

**§ 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 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 Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. 20408.

(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) FDA is developing food-grade specifications for copper sulfate in cooperation with the National Academy of Sciences. 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 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]

**§ 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 Food and Drug Administration, in cooperation with the National Academy of Sciences, is developing food-grade specifications for corn silk and corn silk extract. In the interim, this ingredient must be of a suitable purity for its intended use.

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

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Category of food	Maximum level of use in food (as served) <sup>1</sup>	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.
All other food categories.	4	Do.

<sup>1</sup> Parts per million.

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

[47 FR 29953, July 9, 1982]

**§ 184.1265 Cuprous iodide.**

(a) Cuprous iodide (copper (I) iodide, CuI, CAS Reg. No. 7681-65-4) is a pure white crystalline powder. It is prepared by the reaction of copper sulfate with potassium iodide under slightly acidic conditions.

(b) FDA is developing food-grade specifications for cuprous iodide in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

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

Category of food	Maximum treatment level in food	Functional use
Table salt.	0.01 percent .....	Source of dietary iodine.

(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]

**§ 184.1271 L-Cysteine.**

(a) L-Cysteine is the chemical L-2-amino-3-mercaptopropanoic acid (C<sub>3</sub>H<sub>7</sub>O<sub>2</sub>NS).

(b) The ingredient meets the appropriate part of the specification set forth in the "Food Chemicals Codex," 3d Ed. (1981), pp. 92-93, 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 Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) The ingredient is used to supply up to 0.009 part of total L-cysteine per 100 parts of flour in dough as a dough strengthener as defined in §170.3(o)(6) of this chapter in yeast-leavened baked goods and baking mixes as defined in §170.3(n)(1) of this chapter.

(d) This regulation is issued prior to a general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5612, Feb. 14, 1984]

**§ 184.1272 L-Cysteine monohydrochloride.**

(a) L-Cysteine monohydrochloride is the chemical L-2-amino-3-mercaptopropanoic acid monohydrochloride monohydrate (C<sub>3</sub>H<sub>7</sub>O<sub>2</sub>NS HCl H<sub>2</sub>O).

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 92-93, 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 Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) The ingredient is used to supply up to 0.009 part of total L-cysteine per 100 parts of flour in dough as a dough strengthener as defined in §170.3(o)(6) of this chapter in yeast-leavened baked goods and baking mixes as defined in §170.3(n)(1) of this chapter.

(d) This regulation is issued prior to a general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5612, Feb. 14, 1984]