§ 177.1637

this section may contain optional adjuvant substances required in the production of such basic polymers. Such optional adjuvant substances may include substances permitted for such use by applicable regulations in this chapter, substances generally recognized as safe in food, substances generally recognized as safe in indirect additives, and substances used in accordance with prior sanction or approval.

- (c) Specifications. (1) Poly(nmethylstyrene) basic polymers identified in paragraph (a)(1) of this section shall contain not more than 1 weight total residual of methystyrene monomer, as determined by a gas chromatographic method ti-"Gas Chromatographic Determination of PMS and PET in PPMS Basic Polymers," 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/ $ibr \ \overline{locations.html}$.
- (2) Rubber-modified poly(p-methylstyrene) basic polymers identified in paragraph (a)(2) of this section shall contain not more than 0.5 weight percent of total residual p-methylstyrene monomer, as determined by the method identified in paragraph (c)(1) of this section
- (d) Other specifications and limitations. The poly(p-methylstyrene) and rubber-modified poly(p-methylstyrene) identified in and complying with this section, when used as components of the food-contact surface of any article that is the subject of a regulation in parts 175, 176, 177, 178 and §179.45 of this chapter, shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.
- (e) Conditions of use. Poly(p-methylstyrene) basic polymers and rubber-modified poly(p-methylstyrene) basic polymers identified in paragraphs

(a)(1) and (a)(2), respectively, of this section shall be used in contact with food only under conditions of use B through H set forth in table 2 of §176.170(c) of this chapter.

[48 FR 31384, July 8, 1983, as amended at 54 FR 24898, June 12, 1989; 55 FR 52989, Dec. 26, 1990]

§ 177.1637 Poly(oxy-1,2ethanediyloxycarbonyl-2,6naphthalenediylcarbonyl) resins.

Poly(oxy-1,2-ethanediyloxycarbonyl-2,6-naphthalenediylcarbonyl) resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food in accordance with the following conditions:

- (a) Identity. For the purpose of this section, poly(oxy-1,2-ethanediyloxycarbonyl-2,6-naphthalenediylcarbonyl) resins (CAS Reg. No. 24968-11-4) are polymers formed by catalytic transesterification of 2,6-dimethylnaphthalene dicarboxylate with ethylene glycol followed by catalytic polycondensation.
- (b) Specifications—(1) Density. The density of poly(oxy-1,2-ethanediyloxycarbonyl-2,6-naphthalenediylcarbonyl) resins shall be between 1.33 and 1.40 grams per cubic centimeter.
- (2) Inherent viscosity. The finished food-contact article shall have a minimum inherent viscosity of 0.55 deciliter per gram in a solution of 0.1 gram of polymer in 100 milliliters of a 25/40/ 35 (weight/weight) solution of pchlorophenol/tetrachloroethane/phenol. The viscosity is determined by Eastman Chemical Co.'s method ECD-A-AC-G-V-1-5, "Determination of Dilute Solution Viscosity of Polyesters," dated May 31, 1988, 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.

- (c) Extraction limitations. A 0.5 millimeter (0.02 inch) thick sheet of resin when extracted with water at 121 °C (250 °F) for 2 hours shall yield total nonvolatile extractives not exceeding 2.0 micrograms per square inch of exposed resin surface.
- (d) Conditions of use. The finished food contact article shall be:
- (1) Used in contact only with food of Types I, II, IVB, VIA, VIB, VIIB, and VIII identified in table 1 of §176.170(c) of this chapter, under conditions of use A through H described in table 2 of §176.170(c) of this chapter; and with food of Types III, IVA, V, VIC, VIIA, and IX identified in table 1 of §176.170(c) of this chapter, under conditions of use C through H described in table 2 of §176.170(c) of this chapter; and
- (2) Identified in a manner that will differentiate the article from articles made of other polymeric resins to facilitate collection and sorting.

[61 FR 14965, Apr. 4, 1996]

§ 177.1640 Polystyrene and rubbermodified polystyrene.

Polystyrene and rubber-modified polystyrene identified in this section may be safely used as components of articles intended for use in contact with food, subject to the provisions of this section.

- (a) *Identity*. For the purposes of this section, polystyrene and rubber-modified polystyrene are basic polymers manufactured as described in this paragraph so as to meet the specifications prescribed in paragraph (c) of this section when tested by the method described in paragraph (d) of this section.
- (1) Polystyrene consists of basic polymers produced by the polymerization of styrene.
- (2) Rubber-modified polystyrene consists of basic polymers produced by combining styrene-butadiene copolymers and/or polybutadiene with polystyrene, either during or after polymerization of the polystyrene, such that the finished basic polymers contain not

less than 75 weight percent of total polymer units derived from styrene monomer.

- (b) Optional adjuvants. The basic polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic polymers. Such optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 189 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.
- (c) Specifications. (1) Polystyrene basic polymers identified in paragraph (a)(1) of this section shall contain not more than 1 weight percent of total residual styrene monomer, as determined by the method described in paragraph (d) of this section, except that when used in contact with fatty foods of Types III, IV-A, V, VII-A, and IX described in table 1 of §176.170(c) of this chapter, such polystyrene basic polymers shall contain not more than 0.5 weight percent of total residual styrene monomer.
- (2) Rubber-modified polystyrene basic polymers identified in paragraph (a)(2) of this section shall contain not more than 0.5 weight percent of total residual styrene monomer, as determined by the method described in paragraph (d) of this section.
- (d) Analytical method for determination of total residual styrene monomer content—(1) Scope. This method is suitable for the determination of residual styrene monomer in all types of styrene polymers.
- (2) Principle. The sample is dissolved in methylene chloride. An aliquot of the solution is injected into a gas chromatograph. The amount of styrene monomer present is determined from the area of the resulting peak.
- (3) Apparatus—(i) Gas chromatograph. Beckman GC-2A gas chromatograph with hydrogen flame detector or apparatus of equivalent sensitivity.
- (ii) Chromatograph column. One-quarter inch outside diameter stainless steel tubing (0.028 inch wall thickness), 4 feet in length, packed with 20 percent polyethylene glycol (20,000 molecular weight) on alkaline treated 60-80 mesh firebrick.