

§ 184.1854

21 CFR Ch. I (4-1-98 Edition)

(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 63897, Dec. 12, 1994]

§ 184.1854 Sucrose.

(a) Sucrose (C₁₂H₂₂O₁₁, CAS Reg. No. 57-50-11-1) sugar, cane sugar, or beet sugar is the chemical β-D-fructofuranosyl-α-D-glucopyranoside. Sucrose is obtained by crystallization from sugar cane or sugar beet juice that has been extracted by pressing or diffusion, then clarified and evaporated.

(b) FDA is developing food-grade specifications for sucrose 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.

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

[53 FR 44876, Nov. 7, 1988; 54 FR 228, Jan. 4, 1989]

§ 184.1857 Corn sugar.

(a) Corn sugar (C₆H₁₂O₆, CAS Reg. No. 50-99-7), commonly called D-glucose or dextrose, is the chemical α-D-glucopyranose. It occurs as the anhydrous or the monohydrate form and is produced by the complete hydrolysis of corn starch with safe and suitable acids or enzymes, followed by refinement and crystallization from the resulting hydrolysate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 97-98 under the heading "Dextrose," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 1. 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.

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

[53 FR 44876, Nov. 7, 1988]

§ 184.1859 Invert sugar.

(a) Invert sugar (CAS Reg. No. 8013-17-0) is an aqueous solution of inverted or partly inverted, refined or partly refined sucrose, the solids of which contain not more than 0.3 percent by weight of ash. The solution is colorless, odorless, and flavorless, except for sweetness. It is produced by the hydrolysis or partial hydrolysis of sucrose with safe and suitable acids or enzymes.

(b) FDA is developing food-grade specifications for invert sugar 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.

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

[53 FR 44876, Nov. 7, 1988; 54 FR 228, Jan. 4, 1989]

§ 184.1865 Corn syrup.

(a) Corn syrup, commonly called "glucose sirup" or "glucose syrup," is obtained by partial hydrolysis of corn starch with safe and suitable acids or enzymes. It may also occur in the dehydrated form (dried glucose sirup). Depending on the degree of hydrolysis, corn syrup may contain, in addition to glucose, maltose and higher saccharides.

(b) The ingredient meets the specifications as defined and determined in §168.120(b) or §168.121(a) of this chapter, as appropriate. FDA, in cooperation with the National Academy of Sciences, is undertaking a study to determine if additional food-grade specifications for corn syrup are necessary.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than 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.

[53 FR 44876, Nov. 7, 1988]

§ 184.1866 High fructose corn syrup.

(a) High fructose corn syrup, a sweet, nutritive saccharide mixture containing either approximately 42 or 55 percent fructose, is prepared as a clear aqueous solution from high dextrose-equivalent corn starch hydrolysate by partial enzymatic conversion of glucose (dextrose) to fructose using an insoluble glucose isomerase enzyme preparation described in §184.1372. The product containing more than 50 percent fructose (dry weight) is prepared through concentration of the fructose portion of the mixture containing less than 50 percent fructose.

(b) The ingredient shall conform to the identity and specifications listed in the monograph entitled "High-Fructose Corn Syrup" in the Food Chemicals Codex, 4th ed. (1996), pp. 191-192, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

[61 FR 43450, Aug. 23, 1996]

§ 184.1875 Thiamine hydrochloride.

(a) Thiamine hydrochloride ($C_{12}H_{17}ClN_4OS$, CAS Reg. No. 67-03-8) is the chloride-hydrochloride salt of thiamine. It occurs as hygroscopic white crystals or a white crystalline powder. The usual method of preparing this substance is by linking the

performed thiazole and pyrimidine ring systems.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 324, 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 flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter or as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Thiamine hydrochloride 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.

[48 FR 55124, Dec. 9, 1983]

§ 184.1878 Thiamine mononitrate.

(a) Thiamine mononitrate ($C_{12}H_{17}N_5O_4S$, CAS Reg. No. 532-43-4) is the mononitrate salt of thiamine. It occurs as white crystals or a white crystalline powder and is prepared from thiamine hydrochloride by dissolving the hydrochloride salt in alkaline solution followed by precipitation of the nitrate half-salt with a stoichiometric amount of nitric acid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 325, which is incorporated by reference. Copies are available from the National Academy Press,