

§ 177.2490

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

Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(4) Melting point is between 172 °C and 184 °C as determined by ASTM method D2133-66, "Specifications for Acetal Resin Injection Molding and Extrusion Materials" (Revised 1966), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(d) *Extractive limitations.* (1) Polyoxymethylene homopolymer, in the finished form which is to contact food, when extracted with the solvent or solvents characterizing the type of food and under conditions of time and temperature characterizing the conditions of intended use under paragraphs (c)(3) and (d) of § 175.300 of this chapter and as limited by paragraph (e) of this section, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface.

(2) Polyoxymethylene homopolymer, with or without the optional adjuvant substances described in paragraph (b) of this section, when ground or cut into particles that pass through a U.S.A. Standard Sieve No. 6 and that are retained on a U.S.A. Standard Sieve No. 10, shall yield extractives as follows:

(i) Formaldehyde not to exceed 0.0050 percent by weight of homopolymer as determined by a method titled "Formaldehyde Release and Formaldehyde Analysis," which is incorporated by reference. Copies are available from Center for Food Safety and Applied Nutrition (HFS-200) Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(ii) Total extractives not to exceed 0.20 percent by weight of homopolymer when extracted for 6 hours with distilled water at reflux temperature and 0.15 percent by weight of homopolymer when extracted for 6 hours with *n*-heptane at reflux temperature.

(e) *Conditions of use.* (1) Polyoxymethylene homopolymer is for use as

articles or components of articles intended for repeated use.

(2) Use temperature shall not exceed 250 °F.

(3) In accordance with good manufacturing practice, finished articles containing polyoxymethylene homopolymer shall be thoroughly cleansed prior to first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 43 FR 44835, Sept. 29, 1978; 47 FR 11846, Mar. 19, 1982; 47 FR 51562, Nov. 16, 1982; 49 FR 10111, Mar. 19, 1984; 54 FR 24898, June 12, 1989]

§ 177.2490 Polyphenylene sulfide resins.

Polyphenylene sulfide resins (poly(1,4-phenylene sulfide) resins) may be safely used as coatings or components of coatings of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions.

(a) Polyphenylene sulfide resins consist of basic resins produced by the reaction of equimolar parts of *p*-dichlorobenzene and sodium sulfide, such that the finished resins meet the following specifications as determined by methods titled "Oxygen Flask Combustion-Gravimetric Method for Determination of Sulfur in Organic Compounds," "Determination of the Inherent Viscosity of Polyphenylene Sulfide," and "Analysis for Dichlorobenzene in Ryton Polyphenylene Sulfide," which are incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(1) Sulfur content: 28.2-29.1 percent by weight of finished resin.

(2) Minimum inherent viscosity: 0.13 deciliters per gram.

(3) Maximum residual *p*-dichlorobenzene: 0.8 ppm.

(b) Subject to any limitations prescribed in parts 170 through 189 of this chapter, the following optional substances may be added to the polyphenylene sulfide basic resins in an amount not to exceed that reasonably

required to accomplish the intended physical or technical effect.

(1) Substances generally recognized as safe in food.

(2) Substances used in accordance with prior sanction or approval.

(3) Substances the use of which is permitted in coatings under regulations in parts 170 through 189 of this chapter.

(c) The finished coatings are thermally cured at temperatures of 700 °F and above.

(d) Polyphenylene sulfide resin coatings may be used in contact with food at temperatures not to exceed the boiling point of water; provided that the finished cured coating, when extracted at reflux temperatures for 8 hours separately with distilled water, 50 percent ethanol in water, and 3 percent acetic acid, yields total extractives in each extracting solvent not to exceed 0.02 milligram per square inch of surface and when extracted at reflux temperature for 8 hours with heptane yields total extractives not to exceed 0.1 milligram per square inch of surface.

(e) Polyphenylene sulfide resin coatings containing perfluorocarbon resins complying with §177.1550 may be used in contact with food at temperatures up to and including normal baking and frying temperatures; provided that the finished cured coating, when extracted at reflux temperatures for 2 hours separately with distilled water, 50 percent ethanol in water, 3 percent acetic acid and heptane, yields total extractives in each extracting solvent not to exceed 0.2 milligram per square inch of surface and when extracted at reflux temperature for 1 hour with diphenyl ether yields total extractives not to exceed 4.5 milligrams per square inch of surface.

[42 FR 14572, Mar. 15, 1977, as amended at 47 FR 11846, Mar. 19, 1982; 54 FR 24898, June 12, 1989]

§177.2500 Polyphenylene sulfone resins.

The polyphenylene sulfone resins (CAS Reg. No. 31833-61-1) identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food, subject to the provisions of this section.

(a) *Identity.* For the purpose of this section, polyphenylene sulfone resins consist of basic resin produced by reacting polyphenylene sulfide with peracetic acid such that the finished resins meet the specifications set forth in paragraph (c) of this section. The polyphenylene sulfide used to manufacture polyphenylene sulfone is prepared by the reaction of sodium sulfide and *p*-dichlorobenzene, and has a minimum weight average molecular weight of 5,000 Daltons.

(b) *Optional adjuvant substances.* The basic polyphenylene sulfone resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. These 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, or substances used in accordance with a prior sanction or approval.

(c) *Specifications.* The glass transition temperature of the polymer is 360±5 °C as determined by the use of differential scanning calorimetry.

[65 FR 15053, Mar. 21, 2000]

§177.2510 Polyvinylidene fluoride resins.

Polyvinylidene fluoride resins may be safely used as articles or components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) For the purpose of this section, the polyvinylidene fluoride resins consist of basic resins produced by the polymerization of vinylidene fluoride.

(b) The finished food-contact article, when extracted at reflux temperatures for 2 hours with the solvents distilled water, 50 percent (by volume) ethyl alcohol in distilled water, and *n*-heptane, yields total extractives in each extracting solvent not to exceed 0.01 milligram per square inch of food-contact surface tested; 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