

§ 172.755

www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(4) 1,4-Dioxane, not greater than 10 milligrams per kilogram (mg/kg), and ethylene oxide, not greater than 1 mg/kg, as determined by a gas chromatographic method entitled “Determination of Ethylene Oxide and 1,4-Dioxane by Headspace Gas Chromatography,” approved November 5, 1998, printed by Gattefosse S.A.S., and incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51; see paragraph (b)(1) of this section for availability of the incorporation by reference.

(c) The additive is used or intended for use as an excipient in dietary supplement tablets, capsules, and liquid formulations that are intended for ingestion in daily quantities measured in drops or similar small units of measure.

[71 FR 12620, Mar. 13, 2006, as amended at 78 FR 71463, Nov. 29, 2013]

§ 172.755 Stearyl monoglyceridyl citrate.

The food additive stearyl monoglyceridyl citrate may be safely used in food in accordance with the following provisions:

(a) The additive is prepared by controlled chemical reaction of the following:

Reactant	Limitations
Citric acid	Prepared by the glycerolysis of edible fats and oils or derived from fatty acids conforming with § 172.860.
Monoglycerides of fatty acids.	
Stearyl alcohol	Derived from fatty acids conforming with § 172.860, or derived synthetically in conformity with § 172.864.

(b) The additive stearyl monoglyceridyl citrate, produced as described under paragraph (a) of this section, meets the following specifications:

Acid number 40 to 52.
Total citric acid 15 to 18 percent.
Saponification number 215–255.

(c) The additive is used or intended for use as an emulsion stabilizer in or with shortenings containing emulsifiers.

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§ 172.765 Succistearin (stearoyl propylene glycol hydrogen succinate).

The food additive succistearin (stearoyl propylene glycol hydrogen succinate) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is the reaction product of succinic anhydride, fully hydrogenated vegetable oil (predominantly C₁₆ or C₁₈ fatty acid chain length), and propylene glycol.

(b) The additive meets the following specifications:

Acid number 50–150.
Hydroxyl number 15–50.
Succinated ester content 45–75 percent.

(c) The additive is used or intended for use as an emulsifier in or with shortenings and edible oils intended for use in cakes, cake mixes, fillings, icings, pastries, and toppings, in accordance with good manufacturing practice.

§ 172.770 Ethylene oxide polymer.

The polymer of ethylene oxide may be safely used as a foam stabilizer in fermented malt beverages in accordance with the following conditions.

(a) It is the polymer of ethylene oxide having a minimum viscosity of 1,500 centipoises in a 1 percent aqueous solution at 25 °C.

(b) It is used at a level not to exceed 300 parts per million by weight of the fermented malt beverage.

(c) The label of the additive bears directions for use to insure compliance with paragraph (b) of this section.

§ 172.775 Methacrylic acid-divinylbenzene copolymer.

Methacrylic acid-divinylbenzene copolymer may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is produced by the polymerization of methacrylic acid and divinylbenzene. The divinylbenzene functions as a cross-linking agent and constitutes a minimum of 4 percent of the polymer.

(b) Aqueous extractives from the additive do not exceed 2 percent (dry basis) after 24 hours at 25 °C.

(c) The additive is used as a carrier of vitamin B₁₂ in foods for special dietary use.

§ 172.780 Acacia (gum arabic).

The food additive may be safely used in food in accordance with the following prescribed conditions:

(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, 8th ed. (2012), p. 516, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1

CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address: <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, 3d Floor, Silver Spring, MD 20993, 301-796-2039, 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/cfr/abbreviations.html>.

(c) The ingredient is used in food in accordance with good manufacturing practices under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Beverages, alcoholic	20.0	Thickener, emulsifier, or stabilizer.
Breakfast cereals, § 170.3(n)(4) of this chapter	6.0	Dietary fiber; emulsifier and emulsifier salt; flavoring agent and adjuvant; formulation aid; processing aid; stabilizer and thickener; surface-finishing agent; texturizer.
Cakes, brownies, pastries, biscuits, muffins, and cookies.	3.0	Do.
Grain-based bars (e.g., breakfast bars, granola bars, rice cereal bars).	35.0	Do.
Soups and soup mixes, § 170.3(n)(40) of this chapter, except for soups and soup mixes containing meat or poultry that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act.	2.5	Do.
Food categories listed in § 184.1330 of this chapter, except for meat, poultry, and foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act preclude the use of acacia.	Levels prescribed in § 184.1330 of this chapter.	Dietary fiber.

[70 FR 8034, Feb. 17, 2005, as amended at 78 FR 71464, Nov. 29, 2013; 78 FR 73437, Dec. 6, 2013]

§ 172.785 *Listeria*-specific bacteriophage preparation.

The additive may be safely used as an antimicrobial agent specific for *Listeria monocytogenes* (*L. monocytogenes*) in accordance with the following conditions:

(a) *Identity.* (1) The additive consists of a mixture of equal proportions of six different individually purified lytic-type (lacking lysogenic activity) bacteriophages (phages) specific against *L. monocytogenes*.

(2) Each phage is deposited at, and assigned an identifying code by, a sci-

entifically-recognized culture collection center, and is made available to FDA upon request.

(3) The additive is produced from one or more cell cultures of *L. monocytogenes* in a safe and suitable nutrient medium.

(b) *Specifications.* (1) The additive achieves a positive lytic result (OD₆₀₀ ≤ 0.06) when tested against any of the following *L. monocytogenes* isolates available from American Type Culture Collection (ATCC): ATCC 35152 (serogroup 1/2a), ATCC 19118 (serogroup 4b), and ATCC 15313 (serogroup 1/2b). The analytical method for determining the potency of the additive entitled "Determination of Potency of LMP-