

§ 177.1590

21 CFR Ch. I (4-1-02 Edition)

of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC; or

(ii) A minimum weight-average molecular weight of 27,000, as determined by gel permeation chromatography using polystyrene standards.

(2) *Extractives limitations.* The polyestercarbonate resins to be tested shall be ground or cut into small particles that will pass through a U.S. standard sieve No. 6 and that will be held on U.S. standard sieve No. 10.

(i) Polyestercarbonate resins, when extracted with distilled water at reflux temperature for 6 hours, shall yield total nonvolatile extractives not to exceed 0.005 percent by weight of the resins.

(ii) Polyestercarbonate resins, when extracted with 50 percent (by volume) ethyl alcohol in distilled water at reflux temperature for 6 hours, shall yield total nonvolatile extractives not to exceed 0.005 percent by weight of the resins.

(iii) Polyestercarbonate resins, when extracted with *n*-heptane at reflux temperature for 6 hours, shall yield total nonvolatile extractives not to exceed 0.002 percent by weight of the resins.

(3) *Residual methylene chloride levels in polyestercarbonate resins.* Polyestercarbonate resin articles in the finished form shall not contain residual methylene chloride in excess of 5 parts per million as determined by a method titled "Analytical Method for Determination of Residual Methylene Chloride in Polyestercarbonate Resin," developed by the General Electric Co., July 23, 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. 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 may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

[57 FR 3940, Feb. 3, 1992, as amended at 64 FR 27178, May 19, 1999]

§ 177.1590 Polyester elastomers.

The polyester elastomers identified in paragraph (a) of this section may be

safely used as the food-contact surface of articles intended for use in contact with bulk quantities of dry food of the type identified in §176.170(c) of this chapter, table 1, under Type VIII, in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyester elastomers are those produced by the ester exchange reaction when one or more of the following phthalates—dimethyl terephthalate, dimethyl orthophthalate, and dimethyl isophthalate—is made to react with alpha-hydroomega-hydroxypoly (oxytetramethylene) and/or 1,4-butanediol such that the finished elastomer has a number average molecular weight between 20,000 and 30,000.

(b) Optional adjuvant substances employed in the production of the polyester elastomers or added thereto to impart desired technical or physical properties may include the following substances:

List of substances	Limitations
4,4' - Bis (<i>alpha</i> , <i>alpha</i> -dimethyl-benzyl) diphenylamine .	For use only as an anti-oxidant.
Tetrabutyl titanate	For use only as a catalyst.

(c) An appropriate sample of the finished polyester elastomer in the form in which it contacts food when subjected to ASTM method D968-81, "Standard Test Methods for Abrasion Resistance of Organic Coatings by the Falling Abrasive Tester," which is incorporated by reference (copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408), using No. 50 emery abrasive in lieu of Ottawa sand, shall exhibit an abrasion coefficient of not less than 100 liters per mil of thickness.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10109, Mar. 19, 1984]

§ 177.1595 Polyetherimide resin.

The polyetherimide resin identified in this section may be safely used as an article or component of an article intended for use in contact with food,

subject to the provisions of this section.

(a) *Identity.* For the purpose of this section, the polyetherimide resin is 1,3-isobenzofurandione, 5,5'[(1-methyl-ethylidene)bis(4,1-phenyleneoxy)] bis-polymer with 1,3-benzenediamine (CAS Reg. No. 61128-46-9), and is derived from the condensation reaction of *m*-phenylenediamine and bisphenol A-dianhydride.

(b) *Optional adjuvants.* The basic polymer identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of basic resins or finished food-contact articles. The optional adjuvant substances required in the production of the basic polymer may include substances permitted for such use by applicable regulations as set forth in part 174 of this chapter.

(c) *Specifications and extractives limitations—(1) Specifications.* Polyetherimide resin identified in paragraph (a) of this section shall have an intrinsic viscosity in chloroform at 25 °C (77 °F) of not less than 0.35 deciliter per gram as determined by a method titled "Intrinsic Viscosity of ULTEM Polyetherimide Using Chloroform as the Solvent," 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 Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(2) *Extractive limitations.* Extractive limitations are applicable to the basic polyetherimide resin in the form of molded discs of thickness 0.16 centimeter (0.063 inch). The resin discs when extracted with distilled water at 121 °C (250 °F) for 2 hours yield total nonvolatile extractives of not more than 12.3 micrograms per square centimeter.

[50 FR 31351, Aug. 2, 1985; 50 FR 35535, Sept. 3, 1985]

§ 177.1600 Polyethylene resins, carboxyl modified.

Carboxyl-modified polyethylene resins may be safely used as the food-contact surface of articles intended for use in contact with food in accordance

with the following prescribed conditions:

(a) For the purpose of this section, carboxyl-modified polyethylene resins consist of basic polymers produced when ethylene-methyl acrylate basic copolymers, containing no more than 25 weight percent of polymer units derived from methyl acrylate, are made to react in an aqueous medium with one or more of the following substances:

Ammonium hydroxide.
Calcium carbonate.
Potassium hydroxide.
Sodium hydroxide.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, yields total extractives in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface as determined by the methods described in § 176.170(d) of this chapter; and if the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178, and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation. In testing the finished food-contact articles, a separate test sample is to be used for each required extracting solvent.

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

§ 177.1610 Polyethylene, chlorinated.

Chlorinated polyethylene identified in this section may be safely used as articles or components of articles that contact food, except for articles used for packing or holding food during cooking, subject to the provisions of this section.

(a) For the purpose of this section, chlorinated polyethylene consists of basic polymers produced by the direct chlorination of polyethylene conforming to the density, maximum *n*-