

§ 177.1655

21 CFR Ch. I (4-1-07 Edition)

List of substances	Limitations
Sodium dibutyl naphthalene sulfonate.	Wetting agent.
Sodium hydrosulfide. Sodium polysulfide. β,β',γ,γ'-Tetrachloro normal propyl ether.	Cross-linking agent.
Titanium dioxide.	
Toluene .....	Solvent.
Trichloroethane .....	Cross-linking agent.
1,2,3-Trichloropropane .....	Do.
Urea-formaldehyde resins.	
Xylene .....	Solvent.

(b) The resins are used as the food-contact surface for dry food.

(c) An appropriate sample of the finished resin in the form in which it contacts food, when subjected to ASTM method D968-81, "Standard Test Methods for Abrasion Resistance of Organic Coatings by the Falling Abrasive Tester," 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)), using No. 50 Emery abrasive in lieu of Ottawa sand, shall exhibit an abrasion coefficient of not less than 20 liters per mil of film thickness.

[42 FR 14572, Mar. 15, 1977, as amended at 49 FR 10110, Mar. 19, 1984]

§ 177.1655 Polysulfone resins.

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

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

(1) Poly(oxy-*p*-phenylenesulfonyl-*p*-phenyleneoxy-*p*-phenyleneisopropylidene-*p*-phenylene) resins (CAS Reg. No. 25154-01-2) consisting of basic resins produced when the disodium salt of 4,4'-isopropylidenediphenol is made to react with 4,4'-dichlorodiphenyl sulfone in such a way that the finished resins have a minimum number average mo-

lecular weight of 15,000, as determined by osmotic pressure in monochlorobenzene; or

(2) 1,1'-Sulfonylbis[4-chlorobenzene] polymer with 4,4'-(1-methylethylidene)bis[phenol] (minimum 92 percent) and 4,4'-sulfonylbis[phenol] (maximum 8 percent) (CAS Reg. No. 88285-91-0) produced when a mixture of 4,4'-isopropylidenediphenol (minimum 92 percent) and 4,4'-sulfonylbis[phenol] (maximum 8 percent) is made to react with 4,4'-dichlorodiphenyl sulfone in such a way that the finished resin has a minimum number average molecular weight of 26,000, as determined by osmotic pressure in dimethylformamide.

(b) The basic polysulfone resins identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic resins. The optional adjuvant substances required in the production of the basic polysulfone resins may include substances described in § 174.5(d) of this chapter and the following:

List of substances	Limitations
Dimethyl sulfoxide .....	Not to exceed 50 parts per million as residual solvent in finished basic resin in paragraph (a)(1) of this section.
Monochlorobenzene ..	Not to exceed 500 parts per million as residual solvent in finished basic resin in paragraph (a)(1) of this section.
<i>N</i> -methyl-2-pyrrolidone.	Not to exceed 0.01 percent (100 parts per million) as residual solvent in finished basic resin in paragraph (a)(2) of this section.

(c) Polysulfone resins, when extracted at reflux temperatures for 6 hours with the solvents—distilled water, 50 percent (by volume) ethyl alcohol in distilled water, 3 percent acetic acid in distilled water, and *n*-heptane, yield total extractives in each extracting solvent not to exceed 0.0078 milligram per square centimeter (0.05 milligram per square inch) of resin surface. Note: In testing the finished polysulfone resins, use a separate resin test sample for each required extracting solvent.

(d) Polysulfone resins intended for repeated use in contact with food may be used under conditions of use A through

H in table 2 of §176.170(c) of this chapter. The resins intended for single-service food-contact use may be used only under condition of use H described in table 2 of §176.170(c) of this chapter.

[51 FR 882, Jan. 9, 1986; 51 FR 4165, Feb. 3, 1986; 61 FR 29475, June 11, 1996]

**§ 177.1660 Poly (tetramethylene terephthalate).**

Poly(tetramethylene terephthalate) (poly (oxytetramethyleneoxyterephthaloyl)) [Chemical Abstracts Service Registry No. 24968-12-5] identified in this section may be safely used as articles or components of articles intended to contact food, in accordance with the following prescribed conditions:

(a) *Identity.* For the purpose of this section, poly (tetramethylene terephthalate) is the reaction product of dimethyl terephthalate with 1,4-butanediol to which may have been added certain optional substances to impart desired technological properties to the polymer.

(b) *Optional adjuvant substances.* Poly(tetramethylene terephthalate) identified in paragraph (a) of this section may contain optional adjuvant substances. The quantity of any optional adjuvant substance employed in the production of the polymer does not exceed the amount reasonably required to accomplish the intended technical or physical effect. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, and substances permitted under applicable regulations in this part.

(c) *Specifications.* (1) Inherent viscosity of a 0.50 percent solution of the polymer in phenol/tetrachloroethane (60/40 weight ratio) solvent is not less than 0.6 as determined using a Wagner viscometer (or equivalent) and calculated from the following equation:

$$\text{Inherent viscosity} = \frac{(\text{natural logarithm of } N_r)}{(c)}$$

where:

$N_r$ =Ratio of flow time of the polymer solution to that of the solvent and  $c$ =polymer concentration of the test solution in grams per 100 milliliters.

(2) Poly(tetramethylene terephthalate) in the finished form in which it is to contact food shall yield total extractives as follows:

(i) Not to exceed 0.08 milligram per square inch of food contact surface when extracted for 2 hours at 250 °F with distilled water.

(ii) Not to exceed 0.02 milligram per square inch of food contact surface when extracted for 2 hours at 150 °F with *n*-heptane.

(iii) Not to exceed 0.04 milligram per square inch of food contact surface when extracted for 2 hours at 212 °F with 3 percent aqueous acetic acid.

(iv) Not to exceed 0.02 milligram per square inch of food contact surface when extracted for 2 hours at 65.6 °C (150 °F) with 50 percent ethanol.

[42 FR 14572, Mar. 15, 1977, as amended at 50 FR 20748, May 20, 1985; 52 FR 20069, May 29, 1987]

**§ 177.1670 Polyvinyl alcohol film.**

Polyvinyl alcohol film may be safely used in contact with food of the types identified in §176.170(c) of this chapter, table 1, under Types V, VIII, and IX, in accordance with the following prescribed conditions:

(a) The polyvinyl alcohol film is produced from polyvinyl alcohol having a minimum viscosity of 4 centipoises when a 4-percent aqueous solution is tested at 20 °C.

(b) The finished food-contact film for use in contact with Food Types V or IX, when extracted with the solvent characterizing the type of food and under the conditions of time and temperature characterizing its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, yields total extractives not to exceed 0.078 milligram per square centimeter (0.5 milligram per square inch) of food-contact surface when tested by ASTM method F34-76 (Reapproved 1980), "Standard Test Method for Liquid Extraction of Flexible Barrier Materials," 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