

List of substances	Limitations
<p>Sodium monoalkylphenoxybenzenedisulfonate and sodium dialkylphenoxybenzenedisulfonate mixtures containing not less than 70 pct of the monoalkylated product where the alkyl group is C₈-C₁₆.</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>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>α-[<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>For use only as a polymerization emulsifier for resins applied to tea-bag material.</p>
<p>α-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>α-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>	

(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, as amended at 43 FR 58557, Dec. 15, 1978; 44 FR 42679, July 20, 1979; 45 FR 67321, Oct. 10, 1980; 48 FR 24870, June 3, 1983; 49 FR 5748, Feb. 15, 1984; 51 FR 31763, Sept. 5, 1986; 56 FR 41457, Aug. 21, 1991; 58 FR 26687, May 5, 1993; 60 FR 18351, Apr. 11, 1995; 61 FR 14246, Apr. 1, 1996; 62 FR 33997, June 24, 1997; 62 FR 42051, Aug. 5, 1997]

§ 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:

(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, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(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 used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The additive is applied to the surface of calcium carbonate at a level not to exceed 1 weight-percent of the total mixture.

(b) The calcium carbonate/glyceryl tri-(12-acetoxystearate) mixture is used as an adjuvant in polymers in contact with nonfatty foods at a level not to exceed 20 weight-percent of the polymer.

[50 FR 1503, Jan. 11, 1985]

§178.3520 Industrial starch-modified.

Industrial starch-modified may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.