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

material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) The finished food-contact film shall not be used as a component of food containers intended for use in contact with water.

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

§ 177.1680 Polyurethane resins.

The polyurethane resins identified in paragraph (a) of this section may be safely used as the food-contact surface of articles intended for use in contact with bulk quantities of dry food of the type identified in §176.170(c) of this chapter, table 1, under Type VIII, in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyurethane resins are those produced when one or more of the isocyanates listed in paragraph (a)(1) of this section is made to react with one or more of the substances listed in paragraph (a)(2) of this section:

(1) Isocyanates:

Bis(isocyanatomethyl) benzene (CAS Reg. No. 25854–16–4).
Bis(isocyanatomethyl) cyclohexane (CAS Reg. No. 38661–72–2).
4,4′-Diisocyanato-3,3′-dimethylbiphenyl (bitolylene diisocyanate).
Diphenylmethane diisocyanate.
Hexamethylene diisocyanate.
3-Isocyanatomethyl - 3,5,5 - trimethylcyclohexyl isocyanate.
4,4-Methylenebis(cyclohexyl isocyanate).
Toluene diisocyanate.

(2) List of substances:

Adipic acid.
1,4-Butanediol.
1,3-Butylene glycol.
1,4–Cyclohexane dimethanol (CAS Reg. No. 105–08–8).
2,2-Dimethyl-1,3-propanediol.
Ethylene glycol.
1,6–Hexanediol (CAS Reg. No. 629–11–8).α–Hydro–ω–hydroxypoly(oxy–1,4–butanediyl) (CAS Reg. No. 25190–06–1).
α-Hydro-*omega*-hydroxypoly (oxytetramethylene).
α,α′-(Isopropylidenedi-*p*-phenylene)bis[*omega*-hydroxypoly (oxypropylene)(3–4 moles)], average molecular weight 675.
Maleic anhydride.
Methyl oxirane polymer with oxirane (CAS Reg. No. 9003–11–6).
Methyl oxirane polymer with oxirane, ether with 1,2,3–propanetriol (CAS Reg. No. 9082–00–2).
α,α′α″,α‴-Neopentanetetrayltetrakis [*omega*-hydroxypoly (oxypropylene) (1–2 moles)], average molecular weight 400.
Pentaerythritol-linseed oil alcoholysis product.
Phthalic anhydride.
Polybutylene glycol.
Polyethyleneadipate modified with ethanolamine with the molar ratio of the amine to the adipic acid less than 0.1 to 1.
Poly(oxycarbonylpentamethylene).
Polyoxypropylene ethers of 4.4′-isopropylidenediphenol (containing an average of 2–4 moles of propylene oxide).
Polypropylene glycol.
α,α′,α″-1,2,3-Propanetriyltris [*omega*-hydroxypoly (oxypropylene) (15–18 moles)], average molecular weight 3,000.
Propylene glycol.
α,α′,α″-[Propylidynetris (methylene)] tris [*omega*-hydroxypoly (oxypropylene) (minimum 1.5 moles)], minimum molecular weight 400.
α-[ρ(1,1,3,3-Tetramethylbutyl) - phenyl]-*omega*-hydroxypoly(oxyethylene) (5 moles), average molecular weight 425.
Trimethylol propane.

(b) Optional adjuvant substances employed in the production of the polyurethane resins or added thereto to impart desired technical or physical properties may include the following substances:

List of substances	Limitations
1-[(2-Aminoethyl)amino]2-propanol	As a curing agent.
1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	As a preservative.
Colorants used in accordance with § 178.3297 of this chapter.	
Dibutyltin diacetate	As a catalyst.
Dibutyltin dichloride	Do.
Dibutyltin dilaurate	Do.
N,N-Dimethyldodecylamine	Do.
N-Dodecylmorpholine	Do.
a,a′-[Isopropylidenebis[*p*-phenyleneoxy(2-hydroxytrimethylene)]]bis[*omega*-hydroxypoly-(oxyethylene) (136–170 moles)], average molecular weight 15,000.	As a stabilizer.
4,4′-Methylenedianiline	As a curing agent.
1,1′,1″-Nitrilotri-2-propanol	Do.