

§ 177.1550

21 CFR Ch. I (4–1–12 Edition)

(f) The olefin polymers 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.

(g) The provisions of this section are not applicable to olefin polymers identified in §175.105(c) (5) of this chapter and used in food-packaging adhesives complying with §175.105 of this chapter.

[42 FR 14572, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §177.1520, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 177.1550 Perfluorocarbon resins.

Perfluorocarbon resins identified in this section may be safely used as articles or components of articles intended to contact food, subject to the provisions of this section:

(a) *Identity.* For the purpose of this section, perfluorocarbon resins are those produced by: (1) The homopolymerization and/or copolymerization of hexafluoropropylene and tetrafluoroethylene, and (2) the copolymerization of perfluoropropylvinylether and tetrafluoroethylene (CAS Reg. No. 26655–00–5). The resins shall meet the extractives limitations in paragraph (d) of this section.

(b) *Optional components.* The perfluorocarbon resins identified in paragraph (a) of this section as well as articles or coating made from these resins may include the following optional components except that the resin identified in paragraph (a)(2) of this section may not be used with the optional component, lithium polysilicate, mentioned in paragraph (b)(4) of this section.

(1) Substances generally recognized as safe (GRAS) in food or food packaging subject to any limitations cited on their use.

(2) Substances used in accordance with a prior sanction or approval, subject to any limitations cited in the prior sanction or approval.

(3) Substances authorized under applicable regulations in this part and in parts 175 and 178 of this chapter and subject to any limitations prescribed therein.

(4) The following substances, subject to any limitations prescribed:

List of substances	Limitations
Lithium polysilicate containing not more than 20 weight percent silica, not more than 2.1 percent lithium oxide and having a maximum mole ratio of SiO ₂ /Li ₂ O of 8.5 to 1.	For use only as a component of repeated-use coatings not exceeding 0.030 millimeter (0.0012 inch) in thickness where the coatings are thermally cured at minimum sintering temperatures of 371 °C (700 °F). Lithium extractives shall not exceed 1.55 milligrams per square decimeter (0.1 milligram per square inch) of coating surface when tested in accordance with paragraph (e)(2) of this section.
Naphthalene sulfonic acid formaldehyde condensate, sodium salt.	For use only: 1. As a component of repeated-use coatings, based on the perfluorocarbon resin identified in paragraph (a)(1) of this section, not to exceed 0.030 millimeter (0.0012 inch) in thickness, and at a level not to exceed 0.4 weight percent of the coating. 2. As a component of repeated-use coatings, based on the perfluorocarbon resin identified in paragraph (a)(2) of this section, not to exceed 0.10 millimeter (0.004 inch) in thickness, and at a level not to exceed 0.4 weight percent of the coating.

(c) *Optional processing.* Poly-tetrafluoroethylene resins may be irradiated by either a cobalt-60 sealed source, at a maximum dose of gamma radiation not to exceed 7.5 megarads, or an electron beam at energy levels not to exceed 2.5 million electron volts with a maximum dosage of 7.5 megarads, to produce lubricant powders having a particle diameter of not more than 20 microns for use only as components of articles intended for repeated use in contact with food.

(d) *Specifications—(1) Infrared identification.* Perfluorocarbon resins can be identified by their characteristic infrared spectra.

(2) *Melt-viscosity.* (i) The perfluorocarbon resins identified in paragraph (a)(1) of this section shall have a melt viscosity of not less than 10^4 poises at 380 °C (716 °F) as determined by ASTM method D1238-82, "Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined 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. The melt viscosity of the perfluorocarbon resins identified in paragraph (a)(1) of this section shall not vary more than 50 percent within one-half hour at 380 °C (716 °F).

(ii) Perfluorocarbon resins identified in paragraph (a)(2) of this section shall have a melt viscosity of not less than 10^4 poises at 372 °C (702 °F) as determined by a more detailed method titled "Determination of Melt Viscosity, Molecular Weight Distribution Index and Viscosity Stability," 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.

(3) *Thermal instability index.* The thermal instability index of the tetrafluoroethylene homopolymer shall not exceed 50 as determined by ASTM method D1457-56T, "Test for Thermal Instability index of Tetrafluoroethylene Homopolymer" (Revised 1956), which is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, 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. The requirements of this paragraph do not apply to polytetrafluoroethylene resin lubricant powders described in paragraph (c) of this section.

(e) *Limitations.*¹ (1) Perfluorocarbon-molded articles having a surface area of 6.45 square decimeters (100 square inches) or more and at least 1.27 millimeters (0.05 inch) thick shall be extracted at reflux temperatures for 2 hours separately with distilled water, 50 percent ethanol, *n*-heptane, and ethyl acetate.

