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(2) *Softening point.* Ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer identified in paragraph (a) of this section has a softening point of 63±5 °C as measured by ASTM Method D 1525-87, "Standard Test Method for VICAT Softening Temperature of Plastics," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this material is provided in paragraph (b)(1) of this section.

(c) *Optional adjuvant substances.* Ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer, identified in paragraph (a) of this section, may contain optional adjuvant substances required in their production. The optional adjuvants may include substances used in accordance with §174.5 of this chapter.

(d) *Limitations.* Copolymer blends described above shall not exceed 30 percent by weight of ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer. The finished blend may be used in contact with food only under conditions of use C through G, as described in table 2 of §176.170(c) of this chapter, except that with food identified as Type III, IV-A, V, VII-A, and IX in §176.170(c), table 1, the copolymer may be used under condition of use C at temperatures not to exceed 160 °F (71 °C).

[57 FR 43399, Sept. 21, 1992, as amended at 59 FR 62318, Dec. 5, 1994; 61 FR 14481, Apr. 2, 1996; 62 FR 34628, June 27, 1997]

§177.1350 Ethylene-vinyl acetate copolymers.

Ethylene-vinyl acetate copolymers may be safely used as articles or components of articles intended for use in

producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a)(1) Ethylene-vinyl acetate copolymers consist of basic resins produced by the catalytic copolymerization of ethylene and vinyl acetate to which may have been added certain optional substances to impart desired technological or physical properties to the resin. Subject to any limitations prescribed in this section, the optional substances may include:

(i) Substances generally recognized as safe in food and food packaging.

(ii) Substances the use of which is permitted under applicable regulations in parts 170 through 189 of this chapter, prior sanction, or approvals.

(iii) Substances identified in §175.300(b)(3) (xxv), (xxvii), (xxx), and (xxxiii) of this chapter, and colorants used in accordance with §178.3297 of this chapter.

(iv) Erucamide as identified in §178.3860 of this chapter.

(v) Xanthan gum as identified in §172.695 for use as a thickening agent at a level not to exceed 1 percent by weight of coating solids in aqueous dispersions of ethylene-vinyl acetate copolymers, where such copolymers are used only as coatings or a component of coatings.

(vi) The copolymer of vinylidene fluoride and hexafluoropropene (CAS Reg. No. 9011-17-0), containing 65 to 71 percent fluorine and having a Mooney Viscosity of at least 28, for use as a processing aid at a level not to exceed 0.2 percent by weight of ethylene-vinyl acetate copolymers.

(2) Maleic anhydride-grafted ethylene-vinyl acetate copolymers (CAS Reg. No. 28064-24-6) consist of basic resins produced by the catalytic copolymerization of ethylene and vinyl acetate, followed by reaction with maleic anhydride. Such polymers shall contain not more than 11 percent of polymer units derived from vinyl acetate by weight of total polymer prior to reaction with maleic anhydride, and not more than 2 percent of grafted maleic anhydride by weight of the finished polymer. Optional adjuvant substances that may be

added to the copolymers include substances generally recognized as safe in food and food packaging, substances the use of which is permitted under applicable regulations in parts 170 through 189 of this chapter, and substances identified in §175.300(b)(3)(xxv), (xxvii), (xxxiii), and (xxx) of this chapter and colorants for polymers used in accordance with the provisions of §178.3297 of this chapter.

(b)(1) Ethylene-vinyl acetate copolymers, with or without the optional substances described in paragraph (a) of this section, when extracted with the solvent or solvents characterizing the type of food, and under conditions of time and temperature characterizing the conditions of their intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, shall yield net chloroform-soluble extractives corrected for zinc as zinc oleate not to exceed 0.5 milligram per square inch of an appropriate sample.

(2) Maleic anhydride grafted ethylene-vinyl acetate copolymers shall have a melt flow index not to exceed 2.1 grams per 10 minutes as determined by ASTM method D 1238-82, "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). Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or at the Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 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. Compliance of the melt flow index specification shall be determined using conditions and procedures corresponding to those described in the method as Condition E, Procedure A). The copolymers shall be used in blends with other polymers at levels

not to exceed 17 percent by weight of total polymer, subject to the limitation that when contacting food of types III, IV-A, V, VI-C, VII-A, and IX, identified in §176.170(c) of this chapter, Table 1, the polymers shall be used only under conditions of use C, D, E, F, and G, described in §176.170(c) of this chapter, Table 2.

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

(d) Ethylene-vinyl acetate copolymers may be irradiated under the following conditions to produce molecular crosslinking of the polymers to impart desired properties such as increased strength and increased ability to shrink when exposed to heat:

(1) Electron beam source of ionizing radiation at a maximum energy of 3 million electron volts: Maximum absorbed dose not to exceed 150 kiloGray (15 megarads).

(2) The finished food-contact film shall meet the extractives limitations prescribed in paragraph (e)(2) of this section.

(3) The ethylene-vinyl acetate copolymer films may be further irradiated in accordance with the provisions of paragraph (e)(1) of this section: *Provided*, That the total accumulated radiation dose from both electron beam and gamma ray radiation does not exceed 150 kiloGray (15 megarads).

(e) Ethylene-vinyl acetate copolymer films intended for contact with food may be irradiated to control the growth of microorganisms under the following conditions:

(1) Gamma photons emitted from a cobalt-60 sealed source in the dose range of 5-50 kiloGray (0.5-5.0 megarads).

(2) The irradiated ethylene-vinyl acetate copolymer films, when extracted with reagent grade n-heptane (freshly redistilled before use) according to methods described under §176.170(d)(3) of this chapter, at 75 °F for 30 minutes shall yield total extractives not to exceed 4.5 percent by weight of the film.

[42 FR 14572, Mar. 15, 1977, as amended at 43 FR 29287, July 7, 1978; 54 FR 35874, Aug. 30, 1989; 55 FR 18595, May 3, 1990; 56 FR 42932, Aug. 30, 1991; 64 FR 47108, Aug. 30, 1999]