

List of substances	Limitations
<p>Polysorbate 85 (polyoxyethylene (20) sorbitan trioleate) meeting the following specifications: Saponification number 80–95, oxyethylene content 46–50 percent.</p> <p>Sodium 1,4-dicyclohexyl sulfosuccinate.</p> <p>Sodium 1,4-dihexyl sulfosuccinate.</p> <p>Sodium 1,4-diisobutyl sulfosuccinate.</p> <p>Sodium dioctyl sulfosuccinate.</p> <p>Sodium 1,4-dipentyl sulfosuccinate.</p> <p>Sodium 1,4-ditridecyl sulfosuccinate.</p> <p>Sodium lauryl sulfate.</p> <p>Sodium monoalkylphenoxybenzenedisulfonate and sodium dialkylphenoxybenzenedisulfonate mixtures containing not less than 70 pct of the monoalkylated product where the alkyl group is C<sub>8</sub>C<sub>16</sub>.</p> <p>Sorbitan monolaurate meeting the following specifications. Saponification number 153–170; and hydroxyl number 330–360.</p> <p>Sorbitan monooleate meeting the following specifications: Saponification number 145–160, hydroxyl number 193–210.</p> <p>Sorbitan monopalmitate meeting the following specifications: Saponification No. 140–150; and hydroxyl No. 275–305.</p> <p>Sorbitan monostearate conforming to the identity prescribed in § 172.842 of this chapter.</p> <p>Sorbitan trioleate meeting the following specifications: Saponification No. 170–190; and hydroxyl No. 55–70.</p> <p>Sorbitan tristearate meeting the following specifications: Saponification No. 176–188; and hydroxyl No. 66–80.</p> <p>Sulfosuccinic acid 4-ester with polyethylene glycol dodecyl ether, disodium salt (CAS Reg. No. 39354–45–5).</p> <p>Sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt (alcohol moiety produced by condensation of 1 mole nonylphenol and an average of 9–10 moles of ethylene oxide) (CAS Reg. No. 9040–38–4).</p> <p><math>\alpha</math>-[<i>p</i>-(1,1,3,3-Tetramethylbutyl)phenyl] <i>omega</i>-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of <i>p</i>-(1,1,3,3-tetramethylbutyl) phenol with an average of 4–14 or 30–40 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4–14 or 30–50.</p> <p>Tetrasodium <i>N</i>-(1,2-dicarboxyethyl)-<i>N</i>-octadecyl-sulfosuccinate</p> <p><math>\alpha</math>-Tridecyl-<i>omega</i>-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 75–85 and that are produced by the esterification of the condensation product of one mole of "oxo" process tridecyl alcohol with 5.5–6.5 moles of ethylene oxide.</p> <p><math>\alpha</math>-Tridecyl-<i>omega</i>-hydroxypoly (oxyethyl-ene) mixture of dihydrogen phosphate and monohydrogen phosphate esters that have an acid number (to pH 5.2) of 58–70 and that are produced by the esterification of the condensation product of one mole of "oxo" process tridecyl alcohol with 9–10 moles of ethylene oxide.</p>	<p>For use only at levels not to exceed 5 percent by weight of total monomers used in the emulsion polymerization of polyvinyl acetate, acrylic, and vinyl/acrylic polymers intended for use as coatings for paper and paperboard.</p> <p>For use only at levels not to exceed 5 percent by weight of the total coating monomers used in the emulsion polymerization of polyvinyl acetate and vinyl-acrylate copolymers intended for use as coatings for paper and paperboard.</p> <p>For use only as a polymerization emulsifier for resins applied to tea-bag material.</p>

(d) The provisions of this section are not applicable to emulsifiers and/or surface-active agents listed in § 175.105(c)(5) of this chapter and used in food-packaging adhesives complying with § 175.105 of this chapter.

[42 FR 14609, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 178.3400, see the List of CFR Sections Affected, which appears in the

Finding Aids section of the printed volume and on GPO Access.

**§ 178.3450 Esters of stearic and palmitic acids.**

The ester stearyl palmitate or palmityl stearate or mixtures thereof may be safely used as adjuvants in food-packaging materials when used in accordance with the following prescribed conditions:

**§ 178.3480**

**21 CFR Ch. I (4-1-07 Edition)**

(a) They are used or intended for use as plasticizers or lubricants in polystyrene intended for use in contact with food.

(b) They are added to the formulated polymer prior to extrusion.

(c) The quantity used shall not exceed that required to accomplish the intended technical effect.

**§ 178.3480 Fatty alcohols, synthetic.**

Synthetic fatty alcohols may be safely used as components of articles intended for use in contact with food, and in synthesizing food additives and other substances permitted for use as components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) The food additive consists of fatty alcohols meeting the specifications and definition prescribed in §172.864 of this chapter, except as provided in paragraph (c) of this section.

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

(1) As substitutes for the corresponding naturally derived fatty alcohols permitted for use as components of articles intended for use in contact with food by existing regulations in parts 174, 175, 176, 177, 178 and §179.45 of this chapter: *Provided*, That the use is in compliance with any prescribed limitations.

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted for use as components of food-contact articles.

(c) Synthetic fatty alcohols identified in paragraph (c)(1) of this section may contain not more than 0.8 weight percent of total diols as determined by a method titled "Diols in Monohydroxy Alcohol by Miniature Thin Layer Chromatography (MTLC)," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection 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://](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html)

[www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(1) *Synthetic fatty alcohols.* (i) Hexyl, octyl, decyl, lauryl, myristyl, cetyl, and stearyl alcohols meeting the specifications and definition prescribed in §172.864 of this chapter, except that they may contain not more than 0.8 weight percent total diols.

(ii) Lauryl, myristyl, cetyl, and stearyl alcohols manufactured by the process described in §172.864(a)(2) of this chapter such that lauryl and myristyl alcohols meet the specifications in §172.864(a)(1)(i) of this chapter, and cetyl and stearyl alcohols meet the specifications in §172.864(a)(1)(ii) of this chapter.

(2) *Conditions of use.* (i) Synthetic fatty alcohols as substitutes for the corresponding naturally derived fatty alcohols permitted for use in compliance with §178.3910.

(ii) Synthetic lauryl alcohol as a substitute for the naturally derived lauryl alcohol permitted as an intermediate in the synthesis of sodium lauryl sulfate used in compliance with §178.3400.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 54 FR 24898, June 12, 1989]

**§ 178.3500 Glycerin, synthetic.**

Synthetic glycerin may be safely used as a component of articles intended for use in packaging materials for food, subject to the provisions of this section:

(a) It is produced by the hydrogenolysis of carbohydrates, and shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used in a quantity not to exceed that amount reasonably required to produce its intended physical or technical effect, and in accordance with any limitations prescribed by applicable regulations in parts 174, 175, 176, 177, 178 and 179 of this chapter. It shall not be intended to, nor in fact accomplish, any direct physical or technical effect in the food itself.

**§ 178.3505 Glyceryl tri-(12-acetoxystearate).**

Glyceryl tri-(12-acetoxystearate) (CAS Reg. No. 139-43-5) may be safely