 7, 1978]

Sec. 173.350 Combustion product gas.

The food additive combustion product gas may be safely used in the processing and packaging of the foods designated in paragraph (c) of t of removing and displacing oxygen in accordance with the following prescribed conditions:

(a) The food additive is manufactured by the controlled combustion in air of butane, propane, or natural gas. The combustion equipment sh absorption-type filter capable of removing possible toxic impurities, through which all gas used in the treatment of food shall pass; and insure that any combustion products failing to meet the specifications provided in this section will be prevented from reaching the food

(b) The food additive meets the following specifications:

(1) Carbon monoxide content not to exceed 4.5 percent by volume.

(2) The ultraviolet absorbance in isooctane solution in the range 255 millimicrons to 310 millimicrons not to exceed one-third of the sta when tested as described in paragraph (e) of this section.

(c) It is used or intended for use to displace or remove oxygen in the processing, storage, or packaging of beverage products and other f

(d) To assure safe use of the additive in addition to the other information required by the act, the label or labeling of the combustion directions for use to provide a combustion product gas that complies with the limitations prescribed in paragraph (b) of this section, in assure proper filtration.

(e) The food additive is tested for compliance with paragraph (b)(2) by the following empirical method:

Spectrophotometric measurements. All measurements are made in an ultraviolet spectrophotometer in optical cells of 5 centimeters in lengt millimicrons to 310 millimicrons, under the same instrumental conditions. The standard reference absorbance is the absorbance at 275 mill

reference solution of naphthalene (National Bureau of Standards Material No. 577 or equivalent in purity) containing a concentration of 1 purified isooctane, measured against isooctane of the same spectral purity in 5-centimeter cells. (This absorbance will be approximately

Solvent. The solvent used is pure grade isooctane having an ultraviolet absorbance not to exceed 0.05 measured against distilled water as of purified inert gas through some isooctane under the identical conditions of the test, a lowering of the absorbance value has been obse isooctane to be used in this procedure shall not be more than 0.02 lower in the range 255 millimicrons to 310 millimicrons, inclusive, th solvent as measured in a 5-centimeter cell. If necessary to obtain the prescribed purities, the isooctane may be passed through activated

Apparatus. To assure reproducible results, the additive is passed into the isooctane solution through a gas-absorption train consisting o and necessary connections:

1. A gas flow meter with a range up to 30 liters per hour provided with a constant differential relay or other device to maintain a const the input pressure.

2. An absorption apparatus consisting of an inlet gas dispersion tube inserted to the bottom of a covered cylindrical vessel with a suita effluent gas. The dimensions and arrangement of tube and vessel are such that the inlet tube introduces the gas at a point not above 5 1/ of the solvent through a sintered glass outlet. The dimensions of the vessel are such, and both inlet and vessel are so designed, that th 60 milliliters of isooctane solvent at a rate up to 30 liters per hour without mechanical loss of solvent. The level corresponding to 60 on the vessel.

3. A cooling bath containing crushed ice and water to permit immersion of the absorption vessel at least to the solvent level mark.

Caution. The various parts of the absorption train must be connected by gas-tight tubing and joints composed of materials which will neit nor add components to the gas stream. The gas source is connected in series to the flow-rate device, the flow meter, and the absorption a Ventilation should be provided for the effluent gases which may contain carbon monoxide.

Sampling procedure. Immerse the gas-absorption apparatus containing 60 milliliters of isooctane in the coolant bath so that the solvent i for at least 15 minutes and then pass 120 liters of the test gas through the absorption train at a rate of 30 liters per hour or less. Ma deg. C throughout. Remove the absorption vessel from the bath, disconnect, and warm to room temperature. Add isooctane to bring the conte to 60 milliliters, and mix. Determine the absorbance of the solution in the 5-centimeter cell in the range 255 millimicrons to 310 millim to isooctane. The absorbance of the solution of combustion product gas shall not exceed that of the isooctane solvent at any wavelength i more than one-third of the standard reference absorbance.

Sec. 173.355 Dichlorodifluoromethane.

The food additive dichlorodifluoromethane may be safely used in food in accordance with the following prescribed conditions:

(a) The additive has a purity of not less than 99.97 percent.

(b) It is used or intended for use, in accordance with good manufacturing practice, as a direct-contact freezing agent for foods.

(c) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, dichlorodifluoromethane, with or without the parenthetical name "Food Freezant 12".

(ii) The designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

Sec. 173.356 Hydrogen peroxide.

