§ 184.1259 Cocoa butter substitute.

(a) The common or usual name for the triglyceride 1-palmitoyl-2-oleoyl-3-stearin is “cocoa butter substitute primarily from palm oil.” The common or usual name for the triglyceride 1,3-distearoyl-2-olein is “cocoa butter substitute primarily from high-oleic safflower or sunflower oil.”

(1) The ingredient 1-palmitoyl-2-oleoyl-3-stearin is manufactured by:

(i) Directed esterification of fully saturated 1,3-diacylglycerides (derived from palm oil) with the anhydride of food-grade oleic acid in the presence of the

NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. As determined by analytical methods in the “Food Chemicals Codex,” clove oloesin or other natural extractives (other than clove oils) meet the “Food Chemicals Codex” specifications for clove (clove bud) oil and the following modifications:

(1) The assay for phenols, as eugenol, by the “Food Chemicals Codex” test, 4th ed. (pp. 104–105), or the volatile oils content by the “Food Chemicals Codex” test, 4th ed. (pp. 104–105) should conform to the representation of the vendor;

(2) Optical rotation of the volatile oil between –2° and 0°;

(3) Refractive index of the volatile oil between 1.527 and 1.538 at 20 °C;

(4) Specific gravity of the volatile oil between 1.036 and 1.060; and

(5) Residual solvent free, except those solvents that are GRAS or within tolerance levels as specified in part 173, subpart C, of this chapter.

(1) The ingredient is used in food as a flavoring agent as defined in § 170.3(o)(12) of this chapter. The ingredients are used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). The common or usual name for the triglyceride 1-palmitoyl-2-oleoyl-3-stearin is “cocoa butter substitute primarily from palm oil.”

(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 in food as an enzyme as defined in § 170.3(o)(9) of this chapter for the breakdown of cellulose.

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

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(1) The ingredient 1,3-distearoyl-2-olein is manufactured by interesterification of partially unsaturated 1,2,3-triglycerides (derived from high-oleic safflower or sunflower oil) with ethyl stearate or stearic acid in the presence of a suitable lipase enzyme preparation that is either GRAS or has food additive approval for such use.

(2) The ingredient meets the following specifications:

(a) Over 90 percent triglycerides, not more than 7 percent diglycerides, not more than 1 percent monoglycerides, and not more than 1 percent free fatty acids.

(b) Total glycerides—98 percent minimum.

(c) Heavy metals (as lead), not more than 10 milligrams per kilogram, as determined by the Heavy Metals Test of the "Food Chemicals Codex," 4th ed. (1996), pp. 760–761, 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, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address http://www.nap.edu), or may be examined 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.

(d) Residual methanol—5 parts per million maximum.

(e) Residual fatty acid ethyl esters—not more than 20 parts per million as determined by a "Modification of Japan Institute of Oils and Fats: Analysis Method of Residual Ethyl Esters of Fatty Acids" issued by the Fuji Oil Co., which is incorporated by reference. Copies are available from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200, 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.

(f) Hexane—not more than 5 parts per million as determined by the method of Dupuy et al., "Rapid Quantitative Determination of Residual Hexane in Oils by Direct Gas Chromatography," published in the "Journal of the American Oil Chemists' Society," Vol. 52, p. 118–120, 1975, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA).
§ 184.1261 Copper sulfate.

(a) Copper sulfate (cupric sulfate, CuSO₄·5 H₂O, CAS Reg. No. 7758-99-8) usually is used in the pentahydrate form. This form occurs as large, deep blue or ultramarine, triclinic crystals; as blue granules, or as a light blue powder. The ingredient is prepared by the reaction of sulfuric acid with cupric oxide or with copper metal.

(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 at levels not to exceed 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 and as a processing aid as defined in §170.3(o)(24) of this chapter.

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

[49 FR 24119, June 12, 1984]