

§ 177.1240

a finished absorbent pad or in any suitable flexible porous article, (such as a "tea bag" or infuser), under an applied pressure of 0.15 pounds per square inch (for example, a 4x6 inch square pad is subjected to a 1.6 kilograms applied mass). The solvent used shall be at least 60 milliliters aqueous sodium chloride solution per gram of copolymer.

(d) *Conditions of use.* The copolymers identified in paragraph (a)(1) of this section are limited to use as a fluid absorbent in food-contact materials used in the packaging of frozen or refrigerated poultry. The copolymers identified in paragraph (a)(2) of this section are limited to use as a fluid absorbent in food-contact materials used in the packaging of frozen or refrigerated meat and poultry.

[64 FR 28098, May 25, 1999, as amended at 65 FR 16817, Mar. 30, 2000]

§ 177.1240 1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer.

Copolymer of 1,4-cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate may be safely used as an article or component of articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The copolymer is a basic polyester produced by the catalytic condensation of dimethyl terephthalate and dimethyl isophthalate with 1,4-cyclohexanedimethanol, to which may have been added certain optional substances required in its production or added to impart desired physical and technical properties.

(b) The quantity of any optional substance employed in the production of the copolymer does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of the copolymer that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter conforms with any specification in such regulation.

21 CFR Ch. I (4-1-07 Edition)

(d) Substances employed in the production of the copolymer include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in the copolymer and used in accordance with such sanction or approval.

(3) Substances which by regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter may be safely used as components of resinous or polymeric coatings and film used as food-contact surfaces, subject to the provisions of such regulation.

(e) The copolymer conforms with the following specifications:

(1) The copolymer, when extracted with distilled water at reflux temperature for 2 hours, yields total extractives not to exceed 0.05 percent.

(2) The copolymer, when extracted with ethyl acetate at reflux temperature for 2 hours, yields total extractives not to exceed 0.7 percent.

(3) The copolymer, when extracted with *n*-hexane at reflux temperature for 2 hours, yields total extractives not to exceed 0.05 percent.

[42 FR 14572, Mar. 15, 1977; 49 FR 5748, Feb. 15, 1984, as amended at 55 FR 34555, Aug. 23, 1990]

§ 177.1310 Ethylene-acrylic acid copolymers.

The ethylene-acrylic acid copolymers identified in paragraph (a) of 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) The ethylene-acrylic acid copolymers consist of basic copolymers produced by the copolymerization of ethylene and acrylic acid such that the finished basic copolymers contain no more than:

(1) 10 weight-percent of total polymer units derived from acrylic acid when used in accordance with paragraph (b) of this section; and

(2) 25 weight-percent of total polymer units derived from acrylic acid when used in accordance with paragraph (c) of this section.

(b) The finished food-contact articles made with no more than 10 percent total polymer units derived from acrylic acid, when extracted with the solvent or solvents characterizing the

type of food and under the conditions of its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, yield net acidified chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods prescribed in §177.1330(e)(1), (3)(i) through (iv), (4), (5), and (6), except that

(1) The total residue method using 3 percent acetic acid, as prescribed in §177.1330(e)(6)(i)(a), does not apply, and

(2) The net acidified chloroform-soluble extractives from paper and paperboard complying with §176.170 of this chapter may be corrected for wax, petrolatum, and mineral oil as provided in §176.170(d)(5)(iii)(b) of this chapter.

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 regulation.

(c) The finished food-contact layer made with basic copolymers containing more than 10 weight-percent but no more than 25 weight-percent of total polymer units derived from acrylic acid and with a maximum thickness of 0.0025 inch (2.5 mils) may be used in contact with food types I, II, IVB, VIA, VIB, VIIB, and VIII identified in table 1 of §176.170(c) of the chapter under conditions of use B through H as described in table 2 of §176.170(c) of this chapter, and in contact with food types III, IVA, V, VIIA, and IX identified in table 1 of §176.170(c) of this chapter under conditions of use E through G as described in table 2 of §176.170(c) of this chapter.

(d) The provisions of this section are not applicable to ethylene-acrylic acid copolymers used in food-packaging adhesives complying with §175.105 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 51 FR 19060, May 27, 1986; 53 FR 44009, Nov. 1, 1988]

§ 177.1312 Ethylene-carbon monoxide copolymers.

The ethylene-carbon monoxide copolymers identified in paragraph (a) of 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, ethylene-carbon monoxide copolymers (CAS Reg. No. 25052-62-4) consist of the basic polymers produced by the copolymerization of ethylene and carbon monoxide such that the copolymers contain not more than 30 weight-percent of polymer units derived from carbon monoxide.

(b) *Conditions of use.* (1) The polymers may be safely used as components of the food-contact or interior core layer of multilaminate food-contact articles.

(2) The polymers may be safely used as food-contact materials at temperatures not to exceed 121 °C (250 °F).

(c) *Specifications.* (1) Food-contact layers formed from the basic copolymer identified in paragraph (a) of this section shall be limited to a thickness of not more than 0.01 centimeter (0.004 inch).

(2) The copolymers identified in paragraph (a) of this section shall have a melt index not greater than 500 as determined by ASTM method D1238-82, condition E "Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer," 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 Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the Center for Food Safety and Applied Nutrition (HFS-200), 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.

(3) The basic copolymer identified in paragraph (a) of this section, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use, as determined from tables 1 and 2 of §176.170(c) of this chapter, yields net chloroform-soluble extractives in each extracting solvent