§177.2430

21 CFR Ch. I (4-1-01 Edition)

List of substances	Limitations (limits of addition expressed as percent by weight of finished resin)
N, N-Dimethylaniline Ethylene guanidine hydrochloride 3. Catalysts:	Do. 0.05 percent. Total not to exceed 1.5 percent, except that methyl ethyl ke- tone peroxide may be used as the sole catalyst at levels not to exceed 2 percent.
Azo-bis-isobutyronitrile. Benzoyl peroxide. <i>tert</i> -Butyl perbenzoate. Chlorbenzoyl peroxide. Cumene hydroperoxide.	
Dibutyltin oxide (CAS Reg. No. 818–08–6)	For use in the polycondensation reaction at levels not to exceed 0.2 percent of the polyester resin.
Hydroxybutyltin oxide (CAS Reg. No. 2273–43–0)	For use in the polycondensation reaction at levels not to exceed 0.2 percent of the polyester resin.
Lauroyl peroxide. <i>p</i> -Menthane hydroperoxide. Methyl ethyl ketone peroxide. Monobutyltin tris(2-ethylhexoate) (CAS Reg. No. 23850–	For use in the polycondensation reaction at levels not to ex-
 94–4). 4. Solvents for inhibitors, accelerators, and catalysts: Butyl benzyl phthalate (containing not more than 1.0 per- cent by weight of dibenzyl phthalate). 	ceed 0.2 percent of the polyester resin.
Dibutyl phthalate. Diethylene glycol	As a solvent for benzyl trimethyl ammonium chloride or ethyl- ene guanidine hydrochloride only.
Dimethyl phthalate. Methyl alcohol. Styrene. Trisheyd phosphoto	
5. Reinforcements: Asbestos. Glass fiber. Polyester fiber produced by the condensation of one or	
more of the acids listed in paragraph (a)(1) of this section with one or more of the alcohols listed in paragraph (a)(2) of this section.	
 Miscellaneous materials: Castor oil, hydrogenated. α-Methylstyrene. Polyethylene glycol 6000. 	
Wax, petroleum	Complying with §178.3710 of this chapter.

(c) The cross-linked polyester resins, with or without the optional substances described in paragraph (b) of this section, and in the finished form in which they are to contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of their intended use, as determined from tables 1 and 2 of 16.170(c) of this chapter, shall meet the following extractives limitations:

(1) Net chloroform-soluble extractives not to exceed 0.1 milligram per square inch of food-contact surface tested when the prescribed food-simulating solvent is water or 8 or 50 percent alcohol.

(2) Total nonvolatile extractives not to exceed 0.1 milligram per square inch

of food-contact surface tested when the prescribed food-simulating solvent is heptane.

(d) In accordance with good manufacturing practice, finished articles containing the cross-linked polyester resins shall be thoroughly cleansed prior to their first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 48 FR 37618, Aug. 19, 1983; 54 FR 48858, Nov. 28, 1989]

§177.2430 Polyether resins, chlorinated.

Chlorinated polyether resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in

Food and Drug Administration, HHS

accordance with the following prescribed conditions:

(a) The chlorinated polyether resins are produced by the catalytic polymerization of 3,3-bis(chloromethyl)oxetane, and shall contain not more than 2 percent residual monomer.

(b) In accordance with good manufacturing practice, finished articles containing the chlorinated polyether resins shall be thoroughly cleansed prior to their first use in contact with food.

§177.2440 Polyethersulfone resins.

Polyethersulfone resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyethersulfone resins are:

(1) Poly(oxy-*p*-phenylenesulfonyl-*p*-phenylene) resins (CAS Reg. No. 25667–42–9), which have a minimum number average molecular weight of 16,000.

(2) 1,1'-sulfonylbis[4-chlorobenzene] polymer with 4,4'-(1-methylethylidene)bis[phenol] (maximum 8 percent) and 4,4'-sulfonylbis[phenol] (minimum 92 percent) (CAS Reg. No. 88285–91–0), which have a minimum number average molecular weight of 26,000.

(3) In paragraphs (a)(1) and (a)(2) of this section, the minimum number average molecular weight is determined by reduced viscosity in dimethyl formamide in accordance with ASTM method D2857-70 (Reapproved 1977), "Standard Test Method for Dilute Solution Viscosity of Polymers," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, 1110 Vermont Ave. NW., suite 1200, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(b) The basic resins identified in paragraphs (a)(1) and (a)(2) of this section may contain optional adjuvant substances described in §174.5(d) of this chapter and the following:

List of substances Limitations Diphenvlsulfone Not to exceed 0.2 percent as residual solvent in the finished basic resin described in paragraph (a)(1) of this section. Dimethyl sulfoxide Not to exceed 0.01 percent as residual solvent in the finished basic resin described in paragraph (a)(1) of this section. N-methyl-2-pyrrolidone Not to exceed 0.01 percent as residual solvent in the finished basic resin described in paragraph (a)(2) of this section.

(c) The finished food-contact article, when extracted at reflux temperatures for 2 hours with the following four solvents, yields net chloroform-soluble extractives in each extracting solvent not to exceed 0.02 milligram per square inch of food-contact surface: distilled water, 50 percent (by volume) ethyl alcohol in distilled water, 3 percent acetic acid in distilled water, and *n*heptane. (Note: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.)

(d) In accordance with good manufacturing practice, finished food-contact articles containing the polyethersulfone resins shall be thoroughly cleansed before their first use in contact with food.

[44 FR 34493, June 15, 1979, as amended at 47 FR 38885, Sept. 3, 1982; 49 FR 10111, Mar. 19, 1984; 50 FR 47211, Nov. 15, 1985; 60 FR 48648, Sept. 20, 1995]

§177.2450 Polyamide-imide resins.

Polyamide-imide resins identified in paragraph (a) of this section may be safely used as components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) *Identity.* (1) For the purpose of this section the polyamide-imide resins are derived from the condensation reaction of substantially equimolar parts of trimellitic anhydride and p,p'-diphenylmethane diisocyanate.

(2) The polyamide-imide resins (CAS Reg. No. 31957-38-7) derived from the condensation reaction of equimolar parts of benzoyl chloride-3,4-dicarboxylic anhydride and 4,4'-diphenylmethanediamine.

(b) Specifications. (1) Polyamide-imide resins identified in paragraph (a)(1) of

§177.2450