

**Food and Drug Administration, HHS**

**§ 184.1141b**

this section do not exist or have been waived.

[48 FR 52440, Nov. 18, 1983, as amended at 59 FR 14551, Mar. 29, 1994]

**§ 184.1140 Ammonium citrate, dibasic.**

(a) Ammonium citrate, dibasic ((NH<sub>4</sub>)<sub>2</sub>HC<sub>6</sub>H<sub>5</sub>O<sub>7</sub>, CAS Reg. No. 3012-65-5) is the diammonium salt of citric acid. It is prepared by partially neutralizing citric acid with ammonia.

(b) The Food and Drug Administration, in cooperation with the National Academy of Sciences, is developing food-grade specifications for ammonium citrate, dibasic. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (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 a flavor enhancer as defined in §170.3(o)(11) of this chapter and as a pH control agent as defined in §170.3(o)(23) of this chapter.

(2) The ingredient is used in non-alcoholic beverages as defined in §170.3(n)(3) of this chapter and in cheeses as defined in §170.3(n)(5) of this chapter at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from those set forth in part 181 of this chapter, do not exist or have been waived.

[59 FR 63896, Dec. 12, 1994]

**§ 184.1141a Ammonium phosphate, monobasic.**

(a) Ammonium phosphate, monobasic (NH<sub>4</sub>H<sub>2</sub>PO<sub>4</sub>, CAS Reg. No. 7722-76-1) is manufactured by reacting ammonia with phosphoric acid at a pH below 5.8.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 21, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for in-

spection 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).

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (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 a dough strengthener as defined in §170.3(o)(6) of this chapter and a pH control agent as defined in §170.3(o)(23) of this chapter.

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

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

[48 FR 52440, Nov. 18, 1983]

**§ 184.1141b Ammonium phosphate, dibasic.**

(a) Ammonium phosphate, dibasic ((NH<sub>4</sub>)<sub>2</sub>HPO<sub>4</sub>, CAS Reg. No. 7783-28-0) is manufactured by reacting ammonia with phosphoric acid at a pH above 5.8.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 21, 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](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 practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon

### § 184.1143

the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a dough strengthener as defined in §170.3(o)(6) of this chapter; a firming agent as defined in §170.3(o)(10) of this chapter; a leavening agent as defined in §170.3(o)(17) of this chapter; a pH control agent as defined in §170.3(o)(23) of this chapter; and a processing aid as defined in §170.3(o)(24) of this chapter.

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

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

[48 FR 52440, Nov. 18, 1983]

### § 184.1143 Ammonium sulfate.

(a) Ammonium sulfate ((NH<sub>4</sub>)<sub>2</sub>SO<sub>4</sub>, CAS Reg. No. 7783-20-2) occurs naturally and consists of colorless or white, odorless crystals or granules. It is prepared by the neutralization of sulfuric acid with ammonium hydroxide.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 22-23, 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).

(c) The ingredient is used as a dough strengthener as defined in §170.3(o)(6) of this chapter, firming agent as defined in §170.3(o)(10) of this chapter, and processing aid as defined in §170.3(o)(24) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.15 percent for baked goods as defined in §170.3(n)(1) of this chapter and 0.1 percent for gelatins and puddings as defined in §170.1(n)(22) of this chapter.

### 21 CFR Ch. I (4-1-07 Edition)

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

[45 FR 6086, Jan. 25, 1980; 45 FR 16469, Mar. 14, 1980, as amended at 49 FR 5611, Feb. 14, 1984]

### § 184.1148 Bacterially-derived carbohydrase enzyme preparation.

(a) Bacterially-derived carbohydrase enzyme preparation is obtained from the culture filtrate resulting from a pure culture fermentation of a non-pathogenic and nontoxigenic strain of *Bacillus subtilis* or *B. amyloliquefaciens*. The preparation is characterized by the presence of the enzymes  $\alpha$ -amylase (EC 3.2.1.1) and  $\beta$ -glucanase (EC 3.2.1.6), which catalyze the hydrolysis of O-glycosyl bonds in carbohydrates.

(b) The ingredient meets the general requirements and additional requirements in the monograph on enzyme preparations in the Food Chemicals Codex, 4th ed. (1996), pp. 128-135, 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 Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). In addition, antibiotic activity is absent in the enzyme preparation when determined by an appropriate validated method such as the method "Determination of antibiotic activity" in the Compendium of Food Additive Specifications, vol. 2, Joint FAO/WHO Expert Committee on Food Additives (JECFA), Food and Agriculture Organization of the United Nations, Rome, 1992. Copies are available from Bernan Associates, 4611-F Assembly Dr., Lanham, MD 20706, or from The United Nations Bookshop, General Assembly Bldg., rm. 32, New York, NY 10017, or by inquiries sent to <http://www.fao.org>. Copies may be examined