Food and Drug Administration, HHS

§ 184.1878 Thiamine mononitrate.

(a) Thiamine mononitrate (C₁₂H₁₇N₅O₄S, 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.

§ 184.1890 α-Tocopherols.

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

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


(c) In accordance with §184.1(b)(3), the ingredients are used as inhibitors of nitrosamine formation.

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

§ 184.1901 Triacetin.

(a) Triacetin (C₈H₁₄O₆, 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