

shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface.

(2) Polyoxymethylene copolymer with or without the optional substances described in paragraph (b) of this section, when ground or cut into particles that pass through a U.S.A. Standard Sieve No. 6 and that are retained on a U.S.A. Standard Sieve No. 10, shall yield total extractives as follows:

(i) Not to exceed 0.20 percent by weight of the copolymer when extracted for 6 hours with distilled water at reflux temperature.

(ii) Not to exceed 0.15 percent by weight of the copolymer when extracted for 6 hours with n-heptane at reflux temperature.

(e) *Conditions of use.* (1) The polyoxymethylene copolymer is for use as articles or components of articles intended for repeated use.

(2) Use temperature shall not exceed 250 °F.

(3) In accordance with good manufacturing practice, finished articles containing polyoxymethylene copolymer shall be thoroughly cleansed before their first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 48 FR 56204, Dec. 20, 1983; 49 FR 5748, Feb. 15, 1984; 50 FR 1842, Jan. 14, 1985; 50 FR 20560, May 17, 1985; 52 FR 4493, Feb. 12, 1987, 54 FR 24898, June 12, 1989]

**§ 177.2480 Polyoxymethylene homopolymer.**

Polyoxymethylene homopolymer identified in this section may be safely used as articles or components of articles intended for food-contact use in accordance with the following prescribed conditions:

(a) *Identity.* For the purpose of this section, polyoxymethylene homopolymer is polymerized formaldehyde [Chemical Abstracts Service Registry No. 9002-81-7]. Certain optional adjuvant substances, described in paragraph (b) of this section, may be added to impart desired technological properties to the homopolymer.

(b) *Optional adjuvant substances.* The polyoxymethylene homopolymer identified in paragraph (a) of this section may contain optional adjuvant substances in its production. The quantity

of any optional adjuvant substance employed in the production of the homopolymer does not exceed the amount reasonably required to accomplish the intended effect. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted under applicable regulations in this part, and the following:

(1) *Stabilizers.* The homopolymer may contain one or more of the following stabilizers. The total amount of stabilizers shall not exceed 1.9 percent of homopolymer by weight, and the quantity of individual stabilizer used shall not exceed the limitations set forth below:

| Substances   | Limitations   |
|--|---|
| Hexamethylenebis(3,5-di- <i>tert</i> -butyl-4-hydroxy-hydrocinnamate) (CAS Reg. No. 35074-77-2). | At a maximum level of 1 percent by weight of homopolymer. The finished articles shall not be used for foods containing more than 8 percent alcohol. |
| 2,2'-Methylenebis(4-methyl-6- <i>tert</i> -butylphenol).   | At a maximum level of 0.5 percent by weight of homopolymer.   |
| Nylon 66/610/6 terpolymer, respective proportions of nylon polymers by weight are: 3/2/4.        | At a maximum level of 1.5 percent by weight of homopolymer.   |
| Nylon 612/6 copolymer (CAS Reg. No. 51733-10-9), weight ratio 6/1.                               | Do.   |
| Tetrakis[methylene(3,5-di- <i>tert</i> -butyl-4-hydroxy-hydrocinnamate)] methane.                | At a maximum level of 0.5 percent by weight of homopolymer.   |

(2) *Lubricant.* *N,N'*-Distearoylethylenediamine.

(3) *Molding assistant.* Polyethylene glycol 6,000.

(c) *Specifications.* (1) Polyoxymethylene homopolymer can be identified by its characteristic infrared spectrum.

(2) Minimum number average molecular weight of the homopolymer is 25,000.

(3) Density of the homopolymer is between 1.39 and 1.44 as determined by ASTM method D1505-68 (Reapproved 1979), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," 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 Office of the Federal

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Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(4) Melting point is between 172 °C and 184 °C as determined by ASTM method D2133-66, "Specifications for Acetal Resin Injection Molding and Extrusion Materials" (Revised 1966), which is incorporated by reference. Copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(d) *Extractive limitations.* (1) Polyoxymethylene homopolymer, in the finished form which is to contact food, when extracted with the solvent or solvents characterizing the type of food and under conditions of time and temperature characterizing the conditions of intended use under paragraphs (c)(3) and (d) of § 175.300 of this chapter and as limited by paragraph (e) of this section, shall yield net chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface.

(2) Polyoxymethylene homopolymer, with or without the optional adjuvant substances described in paragraph (b) of this section, when ground or cut into particles that pass through a U.S.A. Standard Sieve No. 6 and that are retained on a U.S.A. Standard Sieve No. 10, shall yield extractives as follows:

(i) Formaldehyde not to exceed 0.0050 percent by weight of homopolymer as determined by a method titled "Formaldehyde Release and Formaldehyde Analysis," which is incorporated by reference. Copies are available from Center for Food Safety and Applied Nutrition (HFS-200) Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(ii) Total extractives not to exceed 0.20 percent by weight of homopolymer when extracted for 6 hours with distilled water at reflux temperature and 0.15 percent by weight of homopolymer when extracted for 6 hours with *n*-heptane at reflux temperature.

(e) *Conditions of use.* (1) Polyoxymethylene homopolymer is for use as

articles or components of articles intended for repeated use.

(2) Use temperature shall not exceed 250 °F.

(3) In accordance with good manufacturing practice, finished articles containing polyoxymethylene homopolymer shall be thoroughly cleansed prior to first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 43 FR 44835, Sept. 29, 1978; 47 FR 11846, Mar. 19, 1982; 47 FR 51562, Nov. 16, 1982; 49 FR 10111, Mar. 19, 1984; 54 FR 24898, June 12, 1989]

§ 177.2490 Polyphenylene sulfide resins.

Polyphenylene sulfide resins (poly(1,4-phenylene sulfide) resins) may be safely used as coatings or components of coatings of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions.

(a) Polyphenylene sulfide resins consist of basic resins produced by the reaction of equimolar parts of *p*-dichlorobenzene and sodium sulfide, such that the finished resins meet the following specifications as determined by methods titled "Oxygen Flask Combustion-Gravimetric Method for Determination of Sulfur in Organic Compounds," "Determination of the Inherent Viscosity of Polyphenylene Sulfide," and "Analysis for Dichlorobenzene in Ryton Polyphenylene Sulfide," which are incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(1) Sulfur content: 28.2-29.1 percent by weight of finished resin.

(2) Minimum inherent viscosity: 0.13 deciliters per gram.

(3) Maximum residual *p*-dichlorobenzene: 0.8 ppm.

(b) Subject to any limitations prescribed in parts 170 through 189 of this chapter, the following optional substances may be added to the polyphenylene sulfide basic resins in an amount not to exceed that reasonably