

§ 172.735

- (1) The name of the additive.
- (2) Adequate directions for use.
- (c) To assure safe use of the additive, the label or labeling of the treated malt shall bear, in addition to other information required by the Act, the statement, "Brewer's Malt—To be used in the production of fermented malt beverages only", or "Distiller's Malt—To be used in the production of distilled spirits only", whichever is the case.

§ 172.735 Glycerol ester of rosin.

Glycerol ester of wood rosin, gum rosin, or tall oil rosin may be safely used in food in accordance with the following prescribed conditions:

- (a) It has an acid number of 3 to 9, a drop-softening point of 88 to 96 °C; and a color of N or paler as determined in accordance with Official Naval Stores Standards of the United States. It is purified by countercurrent steam distillation or steam stripping.
- (b) It is used to adjust the density of citrus oils used in the preparation of beverages whereby the amount of the additive does not exceed 100 parts per million of the finished beverage.

[42 FR 14491, Mar. 15, 1977, as amended at 70 FR 15758, Mar. 29, 2005; 72 FR 46896, Aug. 22, 2007]

§ 172.736 Glycerides and polyglycides of hydrogenated vegetable oils.

The food additive glycerides and polyglycides of hydrogenated vegetable oils may be safely used in food in accordance with the following prescribed conditions:

- (a) The additive is manufactured by heating a mixture of hydrogenated oils of vegetable origin and polyethylene glycol in the presence of an alkaline catalyst followed by neutralization with any acid that is approved or is generally recognized as safe for this use to yield the finished product.
- (b) The additive consists of a mixture of mono-, di- and tri-glycerides and polyethylene glycol mono- and diesters of fatty acids (polyglycides) of hydrogenated vegetable oils and meets the following specifications:

- (1) Total ester content, greater than 90 percent as determined by a method entitled "Determination of Esterified Glycerides and Polyoxyethylene

21 CFR Ch. I (4–1–25 Edition)

Glycols," approved November 16, 2001, printed by Gattefosse S.A.S., and 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 a copy from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1200 or you may examine a copy at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday, 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/code_of_federal_regulations/ibr_locations.html.

- (2) Acid value, not greater than 2, and hydroxyl value, not greater than 56, as determined by the methods entitled "Acid Value," p. 1220 and "Hydroxyl Value," p. 1223, respectively, in the Food Chemicals Codex, 7th ed. (2010), 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 Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday, 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/ibr-locations.html>.

- (3) Lead, not greater than 0.1 mg/kg as determined by the American Oil Chemists' Society (A.O.C.S.) method Ca 18c-91, "Determination of Lead by Direct Graphite Furnace Atomic Absorption Spectrophotometry," updated 1995, and incorporated by reference in

accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from American Oil Chemists' Society, P. O. Box 3489, Champaign, IL 61826-3489, or may be examined at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, between 9 a.m. and 4 p.m., Monday through Friday, 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/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; 81 FR 5591, Feb. 3, 2016; 88 FR 17720, Mar. 24, 2023]

§ 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 Monoglycerides of fatty acids. | Prepared by the glycerolysis of edible fats and oils or derived from fatty acids conforming with § 172.860. |

| Reactant | Limitations |
|-----------------------|--|
| 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.

§ 172.765 Succistearin (stearyl propylene glycol hydrogen succinate).

The food additive succistearin (stearyl 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.