Designation: F 702 – 98a$^{\epsilon 1}$

Standard Specification for Polysulfone Resin for Medical Applications[1]

This standard is issued under the fixed designation F 702; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

ε[1] NOTE—Editorial corrections were made in Sections 1 and 2, 3.2, 8.2, and the References in May 2001.

1. Scope

1.1 This specification covers polysulfone resin (poly(oxy-*p*-phenylenesulfonyl-*p*-phenyleneoxy-*p*-phenyleneisopropylidene-*p*-phenylene)) for medical applications (as defined in Terminology D 883). This specification provides requirements and associated test methods for a form of this thermoplastic which is intended for use in manufacturing medical devices or components of medical devices.

1.2 As with any material, some characteristics may be altered by the processing techniques (such as molding, extrusion, machining, sterilization, and so forth) required for a specific application. Therefore, properties of fabricated forms of this resin should be evaluated using appropriate test methods to assure safety and efficacy.

1.3 The use of this resin in medical devices should be restricted to nonimplant applications until biocompatibility evaluations appropriate for the intended applications are successfully completed.

1.4 The biocompatibility of plastic compounds made up of polysulfone resin containing colorants, fillers, processing aids, or other additives as well as polymer blends which contain polysulfone should not be assumed on the basis of resin compatibility alone. Their biocompatibility must be established by testing the final (end-use) compositions using evaluation methods appropriate for the intended applications. Note that the types, levels, and biological effects of extractives yielded by the additives contained in a compound or blend may also have to be evaluated for some end-use applications.

1.5 All values in this standard are in SI units with the equivalent values in inch-pound units given in parentheses where applicable.

1.6 *This standard does not purport to address all of the concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

D 149 Test Method for Dielectric Breakdown Voltage and Dielectric Strength of Solid Electrical Insulating Materials at Commercial Power Frequencies[2]

D 256 Test Methods for Impact Resistance of Plastics and Electrical Insulating Materials[3]

D 570 Test Method for Water Absorption of Plastics[3]

D 638 Test Method for Tensile Properties of Plastics[3]

D 648 Test Method for Deflection Temperature of Plastics Under Flexural Load[3]

D 696 Test Method for Coefficient of Linear Thermal Expansion of Plastics Between − 30°C and 30°C[3]

D 883 Terminology Relating to Plastics[3]

D 955 Test Method of Measuring Shrinkage from Mold Dimensions of Molded Plastics[3]

D 1238 Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer[3]

D 1505 Test Method for Density of Plastics by the Density-Gradient Technique[3]

D 1898 Practice for Sampling of Plastics[3]

D 3750 Practice for Determination of Number-Average Molecular Weight of Polymers by Membrane Osmometry[4]

F 619 Practice for Extraction of Medical Plastics[5]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[5]

2.2 *Code of Federal Regulations:*

Title 21 CFR Subpart 177.1655[6]

3. Chemical Requirements

3.1 The polysulfone resin consists solely of the alternating copolymer which may be produced when the disodium salt of 4,4′-isopropylidenediphenol is made to react stoichiometrically with 4,4′-dichlorodiphenyl sulfone such that the finished resins have a minimum number average molecular weight of 24 000. The molecular weight shall be determined by osmotic pressure in monochlorobenzene using the method described in

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[2] *Annual Book of ASTM Standards,* Vol 10.01.

[3] *Annual Book of ASTM Standards,* Vol 08.01.

[4] *Annual Book of ASTM Standards,* Vol 08.03.

[5] *Annual Book of ASTM Standards,* Vol 13.01.

[6] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

Practice D 3750 or an equivalent method. The weight average molecular weight shall be equal to or greater than two times the number average molecular weight.

3.2 Polysulfone resins shall conform to the requirements of 21 CFR 177.1655. In addition to the total extractables evaluation described in the CFR, maximum levels and types of extractable metals shall be established in accordance with the requirements of the intended use of the resin **(1, 2)**.[7]

3.3 The polysulfone resin shall yield an infrared transmittance spectrum which exhibits major transmittance bands only at the same wavelengths as appear on the attached reference spectrum (see Fig. 1).

4. Physical Requirements

4.1 Polysulfone resin may be processed by most techniques available for thermoplastic polymers. Medical devices and components of medical devices made of polysulfone may be repeatedly sterilized. Methods used successfully include steam, ethylene oxide, irradiation, and dry heat sterilization.

