## Food and Drug Administration, HHS

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.
N-methyl-2- pyrrolidone.	Not to exceed 0.01 percent (100 parts per million) as residual solvent in finished basic resin in para- graph (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 sec§177.1670

tion 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:

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

where:

N<sub>r</sub>=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  $250 \text{ }^{\circ}\text{F}$  with distilled water.

(ii) Not to exceed 0.02 milligram per square inch of food contact surface when extracted for 2 hours at 150  $^{\circ}$ 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: