of food where it has been used according to paragraph (c) of this section.

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

[46 FR 44439, Sept. 4, 1981, as amended at 51 FR 27172, July 30, 1986]

§ 184.1370 Inositol.

(a) Inositol, or myo-inositol ($C_6H_{12}O_6$, CAS Reg. No. 87–89–8), is *cis*-1,2,3,5-*trans*-4,6-cyclohexanehexol. It occurs naturally and is prepared from an aqueous (0.2 percent sulfur dioxide) extract of corn kernels by precipitation and hydrolysis of crude phytate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 150, 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 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 nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in special dietary foods as defined in part 105 of this chapter at levels not to exceed current good manufacturing practice. It may also be used in infant formula in accordance with section 412(g) of 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 by this section do not exist or have been waived.

[47 FR 38278, Aug. 31, 1982]

§ 184.1372 Insoluble glucose isomerase enzyme preparations.

(a) Insoluble glucose isomerase enzyme preparations are used in the production of high fructose corn syrup described in § 184.1866. They are derived from recognized species of precisely classified nonpathogenic and nontoxicogenic microorganisms, including *Streptomyces rubiginosus*, *Actinoplanes missouriensis*, *Streptomyces olivaceus*, *Streptomyces olivochromogenes*, and *Bacillus coagulans*, that have been grown in a pure culture fermentation that produces no antibiotics. They are fixed (rendered insoluble) for batch production with GRAS ingredients or may be fixed for further immobilization with either GRAS ingredients or materials approved under § 173.357 of this chapter.

(b) The ingredient meets the general and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d Ed. (1981), p. 107, 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 an enzyme, as defined in § 170.3(o)(9) of this chapter, to convert glucose to fructose.

(2) The ingredient is used in high fructose corn syrup, at levels not to exceed current good manufacturing practice.

[48 FR 5720, Feb. 8, 1983, as amended at 61 FR 43450, Aug. 23, 1996]

§ 184.1375 Iron, elemental.

(a) Iron, elemental (CAS Reg. No. 7439–89–6) is metallic iron obtained by

any of the following processes: reduced iron, electrolytic iron, and carbonyl iron.

(1) Reduced iron is prepared by reacting ground ferric oxide with hydrogen or carbon monoxide at an elevated temperature. The process results in a grayish-black powder, all of which should pass through a 100-mesh sieve. It is lusterless or has not more than a slight luster. When viewed under a microscope, it appears as an amorphous powder free from particles having a crystalline structure. It is stable in dry air.

(2) Electrolytic iron is prepared by electrodeposition. It is an amorphous, lusterless, grayish-black powder. It is stable in dry air.

(3) Carbonyl iron is prepared by the decomposition of iron pentacarbonyl. It occurs as a dark gray powder. When viewed under a microscope, it appears as spheres built up with concentric shells. It is stable in dry air.

(b) Iron, elemental (carbonyl, electrolytic, or reduced) meets the specifications of the Food Chemicals Codex, 3d Ed. (1981) (iron, carbonyl, p. 151; iron, electrolytic, pp. 151–152; iron, reduced; pp. 152–153), 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 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(2)).

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

[53 FR 16867, May 12, 1988]

§184.1386 Isopropyl citrate.

(a) Isopropyl citrate is a mixture of the mono-, di-, and triisopropyl esters of citric acid. It is prepared by esterifying citric acid with isopropanol.

(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 an antioxidant as defined in §170.3(o)(3) of this chapter; a sequestrant as defined in §170.3(o)(26) of this chapter; and a solvent and vehicle as defined in §170.3(o)(27) of this chapter.

(2) The ingredient is used in margarine in accordance with §166.110 of this chapter; in nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; and in fats and oils as defined in §170.3(n)(12) of this chapter at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from those set forth in part 181 of this chapter, do not exist or have been waived.

[59 FR 63896, Dec. 12, 1994, as amended at 73 FR 8607, Feb. 14, 2008]

§184.1387 Lactase enzyme preparation from Candida pseudotropicalis.

(a) This enzyme preparation is derived from the nonpathogenic, nontoxicogenic yeast *C. pseudotropicalis*. It contains the enzyme lactase (β-D-galactoside galactohydrolase, EC 3.2.1.23), which converts lactose to glucose and galactose. It is prepared from yeast that has been grown by a pure culture fermentation process.

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), pp. 107–110, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are