

obtained from natural gas by fractionation following absorption in oil, adsorption to surface-active agents, or refrigeration.

(b) The 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 limitations 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 propellant, aerating agent, and gas as defined in §170.3(o)(25) 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 57271, Dec. 29, 1983, as amended at 73 FR 8608, Feb. 14, 2008]

#### § 184.1660 Propyl gallate.

(a) Propyl gallate is the *n*-propylester of 3,4,5-trihydroxybenzoic acid (C<sub>10</sub>H<sub>12</sub>O<sub>5</sub>). Natural occurrence of propyl gallate has not been reported. It is commercially prepared by esterification of gallic acid with propyl alcohol followed by distillation to remove excess alcohol.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 257-258, 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(c) The ingredient is used as an antioxidant as defined in §170.3(o)(3) 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). Good manufacturing prac-

tice results in a maximum total content of antioxidants of 0.02 percent of the fat or oil content, including the essential (volatile) oil content, of the food.

(e) Prior sanctions for this ingredient different from the uses established in this section, or different from that stated in part 181 of this chapter, do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 44 FR 52826, Sept. 11, 1979; 49 FR 5613, Feb. 14, 1984]

#### § 184.1666 Propylene glycol.

(a) Propylene glycol (C<sub>3</sub>H<sub>8</sub>O<sub>2</sub>, CAS Reg. No. 57-55-6) is known as 1,2-propanediol. It does not occur in nature. Propylene glycol is manufactured by treating propylene with chlorinated water to form the chlorohydrin which is converted to the glycol by treatment with sodium carbonate solution. It is also prepared by heating glycerol with sodium hydroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 255, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418. It is also 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) The ingredient is used as an anticaking agent as defined in §170.3(o)(1) of this chapter; antioxidant as defined in §170.3(o)(3) of this chapter; dough strengthener as defined in §170.3(o)(6) of this chapter; emulsifier as defined in §170.3(o)(8) of this chapter; flavor agent as defined in §170.3(o)(12) of this chapter; formulation aid as defined in §170.3(o)(14) of this chapter; humectant as defined in §170.3(o)(16) of this chapter; processing aid as defined in §170.3(o)(24) of this chapter; solvent and vehicle as defined in §170.3(o)(27) of this chapter; stabilizer and thickener as defined in §170.3(o)(28) of this chapter; surface-active agent as defined in §170.3(o)(29) of

## § 184.1670

this chapter; and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in foods at levels not to exceed current good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in maximum levels, as served, of 5 percent for alcoholic beverages, as defined in § 170.3(n)(2) of this chapter; 24 percent for confections and frostings as defined in § 170.3(n)(9) of this chapter; 2.5 percent for frozen dairy products as defined in § 170.3(n)(20) of this chapter; 97 percent for seasonings and flavorings as defined in § 170.3(n)(26) of this chapter; 5 percent for nuts and nut products as defined in § 170.3(n)(32) of this chapter; and 2.0 percent 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.

[47 FR 27812, June 25, 1982]

## § 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](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

## 21 CFR Ch. I (4-1-19 Edition)

this regulation do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5613, Feb. 14, 1984]

## § 184.1676 Pyridoxine hydrochloride.

(a) Pyridoxine hydrochloride (C<sub>8</sub>H<sub>11</sub>NO<sub>3</sub>·HCl, CAS Reg. No. 58-56-0) is the chemical 3-hydroxy-4,5-dihydroxymethyl-2-methylpyridine hydrochloride that is prepared by chemical synthesis.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 260, 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 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