

Ave. NW., Washington, DC 20055 (Internet address <http://www.nap.edu>), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 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.

(4) Color—clear, bright, and free from suspended matter.

(5) Odor and taste—free from foreign and rancid odor and taste.

(6) Residual catalyst (“Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), sections 25.049–25.055, which is incorporated by reference), residual fluorine; limit of detection 0.2 part per million F; multiply fluoride result by 2.63 to convert to residual catalyst. Copies of the material incorporated by reference may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, 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. The ingredient shall be washed three times in batches with 0.5 percent sodium bicarbonate to remove catalyst residuals in accordance with good manufacturing practice.

(7) Residual methanol—5 parts per million maximum.

(8) Residual fatty acid ethyl esters—not more than 20 parts per million as determined by a “Modification of Japan Institute of Oils and Fats: Analysis Method of Residual Ethyl Esters of Fatty Acids” issued by the Fuji Oil Co., which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 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.

(9) Hexane—not more than 5 parts per million as determined by the method of Dupuy et al., “Rapid Quantitative Determination of Residual Hexane in Oils by Direct Gas Chromatography,” published in the “Journal of the American Oil Chemists’ Society,” Vol. 52, p. 118–120, 1975, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 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.

(c) In accordance with §184.1(b)(1), the ingredient is used in the following food categories at levels not to exceed current good manufacturing practice: Confections and frostings as defined in §170.3(n)(9) of this chapter; coatings of soft candy as defined in §170.3(n)(38) of this chapter; and sweet sauces and toppings as defined in §170.3(n)(43) of this chapter; except that the ingredient may not be used in a standardized food unless permitted by the standard of identity.

(d) The ingredient is used in food in accordance with §184.1(b)(1) at levels not to exceed good manufacturing practice.

[43 FR 54239, Nov. 11, 1978, as amended at 47 FR 11852, Mar. 19, 1982; 49 FR 5611, Feb. 14, 1984; 49 FR 22799, June 1, 1984; 52 FR 47920, Dec. 17, 1987; 52 FR 48905, Dec. 28, 1987; 61 FR 36290, July 10, 1996; 64 FR 1760, Jan. 12, 1999]

§ 184.1260 Copper gluconate.

(a) Copper gluconate (cupric gluconate $(\text{CH}_2\text{OH}(\text{CHOH})_4\text{COO})_2\text{Cu}$, CAS Reg. No. 527-09-3) is a substance that occurs as light blue to bluish-green, odorless crystals, or as a fine, light

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blue powder. It is prepared by the reaction of gluconic acid solutions with cupric oxide or basic cupric carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 90, 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.

(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 and as a synergist as defined in §170.3(o)(31) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Copper gluconate may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

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

[49 FR 24119, June 12, 1984]

§ 184.1261 Copper sulfate.

(a) Copper sulfate (cupric sulfate, $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$, CAS Reg. No. 7758-98-7) usually is used in the pentahydrate form. This form occurs as large, deep blue or ultramarine, triclinic crystals; as blue granules, or as a light blue powder. The ingredient is prepared by the reaction of sulfuric acid with cupric oxide or with copper metal.

(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 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 and as 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. Copper sulfate may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

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

[49 FR 24119, June 12, 1984, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1262 Corn silk and corn silk extract.

(a) Corn silk is the fresh styles and stigmas of *Zea mays* L. collected when the corn is in milk. The filaments are extracted with dilute ethanol to produce corn silk extract. The extract may be concentrated at a temperature not exceeding 60 °C.

(b) The ingredient must be of a purity suitable for its intended use.

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

Category of food	Maximum level of use in food (as served) ¹	Functional use
Baked goods and baking mixes, § 170.3(n)(1) of this chapter.	30	Flavoring agent, § 170.3(o)(12) of this chapter.
Nonalcoholic beverages, § 170.3(n)(3) of this chapter.	20	Do.
Frozen dairy desserts, § 170.3(n)(20) of this chapter.	10	Do.
Soft candy, § 170.3(n)(38) of this chapter.	20	Do.