Hydrogen peroxide (CAS Reg. No. 7722-84-1) may be safely used to treat food in accordance with the following conditions:

(a) The additive meets the specifications of the *Food Chemicals Codex,* 7th ed. (2010), pp. 496 and 497, which is incorporated by referenc 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 fro Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at th Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.*

(b) The additive is used as an antimicrobial agent in the production of modified whey (including, but not limited to, whey protein concen isolates) by ultrafiltration methods, at a level not to exceed 0.001 percent by weight of the whey, providing that residual hydrogen pero appropriate chemical or physical means during the processing of the modified whey.

[76 FR 11330, Mar. 2, 2011, as amended at 81 FR 5592, Feb. 3, 2016]

Sec. 173.357 Materials used as fixing agents in the immobilization of enzyme preparations.

Fixing agents may be safely used in the immobilization of enzyme preparations in accordance with the following conditions:

(a) The materials consist of one or more of the following:

(1) Substances generally recognized as safe in food.

(2) Substances identified in this subparagraph and subject to such limitations as are provided:

Substances	Limitations
Acrylamide-acrylic acid resin: Complying with 173.5(a)(1) and (b) of this chapter	May be used as a fixing material in the immobilization preparations for use in the manufacture of high fructos with 184.1372 of this chapter.
Cellulose triacetate	May be used as a fixing material in the immobilization reducing the lactose content of milk.
Diethylaminoethyl-cellulose	May be used as a fixing material in the immobilization preparations for use in the manufacture of high fructos with 184.1372 of this chapter.
Dimethylamine-epichlorohydrin resin: Complying with 173.60(a) and (b) of this chapter	May be used as a fixing material in the immobilization preparations for use in the manufacture of high fructos with 184.1372 of this chapter.
Glutaraldehyde	Do.
Periodic acid (CAS Reg. No. 10450-60-9).	
Polyethylenimine reaction product with 1,2-dichloroethane (CAS Reg. No. 68130-97-2) is the reaction product of homopolymerization of ethylenimine in aqueous hydrochloric acid at 100 deg. C and of cross-linking with 1,2-dichloroethane. The finished polymer has an average molecular weight of 50,000 to 70,000 as determined by gel permeation chromatography. The analytical method is entitled "Methodology for Molecular Weight Detection of Polyethylenimine," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740, and 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	May be used as a fixing material in the immobilization preparations from Aspergillus niger for use in the manu May be used as a fixing material in the immobilization 1. Glucose isomerase enzyme preparations for use in the fructose corn syrup, in accordance with 184.1372 of thi 2. Glucoamylase enzyme preparations from Aspergillus ni manufacture of beer. Residual ethylenimine in the finis will be less than 1 part per million as determined by g spectrometry. The residual ethylenimine is determined b entitled "Methodology for Ethylenimine Detection in Pol incorporated by reference in accordance with 5 U.S.C. 5 Residual 1,2-dichloroethane in the finished polyethylen than 1 part per million as determined by gas chromatogr

availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html

dichloroethane is determined by an analytical method en Ethylenedichloride Detection in Polyethylenimine," whic reference in accordance with 5 U.S.C. 552(a) and 1 CFR obtained from the Office of Food Additive Safety (HFS-2 and Applied Nutrition, 5001 Campus Dr., College Park, M at the Food and Drug Administration's Main Library, 109 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, and Records Administration (NARA). For information on t material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federalregister/codeoffederalre

(b) The fixed enzyme preparation is washed to remove residues of the fixing materials.

[48 FR 5716, Feb. 8, 1983, as amended at 52 FR 39512, Oct. 22, 1987; 55 FR 12172, Apr. 2, 1990; 59 FR 36937, July 20, 1994; 61 FR 4873, F Apr. 1, 1996; 67 FR 42716, June 25, 2002; 81 FR 5592, Feb. 3, 2016]

Sec. 173.360 Octafluorocyclobutane.

The food additive octafluorocyclo-butane may be safely used as a propellant and aerating agent in foamed or sprayed food products in acco conditions:

(a) The food additive meets the following specifications:

99.99 percent octafluorocyclobutane.

Less than 0.1 part per million fluoroolefins, calculated as perfluoroisobutylene.

(b) The additive is used or intended for use alone or with one or more of the following substances: Carbon dioxide, nitrous oxide, and pr aerating agent for foamed or sprayed food products, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive:

(1) The label of the food additive container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, octafluorocyclobutane.

(ii) The percentage of the additive present in the case of a mixture.

(iii) The designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

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 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 commerc 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 re 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 obt States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examine Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: *http://www.archives.gov/ 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 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 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]

Sec. 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-hydroxyethy acid.

