

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.

(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, as amended at 73 FR 8608, Feb. 14, 2008]

§ 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, 5100 Paint Branch Pkwy., College Park, MD 20740, 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 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.

[61 FR 43450, Aug. 23, 1996]

§ 184.1875 Thiamine hydrochloride.

(a) Thiamine hydrochloride (C₁₂H₁₇C₁N₄OS·HCl, 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 preformed 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 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 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

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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, 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.

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

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§ 184.1890 α -Tocopherols.

(a) The α -tocopherols that are the subject of this GRAS affirmation regulation are limited to the following:

(1) *d*- α -Tocopherol (CAS Reg. No. 59-02-9) is the chemical [2R,4'R,8'prime;R]-2,5,7,8-tetramethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol. It occurs commercially as a concentrate and is a red, nearly odorless, viscous oil. It is obtained by vacuum steam distillation of edible vegetable oil products.

(2) *dl*- α -Tocopherol (CAS Reg. No. 10191-41-0) is a mixture of stereoisomers of 2,5,7,8-tetramethyl-2-(4',8',12'-trimethyltridecyl)-6-chromanol. It is chemically synthesized by condensing racemic isophytol with trimethyl hydroquinone. It is a pale yellow viscous oil at room temperature.

(b) The ingredients meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 330-331, 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)(3), the affirmation of the ingredients as generally recognized as safe is limited to the following conditions of use while the agency concludes the general evaluation of all food uses of tocopherols:

(1) The ingredients are used as inhibitors of nitrosamine formation.

(2) The ingredients are used in pump-cured bacon at levels not to exceed current good manufacturing practice.

[49 FR 13348, Apr. 4, 1984]

§ 184.1901 Triacetin.

(a) Triacetin ($C_8H_{14}O_6$, CAS Reg. No. 102-76-1), also known as 1,2,3-propanetriol triacetate or glyceryl triacetate, is the triester of glycerin and acetic acid. Triacetin can be prepared by heating glycerin with acetic anhydride alone or in the presence of