

§ 178.3750

21 CFR Ch. I (4–1–23 Edition)

Substances	Limitations
Polybutene, hydrogenated (minimum viscosity at 99 °F, 39 Saybolt Universal seconds, as determined by ASTM methods D445–82 (“Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and the Calculation of Dynamic Viscosity)”) and D2161–82 (“Standard Method for Conversion of Kinematic Viscosity to Saybolt Universal Viscosity or to Saybolt Furol Viscosity”), and bromine number of 3 or less, as determined by ASTM method D1492–78 (“Standard Test Method for Bromine Index of Aromatic Hydrocarbons by Coulometric Titration”), which are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined 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: <a href="http://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</a> ..	For use only: 1. In polymeric substances used in contact with non-fatty food. 2. In polyethylene complying with § 177.1520 of this chapter and used in contact with fatty food, provided that the hydrogenated polybutene is added in an amount not to exceed 0.5 pct by weight of the polyethylene, and further provided that such plasticized polyethylene shall not be used as a component of articles intended for packing or holding food during cooking. 3. In polystyrene complying with § 177.1640 of this chapter and used in contact with fatty food, provided that the hydrogenated polybutene is added in an amount not to exceed 5 pct by weight of the polystyrene, and further provided that such plasticized polystyrene shall not be used as a component of articles intended for packing or holding food during cooking.
Polyisobutylene (mol weight 300–5,000) .....	For use in polyethylene complying with § 177.1520 of this chapter, provided that the polyisobutylene is added in an amount not exceeding 0.5 pct by weight of the polyethylene, and further provided that such plasticized polyethylene shall not be used as a component of articles intended for packing or holding food during cooking.
Polyisobutylene complying with § 177.1420 of this chapter.	
Polypropylene glycol (CAS registry No. 25322–69–4) (minimum mean molecular weight 1,200).	For use only in polystyrene plastics, identified in § 177.1640(a)(1), in an amount not to exceed 6 pct by weight of the finished food-contact article.
Propylene glycol azelate (average mol. weight 3,000).	For use only at levels not exceeding 41 pct by weight of permitted polyvinyl chloride coatings. Such coatings shall be used only as bulk food contact surfaces of articles intended for repeated use, complying with § 177.2600 of this chapter.
Triethylene glycol .....	Diethylene glycol content not to exceed 0.1 pct.
2,2,4-Trimethyl-1,3-pentanediol diisobutyrate .....	For use only in cellulosic plastics in an amount not to exceed 15 pct by weight of the finished food-contact article, provided that the finished plastic article contacts food only of the types identified in § 176.170(c) of this chapter, table 1, under Categories I, II, VI-B, VII-B, and VIII.

(c) The use of the plasticizers in any polymeric substance or article subject to any regulation in parts 174, 175, 176, 177, 178 and 179 of this chapter must comply with any specifications and limitations prescribed by such regulation for the finished form of the substance or article.

[42 FR 14609, Mar. 15, 1977, as amended at 42 FR 44223, Sept. 2, 1977; 45 FR 56052, Aug. 22, 1980; 48 FR 5748, Feb. 15, 1984; 49 FR 10113, Mar. 19, 1984; 51 FR 47011, Dec. 30, 1986; 87 FR 31089, May 20, 2022]

**§ 178.3750 Polyethylene glycol (mean molecular weight 200-9,500).**

Polyethylene glycol identified in this section may be safely used as a component of articles intended for use in contact with food, in accordance with the following prescribed conditions:

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

(b) It contains no more than 0.2 percent total by weight of ethylene and diethylene glycols if its mean molecular weight is 350 or higher and no more than 0.5 percent total by weight of ethylene and diethylene glycols if its mean molecular weight is below 350, when tested by the analytical methods prescribed in § 172.820(b) of this chapter.

(c) The provisions of paragraph (b) of this section are not applicable to polyethylene glycols used in food-packaging adhesives complying with § 175.105 of this chapter.

**§ 178.3760 Polyethylene glycol (400 monolaurate).**

Polyethylene glycol (400) monolaurate containing not more than 0.1 percent by weight of ethylene and/or diethylene glycol may be used at a level not to exceed 0.3 percent by weight of twine as a finish on twine to be used for tying meat provided the