Food and Drug Administration, HHS § 184.1324

(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 and a texturizer as defined in §170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed 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.

[50 FR 8998, Mar. 6, 1985, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1323 Glyceryl monooleate.

(a) Glyceryl monooleate is prepared by esterification of commerical oleic acid that is derived either from edible sources or from tall oil fatty acids meeting the requirements of §172.862 of this chapter. It contains glyceryl monooleate (C_{18}H_{38}O_{3}, CAS Reg. No. 25496–72–4) and glyceryl esters of fatty acids present in commercial oleic acid.

(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 a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter and as a solvent and vehicle as defined in §170.3(o)(27) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods and baking mixes as defined in §170.3(n)(1) of this chapter; nonalcoholic beverages and beverage bases as defined in §170.3(n)(3) of this chapter; chewing gum as defined in §170.3(n)(6) of this chapter; and meat products as defined in §170.3(n)(29) of this chapter.

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


§ 184.1324 Glyceryl monostearate.

(a) Glyceryl monostearate, also known as monostearin, is a mixture of
variable proportions of glyceryl monostearate ($C_{21}H_{42}O_4$, CAS Reg. No. 31566–31–1), glyceryl monopalmitate ($C_{19}H_{38}O_4$, CAS Reg. No. 26657–96–5) and glyceryl esters of fatty acids present in commercial stearic acid. Glyceryl monostearate is prepared by glycerolysis of certain fats or oils that are derived from edible sources or by esterification, with glycerin, of stearic acid that is derived from edible sources.

(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.

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


§ 184.1328 Glyceryl behenate.

(a) Glyceryl behenate is a mixture of glyceryl esters of behenic acid made from glycerin and behenic acid (a saturated $C_{22}$ fatty acid). The mixture contains predominately glyceryl dibehenate.

(b) The ingredient meets the following specifications:

(1) 10 to 20 percent monoglyceride, 47 to 59 percent diglyceride, 26 to 38 percent triglyceride, and not more than 2.5 percent free fatty acids.

(2) Behenic acid. Between 80 and 90 percent of the total fatty acid content.

(3) Acid value. Not more than 4.

(4) Saponification value. Between 145 and 165.

(5) Iodine number. Not more than 3.

(6) Heavy metals (as Pb). Not more than 10 parts per million.

(c) In accordance with §184.1(b)(1) of this chapter, the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient is 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 formulation aid, as defined in §170.3(o)(14) of this chapter.

(2) The ingredient is used in excipient formulations for use in tablets at levels not to exceed good manufacturing practice.

[52 FR 42430, Nov. 5, 1987]

§ 184.1329 Glyceryl palmitostearate.

(a) Glyceryl palmitostearate is a mixture of mono-, di-, and triglycerides of palmitic and stearic acids made from glycerin, palmitic acid, and stearic acid.

(b) The ingredient meets the following specifications:

(1) The substance is a mixture of mono-, di-, and triglycerides of palmitic acid and stearic acid.

(2) Heavy metals (as lead): Not more than 10 parts per million.

(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 formulation aid, as defined in §170.3(o)(14) of this chapter.

(2) The ingredient is used in excipient formulations for use in tablets at levels not to exceed good manufacturing practice.

[60 FR 63621, Dec. 12, 1995]

§ 184.1330 Acacia (gum arabic).

(a) Acacia (gum arabic) is the dried gummy exudate from stems and branches of trees of various species of the genus *Acacia*, family Leguminosae.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 7, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, 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.