(b)(1) The additive is used as an antimicrobial agent on meat carcasses, parts, trim, and organs in accordance with current industry prac concentration of peroxyacids is 220 parts per million (ppm) as peroxyacetic acid, and the maximum concentration of hydrogen peroxide is 7

(2) The additive is used as an antimicrobial agent on poultry carcasses, poultry parts, and organs in accordance with current industry st manufacturing practice (unless precluded by the U.S. Department of Agriculture's standards of identity in 9 CFR part 381, subpart P) wher of peroxyacids is 220 parts per million (ppm) as peroxyacetic acid, the maximum concentration of hydrogen peroxide is 110 ppm, and the ma 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 Pe Content," July 26, 2000, developed by Ecolab, Inc., St. Paul, MN, which is incorporated by reference. The concentration of 1-hydroxyethyl is determined by a method entitled "Determination of 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) Peroxyacid/Peroxide-Containing Solu developed by Ecolab, Inc., St. Paul, MN, which is incorporated by reference. The Director of the Office of the Federal Register approves 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 Revi and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or you may examine a copy at the Food and D Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records A information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.html.*

[65 FR 70660, Nov. 27, 2000, as amended at 66 FR 48208, Sept. 19, 2001; 67 FR 61784, Oct. 2, 2002; 81 FR 5593, Feb. 3, 2016]

Sec. 173.375 Cetylpyridinium chloride.

Cetylpyridinium chloride (CAS Reg. No. 123-93-5) 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 which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accord and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 2085 at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039 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 which the additive is used to treat raw poultry carcasses shall also contain propylene glycol (CAS Reg. No. 57-55-6) complying with 184.1 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 gram cetylpyridinium chloride per pound of raw poultry carcass, provided that the additive is used in systems that collect and recycle so 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 provided that the additive is used in systems that recapture at least 99 percent of the solution that is applied to the poultry carcasses cetylpyridinium chloride in the solution applied to the carcasses shall not exceed 0.8 percent by weight. When application of the additiv immersion in a chiller, the treatment will be followed by a potable water rinse of the carcass.

[72 FR 67576, Nov. 29, 2007, as amended at 76 FR 59248, Sept. 26, 2011; 81 FR 5593, Feb. 3, 2016]

Sec. 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 bicarbo

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

Sec. 173.395 Trifluoromethane sulfonic acid.

Trifluoromethane sulfonic acid has the empirical formula CF3SO3H (CAS Reg. No. 1493-13-6). The catalyst (Trifluoromethane sulfonic acid) production of cocoa butter substitute from palm oil (1-palmitoyl-2-oleoyl-3-stearin) (see 184.1259 of this chapter) in accordance with th

(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 cata 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 desc of Analysis of the Association of Official Analytical Chemists," sections 25.049-25.055, 13th Ed. (1980), which is incorporated by refere from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.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 6765

Sec. 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 am primarily of dimethyldioctadecylammonium chloride and dimethyldihexadecylammonium chloride. The additive may contain residues of isopropy 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 subseque chloride to form the quaternary ammonium compound known as dimethyl(2-ethylhexyl) hydrogenated tallow ammonium chloride and consisting pr 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 a food additive described in paragraph (a)(2) of this section contains not more than 3 percent by weight, each, of free amine and amine hyd A.O.C.S. method Te 3a-64, "Acid Value and Free Amine Value of Fatty Quaternary Ammonium Chlorides," 2d printing including additions and r 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 Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, and from the American Oil Chemists' Society, P.O. Box 5037, Statio available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/ibrlocations.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 r 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 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 entitled "Colorimetric Determination of Residual Quaternary Ammonium Compounds (Arquad HTL8) in Sugar and Sugar Solutions," June 13, 1990 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 Nutritio Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federalregister/codeoffederalregulations/*

(d) To assure safe use of the additive, the label and labeling of the additive shall bear, in addition to other information required by t Cosmetic Act, adequate directions to assure use in compliance with paragraph (c) of this section.

[56 FR 42686, Aug. 29, 1991]

Sec. 173.405 Sodium dodecylbenzenesulfonate.

Sodium dodecylbenzenesulfonate (CAS No. 25155-30-0) may be safely used in accordance with the following prescribed conditions:

(a) The additive is an antimicrobial agent used in wash water for fruits and vegetables. The additive may be used at a level not to excee kilogram in the wash water. Fruits and vegetables treated by the additive do not require a potable water rinse.

(b) The additive is limited to use in commissaries, cafeterias, restaurants, retail food establishments, nonprofit food establishments, a operations in which food is prepared for or served directly to the consumer.

(c) To assure safe use of the additive, the label or labeling of the additive container shall bear, in addition to the other information Food, Drug, and Cosmetic Act, adequate directions to assure use in compliance with the provisions of this section.

[77 FR 71697, Dec. 4, 2012]

Authority: 21 U.S.C. 321, 342, 348.
Source: 42 FR 14526, Mar. 15, 1977, unless otherwise noted.

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