Food and Drug Administration, HHS

§ 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-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.

(b) Polyestercarbonate resins shall conform to the specifications prescribed in paragraph (c)(1) of this section and shall meet the extractive limitations prescribed in paragraph (c)(2) of this section.

(1) Specifications. Polyestercarbonate resins identified in paragraph (a) of this section can be identified by their characteristic infrared spectrum. The resins shall comply with either or both of the following specifications:

(i) The solution intrinsic viscosity of the polyestercarbonate resins shall be a minimum of 0.44 deciliter per gram, as determined by a method entitled “Intrinsic Viscosity (IV) of Lexan® Polyestercarbonate Resin by a Single Point Method Using Dichloromethane as the Solvent,” developed by the General Electric Co., September 20, 1985, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or 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://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(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) n-heptane at reflux temperature for 6 hours, shall yield total nonvolatile extractives not to exceed 0.002 percent by weight of the resins.
§ 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)] bispolymer 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 extractive 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 National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(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.


§ 177.1600 Polyethylene resins, carboxyl modified.

Carboxy-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, carboxy-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