§ 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-n-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 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>
</table>
| p-tert-Butylphenol | For use only as a chain termi-
| Chloroform         | nator at a level not to exceed
| p-Cumylphenol (CAS Reg.
|                   | No. 599–64–4). |
| Ethylene dichloride.|
| Heptane.           |
| Methylene chloride.|
| Monochlorobenzene  | Not to exceed 500 p.p.m. as re-
|                    | sidual solvent in finished
|                    | resin. |
| Pentaerythritol tetra-
| tetrastearate (CAS Reg.
| No. 115–93–3).     |
| Phenol (CAS Reg. No. 108–
| 95–2).             |
| Pyridine.          |
| Toluene: (CAS Reg. No.
| Triethylamine.     |

(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 character-
istic 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.

§177.1585 Polysterecarbonate resins.

Polysterecarbonate resins may be safely used as articles or components of
articles intended for use in produ-
cing, manufacturing, packing, process-
ing, preparing, treating, packaging,
or holding food, in accordance with the
following prescribed conditions:

(a) Polysterecarbonate resins (CAS Reg.
No. 71519–80–7) are produced by the
condensation of 4,4′-isopropylidenediphenol, carbonyl chlo-
ride, 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
polysterecarbonate 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.

Food and Drug Administration, HHS

[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]