

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](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/cm<sup>3</sup>, and butene/ethylene copolymers have a density of 0.890 to 0.916 gms/cm<sup>3</sup> 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, provided that the maximum extractables do not exceed 2.5 percent by weight of the polymer when film or molded samples are tested for 2 hours at 50 °C (122 °F) in *n*-heptane.

(ii) Butene/ethylene copolymers containing no more than 6 percent by weight of polymer units derived from ethylene may be used as articles or components of articles intended for

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.

(iii) 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.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10109, Mar. 19, 1984; 50 FR 31349, Aug. 2, 1985]

#### § 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.

(3) The condensation of 4,4'-isopropylidenediphenol, carbonyl chloride, and 0.5 percent weight maximum of *o*,*o*'-bis (6-hydroxy-*m*-tolyl) mesitol to which may have been added certain optional adjuvant substances required in the production of branched polycarbonate resins.

(b) The optional adjuvant substances required in the production of resins produced by the methods described in

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paragraph (a)(1) and (3) of this section may include substances generally recognized as safe in food, substances used in accordance with a prior sanction or approval, and the following:

List of substances	Limitations
<i>p</i> -tert-Butylphenol ..... Chloroform ..... <i>p</i> -Cumylphenol (CAS Reg. No. 599-64-4).	For use only as a chain terminator at a level not to exceed 5 percent by weight of the resin.
Ethylene dichloride. Heptane. Methylene chloride. Monochlorobenzene .....	Not to exceed 500 p.p.m. as residual solvent in finished resin.
Pentaerythritol tetrastearate (CAS Reg. No. 115-83-3).	For use only as a mold release agent, at a level not to exceed 0.5 percent by weight of the finished resin.
Phenol (CAS Reg. No. 108-95-2). Pyridine. Toluene: (CAS Reg. No. 108-88-3).	Not to exceed 800 parts per million as residual solvent in finished resin.
Triethylamine.	

(c) Polycarbonate resins shall conform to the specification prescribed in paragraph (c)(1) of this section and shall meet the extractives limitations prescribed in paragraph (c)(2) of this section.

(1) *Specification.* Polycarbonate resins can be identified by their characteristic infrared spectrum.

(2) *Extractives limitations.* The polycarbonate resins to be tested shall be 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.

(i) Polycarbonate resins, when extracted with distilled water at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(ii) Polycarbonate resins, when extracted with 50 percent (by volume) ethyl alcohol in distilled water at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(iii) Polycarbonate resins, when extracted with *n*-heptane at reflux temperature for 6 hours, shall yield total extractives not to exceed 0.15 percent by weight of the resins.

(d) Polycarbonate resins may be used in accordance with this section except

in infant feeding bottles (baby bottles) and spill-proof cups, including their closures and lids, designed to help train babies and toddlers to drink from cups (sippy cups).

[42 FR 14572, Mar. 15, 1977, as amended at 46 FR 23227, Apr. 24, 1981; 49 FR 4372, Feb. 6, 1984; 50 FR 14096, Apr. 10, 1985; 53 FR 29656, Aug. 8, 1988; 59 FR 43731, Aug. 25, 1994; 77 FR 41902, July 17, 2012]

§ 177.1585 Polyester carbonate resins.

Polyester carbonate resins may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, or holding food, in accordance with the following prescribed conditions:

(a) Polyester carbonate resins (CAS Reg. No. 71519-80-7) are produced by the condensation of 4,4'-isopropylidenediphenol, carbonyl chloride, terephthaloyl chloride, and isophthaloyl chloride such that the finished resins are composed of 45 to 85 molepercent ester, of which up to 55 mole-percent is the terephthaloyl isomer. The resins are manufactured using a phthaloyl chloride/carbonyl chloride mole ratio of 0.81 to 5.7/1 and isophthaloyl chloride/terephthaloyl chloride mole ratio of 0.81/1 or greater. The resins are also properly identified by CAS Reg. No. 114096-64-9 when produced with the use of greater than 2 but not greater than 5 weight percent *p*-cumylphenol (CAS Reg. No. 599-64-4), as an optional adjuvant substance in accordance with paragraph (b)(2) of this section.

(b) *Optional adjuvants.* The optional adjuvant substances required in the production of resins identified in paragraph (a) of this section may include:

(1) Substances used in accordance with §174.5 of this chapter.

(2) Substances identified in §177.1580(b).

(3) Substances regulated in §178.2010(b) of this chapter for use in polycarbonate resins complying with §177.1580:

*Provided,* That the substances are used in accordance with any limitation on concentration, conditions of use, and food types specified in §178.2010(b) of this chapter.