(2) Perfluorocarbon resins identified in paragraphs (a)(1) and (2) of this section and intended for use as coatings or components of coatings shall meet extractability limits prescribed in paragraph (e)(3) of this section when the resins in the form of coatings described in paragraphs (e)(2) (i) and (ii) of this section are extracted at reflux temperatures for 2 hours separately with distilled water, 8 percent ethanol, and *n*-heptane:

(i) Perfluorocarbon resin coatings based on resins identified in paragraph (a)(1) of this section shall be applied to both sides of a 0.025-millimeter (0.001 inch) thick aluminum foil to a thickness of 0.025 millimeter (0.001 inch) after thermal curing at 399 °C (750 °F) for 10 minutes. If a primer is used, the total thickness of the primer plus topcoat shall equal 0.025 millimeter (0.001 inch) after heat curing.

(ii) Perfluorocarbon resin coatings based on resins identified in paragraph (a)(2) of this section shall be applied to both sides of a 0.025-millimeter (0.001

¹A more detailed procedure of extraction conditions is entitled, "Preparation of Extracts," 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.

§ 177.1555

inch) thick aluminum foil to a thickness of 0.10 millimeter (0.004 inch) after thermal curing at 427 °C (800 °F) for 10 minutes. If a primer is used, the total thickness of the primer plus topcoat shall equal 0.10 millimeter (0.004 inch) after heat curing.

(3) The extracted surfaces shall meet the following extractability limits:

(i) Total extractives not to exceed 3.1 milligrams per square decimeter (0.2 milligram per square inch).

(ii) Fluoride extractives calculated as fluorine not to exceed 0.46 milligram per square decimeter (0.03 milligram per square inch).

(f) *Conditions of use.* Perfluorocarbon resins identified in paragraph (a)(2) of this section are limited to use as coatings or components of coatings for articles intended for repeated food-contact use.

[43 FR 44834, Sept. 29, 1978, as amended at 47 FR 11843, Mar. 19, 1982; 47 FR 14699, Apr. 6, 1982; 49 FR 10109, Mar. 19, 1984; 50 FR 1502, Jan. 11, 1985; 54 FR 24898, June 12, 1989; 61 FR 14481, Apr. 2, 1996]

§ 177.1555 Polyarylate resins.

Polyarylate resins (CAS Reg. No. 51706-10-6) may be safely used as articles or components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) *Identity.* Polyarylate resins (1, 3-benzenedicarboxylic acid, diphenyl ester, polymer with diphenyl 1,4-benzenedicarboxylate and 4,4'-(1-methylethylidene) bis(phenol)) are formed by melt polycondensation of bisphenol-A with diphenylisophthalate and diphenylterephthalate.

(b) *Specifications.* (1) The finished copolymers shall contain from 70 to 80 weight percent of polymer units derived from diphenylisophthalate and 20 to 30 weight percent of polymer units derived from diphenylterephthalate.

(2) Polyarylate resins shall have a minimum weight average molecular weight of 20,000.

(3) Polyarylate resins may be identified by their characteristic infrared spectra.

(c) *Extractive limitations.* The finished polyarylate resins in sheet form at least 0.5 millimeter (0.020 inch) thick, when extracted with water at 121 °C

21 CFR Ch. I (4-1-12 Edition)

(250 °F) for 2 hours, shall yield total nonvolatile extractives not to exceed 2.33 micrograms per square centimeter (15 micrograms per square inch) of the exposed resin surface.

(d) *Limitations.* Polyarylate resin articles may be used in contact with all foods except beverages containing more than 8 volume percent ethanol under conditions of use A through H, described in table 2 of § 176.170(c) of this chapter.

[52 FR 35540, Sept. 22, 1987]

§ 177.1556 Polyaryletherketone resins.

The poly(oxy-1,4-phenylenecarbonyl-1,4-phenyleneoxy-1,4-phenylenecarbonyl-1,4-phenylene) resins (CAS Reg. No. 55088-54-5 and CAS Reg. No. 60015-05-6 and commonly referred to as polyaryletherketone resins) 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.* Polyaryletherketone resins consist of basic resins produced by reacting 4,4'-diphenoxy benzophenone and terephthaloyl dichloride in such a way that the finished resins have a minimum weight average molecular weight of 20,000 grams per mole, as determined by light scattering measurements in sulfuric acid at room temperature.

(b) *Optional adjuvant substances.* The basic polyaryletherketone resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. These adjuvants may include substances used in accordance with § 174.5 of this chapter and the following:

(1) Benzoyl chloride, poly(tetrafluoro ethylene).

(2) [Reserved]

(c) *Extractive limitations.* The finished food-contact article yields net total extractives in each extracting solvent not to exceed 0.052 milligram per square inch (corresponding to 0.008 milligram per square centimeter) of food-contact surface, when extracted at reflux temperature for 2 hours with the following solvents: Distilled water, 50 percent (by volume) ethyl alcohol in