§ 184.1024  Bromelain.

(a) Bromelain (CAS Reg. No. 9001–00–7) is an enzyme preparation derived from the pineapples Ananas comosus and A. bracteatus. It is a white to light tan amorphous powder. Its characterizing enzyme activity is that of a peptide hydrolase (EC 3.4.22.32).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference. Copies are available 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.

(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 GRAS as a direct 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 to hydrolyze proteins or polypeptides.

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

§ 184.1025 Caprylic acid.

(a) Caprylic acid \(\text{CH}_3\left(\text{CH}_2\right)_6\text{COOH}\), CAS Reg. No. 124–07–2] is the chemical name for octanoic acid. It is considered to be a short or medium chain fatty acid. It occurs normally in various foods and is commercially prepared by oxidation of n-octanol or by fermentation and fractional distillation of the volatile fatty acids present in coconut oil.

(b) The ingredient meets the specifications of the “Food Chemicals Codex,” 3d Ed. (1981), p. 207, 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.

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

(d) The ingredient is used in foods in accordance with §184.1(b)(1), at levels not to exceed good manufacturing practice. Current good manufacturing practices result in maximum levels, as served, of: 0.013 percent for baked goods as defined in §170.3(n)(1) of this chapter; 0.04 percent for cheeses as defined in §170.3(n)(5) of this chapter; 0.05 percent for fats and oils as defined in §170.3(n)(12) of this chapter, for frozen dairy desserts as defined in §170.3(n)(20) of this chapter, for gelatins and puddings as defined in §170.3(n)(22) of this chapter, for meat products as defined in §170.3(n)(29) of this chapter, and for soft candy as defined in §170.3(n)(36) of this chapter; 0.016 percent for snack foods as defined in §170.3(n)(37) of this chapter.
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§ 184.1027 Mixed carbohydrase and protease enzyme product.

(a) Mixed carbohydrase and protease enzyme product is an enzyme preparation that includes carbohydrase and protease activity. It is obtained from the culture filtrate resulting from a pure culture fermentation of a non-pathogenic strain of \textit{B. licheniformis}.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), p. 107, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or 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: \url{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 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, to hydrolyze proteins or carbohydrates.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: alcoholic beverages, as defined in §170.3(n)(2) of this chapter, candy, nutritive sweeteners, and protein hydrolyzates.

[48 FR 240, Jan. 4, 1983]

§ 184.1033 Citric acid.

(a) Citric acid (C$_6$H$_8$O$_7$, CAS Reg. No. 77–92–9) is the compound 2-hydroxy-1,2,3-propanetricarboxylic acid. It is a naturally occurring constituent of plant and animal tissues. It occurs as colorless crystals or a white powder and may be anhydrous or contain one mole of water per mole of citric acid. Citric acid may be produced by recovery from sources such as lemon or pineapple juice; by mycological fermentation using \textit{Candida spp.}, described in §§173.160 and 173.165 of this chapter; and by the solvent extraction process described in §173.220 of this chapter for the recovery of citric acid from \textit{Aspergillus niger} fermentation liquor.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), pp. 86–87, and its third supplement (March 1992), pp. 107–108, which are 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, and the Center for Food Safety and Applied Nutrition (HFS–200), 5100 Paint Branch Pkwy., College Park, MD 20740, 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: \url{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 limitations other than 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.

[59 FR 63895, Dec. 12, 1994]

§ 184.1034 Catalase (bovine liver).

(a) Catalase (bovine liver) (CAS Reg. No. 81457–95–6) is an enzyme preparation obtained from extracts of bovine liver. It is a partially purified liquid or powder. Its characterizing enzyme activity is catalase (EC 1.11.1.6).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from