

§ 184.1005

21 CFR Ch. I (4-1-01 Edition)

person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

(f) The label and labeling of the ingredient and any intermediate mix of the ingredient for use in finished food shall bear, in addition to the other labeling required by the Act:

(1) The name of the ingredient, except where exempted from such labeling in part 101 of this chapter.

(2) A statement of concentration of the ingredient in any intermediate mix; or other information to permit a food processor independently to determine that use of the ingredients will be in accordance with any limitations and good manufacturing practice guidelines prescribed.

(3) Adequate directions for use to provide a final food product that complies with any limitations prescribed for the ingredient(s).

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 48 FR 48457, 48459, Oct. 19, 1983; 62 FR 15110, Mar. 31, 1997]

Subpart B—Listing of Specific Substances Affirmed as GRAS

§ 184.1005 Acetic acid.

(a) Acetic acid ($C_2H_4O_2$, CAS Reg. No. 64-19-7) is known as ethanoic acid. It occurs naturally in plant and animal tissues. It is produced by fermentation of carbohydrates or by organic synthesis. The principal synthetic methods currently employed are oxidation of acetaldehyde derived from ethylene, liquid phase oxidation of butane, and reaction of carbon monoxide with methanol derived from natural gas.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 8, 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) The ingredient is used as a curing and pickling agent as defined in § 170.3(o)(5) of this chapter; flavor enhancer as defined in § 170.3(o)(11) of this chapter; flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; as a solvent and vehicle as defined in § 170.3(o)(27) of this chapter; and as a boiler water additive complying with § 173.310 of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level as served, of 0.25 percent for baked goods as defined in § 170.3(n)(1) of this chapter; 0.8 percent for cheeses as defined in § 170.3(n)(5) of this chapter and dairy product analogs as defined in § 170.3(n)(10) of this chapter; 0.5 percent for chewing gum as defined in § 170.3(n)(6) of this chapter; 9.0 percent for condiments and relishes as defined in § 170.3(n)(8) of this chapter; 0.5 percent for fats and oils as defined in § 170.3(n)(12) of this chapter; 3.0 percent for gravies and sauces as defined in § 170.3(n)(24) of this chapter; 0.6 percent for meat products as defined in § 170.3(n)(29) of this chapter; and 0.15 percent or less for all other food categories. The ingredient may also be used in boiler water additives at levels not to exceed current good manufacturing practice.

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

[47 FR 27814, June 25, 1982]

§ 184.1007 Aconitic acid.

(a) Aconitic acid (1,2,3-propenetricarboxylic acid ($C_6H_6O_6$), CAS Reg. No. 000499-12-7) occurs in the leaves and tubers of *Aconitum napellus* L. and other *Ranunculaceae*. Transaconitic acid can be isolated during sugarcane processing, by precipitation as the calcium salt from cane sugar or molasses. It may be synthesized by sulfuric acid dehydration of

citric acid, but not by the methanesulfonic acid method.

(b) The ingredient meets the following specifications:

(1) *Assay*. Not less than 98.0 percent of $C_3H_3(COOH)_3$, using the "Food Chemicals Codex," 4th ed. (1996), pp. 102-103, test for citric acid, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, and a molecular weight of 174.11. Copies of the material incorporated by reference are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address "http://www.nap.edu"), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(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 the test for citric acid of the "Food Chemicals Codex," 4th ed. (1996), pp. 102-103, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. 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 the "Food Chemicals Codex," 4th ed. (1996), pp. 102-103, test for citric acid, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

(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 chap-

ter, 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; 64 FR 1759, Jan. 12, 1999]

§ 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