

(1) *Assay*. Not less than 98.0 percent of $C_3H_3(COOH)_3$, using the "Food Chemicals Codex," 3d Ed. (1981), pp. 86-87, test for citric acid, which is incorporated by reference, and a molecular weight of 174.11. Copies of the material incorporated by reference may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(2) *Melting point*. Not less than 195 °C and the determination results in decomposition of aconitic acid.

(3) *Heavy metals (as Pb)*. Not more than 10 parts per million.

(4) *Arsenic (as As)*. Not more than 3 parts per million.

(5) *Oxalate*. Passes test.

(6) *Readily carbonizable substances*. Passes "Food Chemicals Codex," 3d Ed. (1981), pp. 86-87, test for citric acid, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

(7) *Residue on ignition*. Not more than 0.1 percent as determined by "Food Chemicals Codex," 3d Ed. (1981), pp. 86-87, test for citric acid, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

The substance should have infrared absorption bands at 3030, 2630, 1720, 1430, 1300, 1240, 910, 860, 780, and 750 cm^{-1} . Also, an aqueous solution of the substance should have major absorption peaks at 411 and 432 nanometers with little or no absorption at 389 nanometers.

(c) The ingredient is used as a flavoring substance and adjuvant as defined in §170.3(o)(12) of this chapter.

(d) The ingredient is used in food, in accordance with §184.1(b)(1), at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.003 percent for baked goods as defined in §170.3(n)(1) of this chapter, 0.002 percent for alcoholic beverages as defined in §170.3(n)(2) of this chapter, 0.0015 percent for frozen dairy products as defined in §170.3(n)(20) of this chapter, 0.0035 percent for soft

candy as defined in §170.3(n)(38) of this chapter, and 0.0005 percent or less for all other food categories.

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

[43 FR 47724, Oct. 17, 1978, as amended at 49 FR 5610, Feb. 14, 1984]

§ 184.1009 Adipic acid.

(a) Adipic acid ($C_6H_{10}O_4$, CAS Reg. No. 00124-04-9) is also known as 1,4-butanedicarboxylic acid or hexanedioic acid. It is prepared by nitric acid oxidation of cyclohexanol or cyclohexanone or a mixture of the two.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 11, which is incorporated by reference (copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408), and the following additional specifications:

(1) The adipic acid is converted to its corresponding amide. The amide is purified by recrystallization from water or aqueous ethanol. The melting range of the amide is 219° to 220 °C.

(2) The adipic acid is converted to its corresponding *bis-p-p*-bromophenacyl ester. The ester is purified by recrystallization from ethanol. The melting range of the ester is 153° to 154 °C.

(c) The ingredient is used as a flavoring agent as defined in §170.3(o)(12) of this chapter; leavening agent as defined in §170.3(o)(17) of this chapter; and pH control agent as defined in §170.3(o)(23) of this chapter.

(d) The ingredient is used in foods at levels not to exceed current good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in maximum levels, as served, of 0.05 percent for baked goods as defined in §170.3(n)(1) of this chapter; 0.005 percent for nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; 5.0 percent for condiments and relishes as defined in §170.3(n)(8) of this chapter; 0.45 percent for dairy product analogs as defined in §170.3(n)(10) of this chapter; 0.3 percent for fats and oil as defined in

§ 170.3(n)(12) of this chapter; 0.0004 percent for frozen dairy desserts as defined in § 170.3(n)(20) of this chapter; 0.55 percent for gelatin and puddings as defined in § 170.3(n)(22) of this chapter; 0.1 percent for gravies as defined in § 170.3(n)(24) of this chapter; 0.3 percent for meat products as defined in § 170.3(n)(29) of this chapter; 1.3 percent for snack foods as defined in § 170.3(n)(37) of this chapter; and 0.02 percent or less for all other food categories.

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

[47 FR 27810, June 25, 1982]

§ 184.1011 Alginate acid.

(a) Alginate acid is a colloidal, hydrophilic polysaccharide obtained from certain brown algae by alkaline extraction.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 13, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

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

Category of food	Maximum level of use in food (as served)	Functional use
Soup and soup mixes, § 170.3(n)(40) of this chapter.	Not to exceed current good manufacturing practice.	Emulsifier, emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer, thickener, § 170.3(o)(28) of this chapter.

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

[47 FR 47375, Oct. 26, 1982]

§ 184.1012 α-Amylase enzyme preparation from *Bacillus stearothermophilus*.

(a) α-Amylase enzyme preparation is obtained from the culture filtrate that results from a pure culture fermentation of a nonpathogenic and nontoxicogenic strain of *Bacillus stearothermophilus*. Its characterizing enzyme activity is α-amylase (1,4 α-D glucan glucanohydrolase (E.C. 3.2.1.1)).

(b) The ingredient meets the general and additional requirements for enzyme preparations in the "Food Chemicals Codex," 3d ed. (1981), pp. 107-110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., suite 1200, Washington, DC, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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

(1) The ingredient is used as an enzyme, as defined in § 170.3(o)(9) of this chapter, in the hydrolysis of edible starch to produce maltodextrins and nutritive carbohydrate sweeteners.

(2) The ingredient is used at levels not to exceed current good manufacturing practices.

[60 FR 55789, Nov. 3, 1995]

§ 184.1021 Benzoic acid.

(a) Benzoic acid is the chemical benzenecarboxylic acid (C₇H₆O₂), occurring in nature in free and combined forms. Among the foods in which benzoic acid occurs naturally are cranberries, prunes, plums, cinnamon, ripe cloves, and most berries. Benzoic acid is manufactured by treating molten phthalic anhydride with steam in the presence of a zinc oxide catalyst, by the hydrolysis of benzotrichloride, or