

§ 177.1640

21 CFR Ch. I (4-1-01 Edition)

(a) *Identity.* For the purpose of this section, poly(oxy-1,2-ethanedioxy-carbonyl-2,6-naphthalenediyl-carbonyl) 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-ethanedioxy-carbonyl-2,6-naphthalenediyl-carbonyl) 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/weight) solution of *p*-chlorophenol/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 Pre-market Approval, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., Washington, DC.

(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 rubber-modified 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.

(iii) *Recorder*. Millivolt range of 0-1, chart speed of 30 inches per hour.

(4) *Reagents*. Compressed air, purified; helium gas; hydrogen gas; methylene chloride, redistilled; and styrene monomer, redistilled.

(5) *Operating conditions for the gas chromatograph*. (i) The column is operated at a temperature of 100 °C with a helium flow rate of 82 milliliters per minute.

(ii) The hydrogen burner is operated with 15 pounds per square inch of air pressure and 7 pounds per square inch of hydrogen pressure.

(iii) The attenuation of the hydrogen flame detector is set at 2×10^2 .

(6) *Standardization*. (i) Prepare a standard solution by weighing accurately 15 to 20 milligrams of styrene monomer into a 2-ounce bottle containing 25.0 milliliters of methylene chloride. Cap the bottle tightly and shake to thoroughly mix the solution.

(ii) By means of a microliter syringe, inject 1 microliter of the standard solution into the gas chromatograph. Measure the area of the styrene monomer peak which emerges after approximately 12 minutes.

(7) *Procedure*. (i) Transfer 1 gram of sample (accurately weighed to the nearest 0.001 gram to a 2-ounce bottle and add several glass beads. Pipette 25.0 milliliters of methylene chloride into the bottle. Cap the bottle tightly and place on a mechanical shaker. Shake until the polymer is completely dissolved. If any insoluble residue remains, allow the bottle to stand (or centrifuge at a low speed) until a clear supernatant layer appears.

(ii) By means of a microliter syringe, inject 3 microliters of the clear supernatant liquid into the gas chromatograph.

(iii) Measure the area of the resulting styrene monomer peak. Compare the sample peak area with the area produced by the standard styrene monomer solution. Calculation:

$$\text{Percent residual styrene monomer} = \frac{\text{Milligrams monomer in standard} \times \text{Peak area of sample}}{\text{Peak area of monomer standard} \times \text{Sample weight in grams}} \times 30$$

(e) *Other specifications and limitations*. The polystyrene and rubber-modified polystyrene 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 174, 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.

(f) *Nonapplicability*. The provisions of this section are not applicable to polystyrene and rubber-modified polystyrene used in food-packaging adhesives complying with §175.105 of this chapter.

§ 177.1650 Polysulfide polymer-polyepoxy resins.

Polysulfide polymer-polyepoxy resins may be safely used as the food-contact surface of articles intended for packaging, transporting, holding, or otherwise contacting dry food, in accordance with the following prescribed conditions: