

**§ 184.1012**

**21 CFR Ch. I (4–1–07 Edition)**

go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

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

(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:

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.

(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]

(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]

**§ 184.1021 Benzoic acid.**

**§ 184.1012  $\alpha$ -Amylase enzyme preparation from *Bacillus stearothermophilus*.**

(a) Benzoic acid is the chemical benzenecarboxylic acid (C<sub>7</sub>H<sub>6</sub>O<sub>2</sub>), 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 by the oxidation of toluene with nitric acid or sodium bichromate or with air in the presence of a transition metal salt catalyst.

(a)  $\alpha$ -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  $\alpha$ -amylase (1,4  $\alpha$ -D glucan glucanohydrolase (E.C. 3.2.1.1)).

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 35, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(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 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/](http://www.archives.gov/federal_register/)

(c) The ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter, and as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice. Current usage results