(2) The labeling of beverage bases containing the additive shall bear adequate directions for use to provide that beverages prepared therefrom shall contain no more than 0.2 percent glycine.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.814 Hydroxylated lecithin.

The food additive hydroxylated lecithin may be safely used as an emulsifier in foods in accordance with the following conditions:

(a) The additive is obtained by the treatment of lecithin in one of the following ways, under controlled conditions whereby the separated fatty acid fraction of the resultant product has an acetyl value of 30 to 38:

(1) With hydrogen peroxide, benzoyl peroxide, lactic acid, and sodium hydroxide.

(2) With hydrogen peroxide, acetic acid, and sodium hydroxide.

(b) It is used or intended for use, in accordance with good manufacturing practice, as an emulsifier in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the Act:

(1) The name of the additive, ''hydroxylated lecithin''.

(2) Adequate directions for its use.

§ 172.816 Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester may be safely used in food in accordance with the following conditions:

(a) It is the methyl glucoside-coconut oil ester having the following specifications:

Acid number: 10–20
Hydroxyl number: 200–300
pH (5% aqueous): 4.8–5.0
Saponification number: 178–190

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

(1) As an aid in crystallization of sucrose and dextrose at a level not to exceed the minimum quantity required to produce its intended effect.

(2) As a surfactant in molasses at a level not to exceed 320 parts per million in the molasses.

§ 172.818 Oxystearin.

The food additive oxystearin may be safely used in foods, when such use is not precluded by standards of identity in accordance with the following conditions:

(a) The additive is a mixture of the glycerides of partially oxidized stearic and other fatty acids obtained by heating hydrogenated cottonseed or soybean oil under controlled conditions, in the presence of air and a suitable catalyst which is not a food additive as so defined. The resultant product meets the following specifications:

Acid number: Maximum 15.
Iodine number: Maximum 15.
Saponification number: 225–240.
Hydroxyl number: 30–45.
Unsaponifiable material: Maximum 0.8 percent.
Refractive index (butyro): 60±1 at 48 °C.

(b) It is used or intended for use as a crystallization inhibitor in vegetable oils and as a release agent in vegetable oils and vegetable shortenings, whereby the additive does not exceed 0.125 percent of the combined weight of the oil or shortening.

(c) To insure safe use of the additive, the label and labeling of the additive container shall bear, in addition to the other information required by the Act:

(1) The name of the additive.

(2) Adequate directions to provide an oil or shortening that complies with the limitations prescribed in paragraph (b) of this section.

§ 172.820 Polyethylene glycol (mean molecular weight 200–9,500).

Polyethylene glycol identified in this section may be safely used in food in accordance with the following prescribed conditions:

(a) *Identity.* (1) The additive is an addition polymer of ethylene oxide and water with a mean molecular weight of 200 to 9,500.

(2) It contains no more than 0.2 percent total by weight of ethylene and diethylene glycols when tested by the analytical methods prescribed in paragraph (b) of this section.

(b) *Analytical method.* (1) The analytical method prescribed in the National Formulary XV (1980), page 1244, for polyethylene glycol 400 shall be used to determine the total ethylene and diethylene glycol content of polyethylene glycols having mean molecular weights of 450 or higher.

(2) The following analytical method shall be used to determine the total ethylene and diethylene glycol content of polyethylene glycols having mean molecular weights below 450.

ANALYTICAL METHOD

ETHYLENE GLYCOL AND DIETHYLENE GLYCOL CONTENT OF POLYETHYLENE GLYCOLS

The analytical method for determining ethylene glycol and diethylene glycol is as follows:

APPARATUS

Gas chromatograph with hydrogen flame ionization detector (Varian Aerograph 600 D or equivalent). The following conditions shall be employed with the Varian Aerograph 600 D gas chromatograph:

Column temperature: 165 °C.

Inlet temperature: 260 °C.

Carrier gas (nitrogen) flow rate: 70 milliliters per minute.

Hydrogen and air flow to burner: Optimize to give maximum sensitivity.

Sample size: 2 microliters.

Elution time: Ethylene glycol: 2.0 minutes. Diethylene glycol: 6.5 minutes.

Recorder: −0.5 to +1.05 millivolt, full span, 1 second full response time.

Syringe: 10-microliter (Hamilton 710 N or equivalent).

Chromatograph column: 5 feet × ⅛ inch. I.D. stainless steel tube packed with sorbitol (Mathieson-Coleman-Bell 2768 Sorbitol SX850, or equivalent) 12 percent in H_2O by weight on 60–80 mesh nonacid washed diatomaceous earth (Chromosorb W. Johns-Manville, or equivalent).

REAGENTS AND MATERIALS

Carrier gas, nitrogen: Commercial grade in cylinder equipped with reducing regulator to provide 50 p.s.i.g. to the gas chromatograph.

Ethylene glycol: Commercial grade. Purify if necessary, by distillation.

Diethylene glycol: Commercial grade. Purify, if necessary, by distillation.

Glycol standards: Prepare chromatographic standards by dissolving known amounts of ethylene glycol and diethylene glycol in water. Suitable concentrations for standardization range from 1 to 6 milligrams of each component per milliliter (for example 10 milligrams diluted to volume in a 10-milliliter volumetric flask is equivalent to 1 milligram per milliliter).

STANDARDIZATION

Inject a 2-microliter aliquot of the glycol standard into the gas chromatograph employing the conditions described above. Measure the net peak heights for the ethylene glycol and for the diethylene glycol. Record the values as follows:

A=Peak height in millimeters of the ethylene glycol peak.

B=milligrams of ethylene glycol per milliliter of standard solution.

C=Peak height in millimeters of the diethylene glycol peak.

D=Milligrams of diethylene glycol per milliliter of standard solution.

PROCEDURE

Weigh approximately 4 grams of polyethylene glycol sample accurately into a 10-milliliter volumetric flask. Dilute to volume with water. Mix the solution thoroughly and inject a 2-microliter aliquot into the gas chromatograph. Measure the heights, in millimeters, of the ethylene glycol peak and of the diethylene glycol peak and record as E and F, respectively.

Percent ethylene glycol=$(E\times B)/(A\times$sample weight in grams)

Percent diethylene glycol=$(F\times D)/(C\times$sample weight in grams)

(c) *Uses.* It may be used, except in milk or preparations intended for addition to milk, as follows:

(1) As a coating, binder, plasticizing agent, and/or lubricant in tablets used for food.

(2) As an adjuvant to improve flavor and as a bodying agent in nonnutritive sweeteners identified in §180.37 of this chapter.

(3) As an adjuvant in dispersing vitamin and/or mineral preparations.

(4) As a coating on sodium nitrite to inhibit hygroscopic properties.

(d) *Limitations.* (1) It is used in an amount not greater than that required to produce the intended physical or technical effect.

(2) A tolerance of zero is established for residues of polyethylene glycol in milk.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.822 Sodium lauryl sulfate.

The food additive sodium lauryl sulfate may be safely used in food in accordance with the following conditions: