

**§ 178.3480**

**21 CFR Ch. I (4-1-11 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