

**Food and Drug Administration, HHS**

**§ 172.836**

exceed 300 milligrams/kilogram of the finished beverage.

[64 FR 29958, June 4, 1999; 64 FR 43072, Aug. 9, 1999]

**§ 172.834 Ethoxylated mono- and diglycerides.**

The food additive ethoxylated mono- and diglycerides (polyoxyethylene (20) mono- and diglycerides of fatty acids) (polyglycerate 60) may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by:

(1) Glycerolysis of edible fats primarily composed of stearic, palmitic, and myristic acids; or

(2) Direct esterification of glycerol with a mixture of primarily stearic, palmitic, and myristic acids;

to yield a product with less than 0.3 acid number and less than 0.2 percent water, which is then reacted with ethylene oxide.

(b) The additive meets the following specifications:

Saponification number, 65–75.

Acid number, 0–2.

Hydroxyl number, 65–80.

Oxyethylene content, 60.5–65.0 percent.

(c) The additive is used or intended for use in the following foods when standards of identity established under section 401 of the Act do not preclude such use:

Use	Limitations
1. As an emulsifier in pan-release agents for and as a dough conditioner in yeast-leavened bakery products.	Not to exceed levels required to produce the intended effects, total not to exceed 0.5 percent by weight of the flour used.
2. As an emulsifier in cakes and cake mixes.	Not to exceed 0.5 percent by weight of the dry ingredients.
3. As an emulsifier in whipped vegetable oil toppings and topping mixes.	Not to exceed 0.45 percent by weight of the finished whipped vegetable oil toppings.
4. As an emulsifier in icings and icing mixes.	Not to exceed 0.5 percent by weight of the finished icings.
5. As an emulsifier in frozen desserts.	Not to exceed 0.2 percent by weight of the finished frozen desserts.
6. As an emulsifier in edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee.	Not to exceed 0.4 percent by weight of the finished vegetable fat-water emulsions.

(d) When the name “polyglycerate 60” is used in labeling it shall be followed by either “polyoxyethylene (20) mono- and diglycerides of fatty acids” or “ethoxylated mono- and diglycerides” in parentheses.

[42 FR 14491, Mar. 15, 1977, as amended at 42 FR 37973, July 26, 1977; 50 FR 49536, Dec. 3, 1985]

**§ 172.836 Polysorbate 60.**

The food additive polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) which is a mixture of polyoxyethylene ethers of mixed partial stearic and palmitic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield a product with a maximum acid number of 10 and a maximum water content of 0.2 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

Saponification number 45–55.

Acid number 0–2.

Hydroxyl number 81–96.

Oxyethylene content 65 percent–69.5 percent.

(c) It is used or intended for use as follows:

(1) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

(i) Sorbitan monostearate;

(ii) Polysorbate 65;

(iii) Polysorbate 80;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping; except that a combination of the additive with sorbitan monostearate may be used in excess of 0.4 percent, provided that the amount of the additive does not exceed 0.77 percent and the amount of sorbitan monostearate does not exceed 0.27 percent of the weight of the finished whipped edible oil topping.

(2) As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:

(i) Polysorbate 65.