Food and Drug Administration, HHS

§ 177.1570 Poly-1-butene resins and butene/ethylene copolymers.

The poly-1-butene resins and butene/ethylene copolymers identified in this section may be safely used as articles or components of articles intended for use in contact with food subject to the provisions of this section.

(a) Identity. Poly-1-butene resins are produced by the catalytic polymerization of 1-butene liquid monomer. Butene/ethylene copolymers are produced by the catalytic polymerization of 1-butene liquid monomer in the presence of small amounts of ethylene monomer so as to yield no higher than a 6-weight percent concentration of polymer units derived from ethylene in the copolymer.

(b) Specifications and limitations. Poly-1-butene resins and butene/ethylene copolymers shall conform to the specifications prescribed in paragraph (b)(1) of this section, and shall meet the extractability limits prescribed in paragraph (b)(2) of this section.

(1) Specifications—(i) Infrared identification. Poly-1-butene resins and butene/ethylene copolymers can be identified by their characteristic infrared spectra.

(ii) Viscosity. Poly-1-butene resins and the butene/ethylene copolymers have
§ 177.1580 Polycarbonate resins.

Polycarbonate resins 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) Polycarbonate resins are polyesters produced by:

1. The condensation of 4,4'-isopropylidenediphenol and carbonyl chloride to which may have been added certain optional adjuvant substances required in the production of the resins; or by

2. The reaction of molten 4,4'-isopropylidenediphenol with molten diphenyl carbonate in the presence of the disodium salt of 4,4'-isopropylidenediphenol.

(b) The optional adjuvant substances required in the production of branched polycarbonate resins.

2. The optional adjuvant substances required in the production of resins produced by the methods described in

an intrinsic viscosity 1.0 to 3.2 as determined by ASTM method D1601–78, “Standard Test Method for Dilute Solution Viscosity of Ethylene Polymers,” 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.

(iii) Density. Poly-1-butene resins have a density of 0.904 to 0.920 gms/cm³, and butene/ethylene copolymers have a density of 0.890 to 0.916 gms/cm³ as determined by ASTM method D1505–68 (Reapproved 1979), “Standard Test Method for Density of Plastics by the Density-Gradient Technique,” which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(ii) of this section.

(iv) Melt index. Poly-1-butene resins have a melt index of 0.1 to 24 and the butene/ethylene copolymers have a melt index of 0.1 to 20 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. The availability of this incorporation by reference is given in paragraph (b)(1)(ii) of this section.

(2) Limitations. Poly-1-butene resins and butene/ethylene copolymers for use in articles that contact food, and for articles used for packing or holding food during cooking shall yield no more than the following extractables:

(i) Poly-1-butene resins may be used as articles or components of articles intended for use in contact with food under conditions of use B, C, D, E, F, G, or H described in table 2 of §176.170(c) of this chapter, subject to the provisions of this section and provided that the maximum extractables from test films 0.1 to 0.2 millimeter (0.004 to 0.008 inch) in thickness do not exceed 0.80 percent by weight of the polymer when extracted in a soxhlet extractor for 6 hours with refluxing 95 percent ethanol.

(ii) Poly-1-butene resins may be used as articles or components of articles intended for packaging or holding food during cooking, provided that the thickness of such polymers in the form in which they contact food shall not exceed 0.1 millimeter (0.004 inch) and yield maximum extractables of not more than 2.5 percent by weight of the polymer when films are extracted for 2 hours at 50 °C (122 °F) in n-heptane.