§ 184.1009 Adipic acid.

(a) Adipic acid (C₆H₁₀O₄, 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 National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.), 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 as defined in §184.1(b)(1), at levels not to exceed current 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)(3) of this chapter; 0.0005 percent for soft candy as defined in §170.3(n)(30) 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.

(e) Prior sanctions for adipic acid different from the uses 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 Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(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, as amended at 78 FR 14666, Mar. 7, 2013]