4.2 Except for nonvolatile content and melt flow, the properties listed in Table 1 are determined from specimens injection molded in accordance with the resin supplier's process recommendations. Additional or different treatments and processing steps (such as extrusion, molding, machining, sterilization, and so forth) may alter the material properties.

5. Sampling

5.1 The material shall be sampled in accordance with the procedure described in Practice D 1898 or equivalent.

6. Inspection, Marking, and Packaging

6.1 The resin shall be inspected for particulate foreign matter contamination using the following or equivalent procedure. Specimen plaques 2.67 ± 0.25 mm (0.105 ± 0.010 in.) thick shall be injection molded in accordance with the resin supplier's process recommendation. A sufficient number of plaques shall be made to provide 390 cm^2(60 $in.^2$) of viewing surface, based on one side of the transparent plaques. The plaques shall be examined visually under fluorescent light using a 2 to 3× magnifier to determine the number and size of any contaminant specks present, rating them in accordance with Table 2. The total level of contamination is then calculated by multiplying the number of specks in each size range by the appropriate numerical rating and summing. A total rating greater than 12 shall be cause for rejection of the material.

6.2 As determined by agreement between the purchaser and the supplier, polysulfone resin may be inspected for pyrogenic contamination using either of the following tests:

6.2.1 USP Pyrogen Test **(3)**.

6.2.2 Limulus Amebocyte Lysate (LAL) Test for Pyrogens **(3)**.

6.3 The material shall be properly identified including lot or batch numbers, date of manufacture, and recommended method of storage.

6.4 The material, before processing, as well as the end-use component, shall be packaged in a suitable container to prevent contamination of contents.

7. Certification

7.1 The manufacturer shall certify that each batch of the polysulfone resin passes Class VI Biological Tests **(5)**, Biological Reactivity Tests **(4)**, and Practice F 748 when indicated for specific applications.

8. Biocompatibility

8.1 Evaluation of the local and systemic tissue response to implant devices, made wholly or in part from polysulfone resin, must be carried out using biological tests appropriate to the intended functions and implantation site of the device.

8.2 Satisfactory tissue response must be established separately for any plastic compounds made up of polysulfone resin which contains colorants, fillers, processing aids, or other additives as well as for polymer blends which contain polysulfone. Note that the types, levels, and biological effects of extractives yielded by the additives contained in a compound or polymer blend may also have to be evaluated for some end-use applications as described in Practice F 619.

8.3 In choosing appropriate test protocols for the material, based upon end use, the recommendations found in Practice F 748 should be considered.

9. Keywords

9.1 plastic surgical devices/applications; polymers—surgical applications; polysulfone resins

[7] The boldface numerals in parentheses refer to the list of references at the end of this specification.

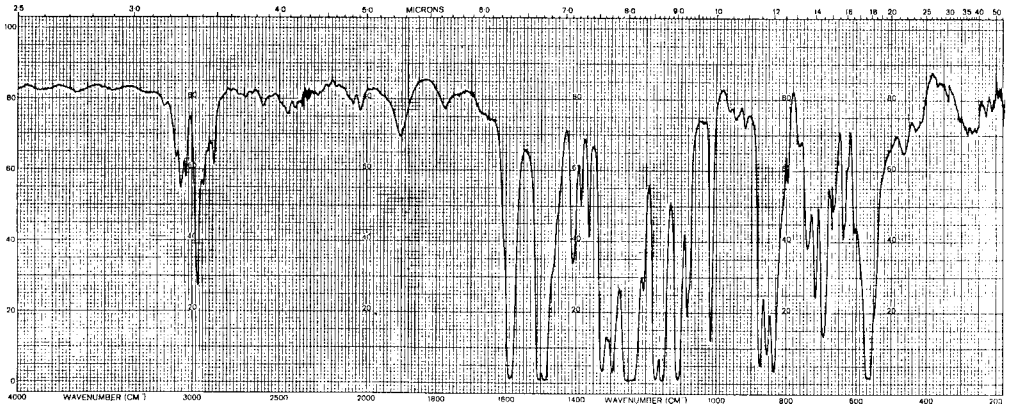

FIG. 1 Polysulfone Infrared Spectrum—Percent Transmittance for 0.0005 in. Film