

§ 184.1328

21 CFR Ch. I (4–1–25 Edition)

this section do not exist or have been waived.

[54 FR 7403 Feb. 21, 1989, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1328 Glyceryl behenate.

(a) Glyceryl behenate is a mixture of glyceryl esters of behenic acid made from glycerin and behenic acid (a saturated C₂₂ 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 triglyceryl esters 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>.

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Beverages and beverage bases, § 170.3(n)(3) of this chapter	2.0	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.

MAXIMUM USAGE LEVELS PERMITTED—Continued

Food (as served)	Percent	Function
Chewing gum, § 170.3(n)(6) of this chapter	5.6	Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; humectant, § 170.3(o)(16) of this chapter; surface-finishing agent, § 170.3(o)(30) of this chapter.
Confections and frostings, § 170.3(n)(9) of this chapter	12.4	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter; surface-finishing agent, § 170.3(o)(30) of this chapter.
Dairy product analogs, § 170.3(n)(10) of this chapter	1.3	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Fats and oils, § 170.3(n)(12) of this chapter	1.5	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Gelatins, puddings, and fillings, § 170.3(n)(22) of this chapter	2.5	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter.; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Hard candy and cough drops, § 170.3(n)(25) of this chapter ..	46.5	Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter.
Nuts and nut products, § 170.3(n)(32) of this chapter	8.3	Formulation aid, § 170.3(o)(14) of this chapter; surface-finishing agent, § 170.3(o)(30) of this chapter.
Quiescently frozen confection products	6.0	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Snack foods, § 170.3(n)(37) of this chapter	4.0	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter.
Soft candy, § 170.3(n)(38) of this chapter	85.0	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; firming agent, § 170.3(o)(10) of this chapter; flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; humectant, § 170.3(o)(16) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter; surface-finishing agent, § 170.3(o)(30) of this chapter.
All other food categories	1.0	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; processing aid, § 170.3(o)(24) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter; surface-finishing agent, § 170.3(o)(30) of this chapter; texturizer, § 170.3(o)(32) of this chapter.

(d) [Reserved]

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

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1983; 53 FR 5766, Feb. 26, 1988]

§ 184.1333 Gum ghatti.

(a) Gum ghatti (Indian gum) is an exudate from wounds in the bark of *Anogeissus latifolia*, a large tree found in the dry deciduous forests of India and Ceylon.

(b) The ingredient complies with the following specifications:

(1) *Viscosity of a 1-percent solution.* Not less than the minimum or within the range claimed by the vendor.

(2) *Limits of impurities*—(i) *Arsenic (as AL).* Not more than 3 parts per million (0.0003 percent);

(ii) *Ash (acid-insoluble).* Not more than 1.75 percent;

(iii) *Ash (total).* Not more than 6.0 percent;

(iv) *Heavy metals (as Pb).* Not more than 40 parts per million (0.004 percent); and

(v) *Lead.* Not more than 10 parts per million (0.001 percent).

(3) *Loss on drying.* Not more than 14 percent dried at 105 °C for 5 hours.

(4) *Identification test.* Add 0.2 ml of diluted lead acetate as outlined in “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), section 31.178(b),