

Food and Drug Administration, HHS

§ 184.1311

this section do not exist or have been waived.

[53 FR 16866, May 12, 1988, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1307d Ferrous fumarate.

(a) Ferrous fumarate (iron (II) fumarate, $C_4H_2FeO_4$), CAS Reg. No. 141-01-5) is an odorless, reddish-orange to reddish-brown powder. It may contain soft lumps that produce a yellow streak when crushed. It is prepared by admixing hot solutions of ferrous sulfate and sodium fumarate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 120-122, 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 as a nutrient supplement as defined in § 170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)), or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

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

[53 FR 16866, May 12, 1988]

§ 184.1308 Ferrous gluconate.

(a) Ferrous gluconate (iron (II) gluconate dihydrate, $C_{12}H_{22}FeO_{14} \cdot 2H_2O$, CAS Reg. No. 6047-12-7) is a fine yellowish-gray or pale greenish-yellow powder or granules. It is prepared by reacting hot solutions of barium or calcium gluconate with ferrous sulfate or by heating freshly prepared ferrous carbonate with gluconic acid in aqueous solution.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 122-123, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Avenue 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 as a nutrient supplement as defined in § 170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

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

[53 FR 16866, May 12, 1988; 53 FR 20939, June 7, 1988]

§ 184.1311 Ferrous lactate.

(a) Ferrous lactate (iron (II) lactate, $C_6H_{10}FeO_6$, CAS Reg. No. 5905-52-2) in the trihydrate form is a greenish-white powder or crystalline mass. It is prepared by reacting calcium lactate or sodium lactate with ferrous sulfate, direct reaction of lactic acid with iron filings, reaction of ferrous chloride with sodium lactate, or reaction of ferrous sulfate with ammonium lactate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 4th ed. (1996), pp. 154 to 155, which is 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, or may be examined at the Center for Food Safety and Applied Nutrition's library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For

§ 184.1315

21 CFR Ch. I (4–1–12 Edition)

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 as a nutrient supplement as defined in §170.3(o)(20) of this chapter and as a color fixative for ripe olives, with no other limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

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

[53 FR 16866, May 12, 1988, as amended at 61 FR 40319, Aug. 2, 1996]

§ 184.1315 Ferrous sulfate.

(a) Ferrous sulfate heptahydrate (iron (II) sulfate heptahydrate, $\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$, CAS Reg. No. 7782–63–0) is prepared by the action of sulfuric acid on iron. It occurs as pale, bluish-green crystals or granules. Progressive heating of ferrous sulfate heptahydrate produces ferrous sulfate (dried). Ferrous sulfate (dried) consists primarily of ferrous sulfate monohydrate (CAS Reg. No. 17375–41–6) with varying amounts of ferrous sulfate tetrahydrate (CAS Reg. No. 20908–72–9) and occurs as a grayish-white to buff-colored powder.

(b) The ingredients meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 123 (Ferrous sulfate heptahydrate) and p. 124 (ferrous sulfate, dried), 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 ingredients are used in food as nutrient supplements 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, with no limitation other than current good manufacturing practice. The ingredients may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

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

[53 FR 16866, May 12, 1988]

§ 184.1316 Ficin.

(a) Ficin (CAS Reg. No. 9001–33–6) is an enzyme preparation obtained from the latex of species of the genus *Ficus*, which include a variety of tropical fig trees. It is a white to off-white powder. Its characterizing enzyme activity is that of a peptide hydrolase (EC 3.4.22.3).

(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 the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and 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: