

chapter. Film samples of 0.013 centimeter (0.005) inch thickness representing the finished article shall meet the following extractive limitation when tested by ASTM method F34-76 (Reapproved 1980), "Standard Test Method for Liquid Extraction of Flexible Barrier Materials," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(1) The film when extracted with distilled water at 21 °C (70 °F) for 48 hours yields total extractives not to exceed 0.0047 milligram per square centimeter (0.03 milligram per square inch) of food-contact surface.

(2) The film when extracted with 50 percent ethyl alcohol at 21 °C (70 °F) for 48 hours yields total extractives not to exceed 0.0062 milligram per square centimeter (0.04 milligram per square inch) of food-contact surface.

(c) The finished food-contact article shall not exceed 0.0076 centimeter (0.003 inch) thickness and shall contact foods only of the types identified in table 1 of § 176.170(c) of this chapter in Categories III, IV-A, VII-A, and IX under conditions of use F and G described in table 2 of § 176.170(c) of this chapter. Film samples of 0.0076 centimeter (0.003 inch) thickness representing the finished articles shall meet the following extractive limitation when tested by ASTM method F34-76 (Reapproved 1980), "Standard Test Method for Liquid Extraction of Flexible Barrier Materials," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b) of this section. The film when extracted with *n*-heptane at 38 °C (100 °F) for 30 minutes yields total extractives not to exceed 0.0078 milligram per square centimeter (0.05 milligram per square inch) of food-contact surface, after correcting the total extractives by dividing by a factor of five.

(d) The finished food-contact article shall not exceed 0.018 centimeter (0.007 inch) thickness and may contact all foods, except those containing more than 8 percent alcohol, under conditions of use B through H described in

table 2 of § 176.170(c) of this chapter. Film samples of 0.018 centimeter (0.007 inch) thickness representing the finished articles shall meet the following extractive limitation when tested by ASTM method F34-76 (Reapproved 1980), "Standard Test Methods for Liquid Extraction of Flexible Barrier Materials," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b) of this section. The film when extracted with distilled water at 100 °C (212 °F) for 30 minutes yields ethylene-vinyl acetate-vinyl alcohol oligomers not to exceed 0.093 milligram per square centimeter (0.6 milligram per square inch) of food contact surface as determined by a method entitled "Analytical Method of Determining the Amount of EVOH in the Extractives Residue of EVOH Film," dated March 23, 1987, as developed by the Kuraray Co., Ltd., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, 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, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(e) The provisions of this section are not applicable to ethylene-vinyl acetate-vinyl alcohol copolymers used in the food-packaging adhesives complying with § 175.105 of this chapter.

[47 FR 41531, Sept. 21, 1982, as amended at 49 FR 10108, Mar. 19, 1984; 65 FR 17135, Mar. 31, 2000]

#### § 177.1380 Fluorocarbon resins.

Fluorocarbon resins 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) For the purpose of this section, fluorocarbon resins consist of basic resins produced as follows:

(1) Chlorotrifluoroethylene resins produced by the homopolymerization of chlorotrifluoroethylene.

(2) Chlorotrifluoroethylene-1,1-difluoroethylene copolymer resins produced by copolymerization of chlorotrifluoroethylene and 1,1-difluoroethylene.

(3) Chlorotrifluoroethylene-1,1-difluoroethylene-tetrafluoroethylene copolymer resins produced by copolymerization of chlorotrifluoroethylene, 1,1-difluoroethylene, and tetrafluoroethylene.

(4) Ethylene-chlorotrifluoroethylene copolymer resins produced by copolymerization of nominally 50 mole percent of ethylene and 50 mole percent of chlorotrifluoroethylene. The copolymer shall have a melting point of 239 to 243 °C and a melt index of less than or equal to 20 as determined by ASTM Method D 3275-89 "Standard Specification for E-CTFE-Fluoroplastic Molding, Extrusion, and Coating Materials," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19013, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(b) Fluorocarbon resins that are identified in paragraph (a) of this section and that comply with extractive limitations prescribed in paragraph (c) of this section may be used as articles or components of articles intended for use in contact with food as follows:

(1) Fluorocarbon resins that are identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section and that comply only with the extractive limitations prescribed in paragraphs (c)(1) and (c)(2) of this section may be used when such use is limited to articles or components of articles that are intended for repeated use in contact with food or that are intended for one-time use in contact with foods only of the types identified in §176.170(c) of this chapter, table 1, under Types I, II, VI, VII-B, and VIII.

(2) Fluorocarbon resins that are identified in paragraph (a)(4) of this section and that comply with the extractive limitations prescribed in paragraphs (c)(1) and (c)(2) of this section may be used only when such use is limited to

articles or components of articles that are intended for repeated use in contact with food.

(3) In accordance with current good manufacturing practice, those food-contact articles intended for repeated use shall be thoroughly cleansed prior to their first use in contact with food.

(c) Extractives limitations are applicable to the basic resins in the form of pellets that have been ground or cut into small particles that will pass through a U.S. Standard Sieve No. 6 and that will be held on a U.S. Standard Sieve No. 10.

(1) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of distilled water at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.003 percent by weight of the resins.

(2) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of 50 percent (by volume) ethyl alcohol in distilled water at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.003 percent by weight of the resins.

(3) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of *n*-heptane at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.01 percent by weight of the resins.

[42 FR 14572, Mar. 15, 1977, as amended at 57 FR 185, Jan. 3, 1992]

**§ 177.1390 Laminate structures for use at temperatures of 250 °F and above.**

(a) The high-temperature laminates identified in this section may be safely used for food contact at temperatures not exceeding 135 °C (275 °F) unless otherwise specified. These articles are layered constructions that are optionally bonded with adhesives. The interior (food-contact) layer(s) may be separated from the exterior layer(s) by a functional barrier, such as aluminum foil. Upon review of the physical properties of a particular construction, the Food and Drug Administration may consider other layers to serve as functional barriers. This regulation is not intended to limit these constructions as to shape, degree of flexibility, thickness, or number of layers. These layers