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, 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.

§ 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 a2,a6-bis (6-hydroxy-m-toly) 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
paragraph (a)(1) and (3) of this section may include substances generally rec-
ognized as safe in food, substances used in accordance with a prior sanction or
approval, and the following:

<table>
<thead>
<tr>
<th>List of substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>p-tert-Butylphenol</td>
<td>For use only as a chain termi-</td>
</tr>
<tr>
<td></td>
<td>nator at a level not to exceed 5 percent by weight of the resin.</td>
</tr>
<tr>
<td>Chloroform</td>
<td>Not to exceed 500 p.p.m. as residual solvent in finished resin.</td>
</tr>
<tr>
<td>p-Cumylphenol (CAS Reg. No. 599–64–4).</td>
<td>For use only as a mold re-</td>
</tr>
<tr>
<td></td>
<td>lease agent, at a level not to exceed 0.5 percent by weight of the finished</td>
</tr>
<tr>
<td>Ethylene dichloride.</td>
<td>resin.</td>
</tr>
<tr>
<td>Heptane.</td>
<td>Not to exceed 800 parts per</td>
</tr>
<tr>
<td>Methylene chloride.</td>
<td>million as residual solvent in finished resin.</td>
</tr>
<tr>
<td>Monochlorobenzene</td>
<td></td>
</tr>
<tr>
<td>Pentaerythritol tetrastearate (CAS Reg. No. 115–83–3).</td>
<td></td>
</tr>
<tr>
<td>Pyridine.</td>
<td></td>
</tr>
<tr>
<td>Triethylamine.</td>
<td></td>
</tr>
</tbody>
</table>

(c) Polycarbonate resins shall con-
form 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 charac-
teristic 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 ex-
tracted with distilled water at reflux
temperature for 6 hours, shall yield
total extractives not to exceed 0.15 per-
cent by weight of the resins.

(ii) Polycarbonate resins, when ex-
tracted 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 ex-
tracted with n-heptane at reflux tem-
perature 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).


§ 177.1585 Polyestercarbonate resins.

Polyestercarbonate resins may be
safely used as articles or components of
articles intended for use in pro-
ducing, manufacturing, packing, pro-
cessing, preparing, treating, packaging,
or holding food, in accordance with the
following prescribed conditions:

(a) Polyestercarbonate 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 fin-
ished resins are composed of 45 to 85 molepercent ester, of which up to 55
mole-percent is the terephthaloyl iso-
mer. 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 pro-
duced 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 para-
graph (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
poly carbonate 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.