§ 184.1670 Propylparaben.

(a) Propylparaben is the chemical propyl p-hydroxybenzoate. It is produced by the n-propanol esterification of p-hydroxybenzoic acid in the presence of sulfuric acid, with subsequent distillation.

(b) The ingredient meets the specifications of the “Food Chemicals Codex,” 3d Ed. (1981), p. 258, 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 an antimicrobial agent as defined in §170.3(o)(2) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice results in a maximum level of 0.1 percent in food.

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

[47 FR 27812, June 25, 1982]

§ 184.1676 Pyridoxine hydrochloride.

(a) Pyridoxine hydrochloride (C8H11NO3·HCl, CAS Reg. No. 58–56–0) is the chemical 3-hydroxy-4,5-dihydroxymethyl-2-methylpyridine hydrochloride that is prepared by chemical synthesis.


(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 nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in §170.3(n)(1) of this chapter; nonalcoholic beverages and beverage bases as defined in §170.3(n)(3) of this chapter; breakfast cereals as defined in §170.3(n)(4) of this chapter; dairy product analogs as defined in §170.3(n)(10) of this chapter; meat products as defined in §170.3(n)(29) of this chapter; milk products as defined in §170.3(n)(31) of this chapter; plant protein products as defined in §170.3(n)(33) of this chapter; and snack foods as defined in §170.3(n)(37) of this chapter. Pyridoxine hydrochloride may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and
§ 184.1685 Rennet (animal-derived) and chymosin preparation (fermentation-derived).

(a)(1) Rennet and bovine rennet are commercial extracts containing the active enzyme rennin (CAS Reg. No. 9001–98–3), also known as chymosin (International Union of Biochemistry Enzyme Commission (E.C.) 3.4.23.4). Rennet is the aqueous extract prepared from cleaned, frozen, salted, or dried fourth stomachs (abomasum) of calves, kids, or lambs. Bovine rennet is the product from adults of the animals listed above. Both products are called rennet and are clear amber to dark brown liquid preparations or white to tan powders.

(2) Chymosin preparation is a clear solution containing the active enzyme chymosin (E.C. 3.4.23.4). It is derived, via fermentation, from a nonpathogenic and nontoxigenic strain of *Escherichia coli* K–12 containing the prochymosin gene. The prochymosin is isolated as an insoluble aggregate that is acid-treated to destroy residual cellular material and, after solubilization, is acid-treated to form chymosin. It must be processed with materials that are generally recognized as safe, or are food additives that have been approved by the Food and Drug Administration for this use.

(b) Rennet and chymosin preparation meet the general and additional requirements for enzyme preparations of the “Food Chemicals Codex,” 3d Ed. (1981), pp. 107–110, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2101 Constitution Avenue NW., Washington, DC 20418, or are 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.

(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; a processing aid as defined in §170.3(o)(24) of this chapter; and a stabilizer and thickener as defined in §170.3(o)(28) of this chapter.

2. The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: In cheeses as defined in §170.3(n)(5) of this chapter; frozen dairy desserts and mixes as defined in §170.3(n)(20) of this chapter; gelatinas, puddings, and fillings.