



Standard Specification for Polysulfone Resin for Medical Applications¹

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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:

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.11 on Polymeric Materials.

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D 149 Test Method for Dielectric Breakdown Voltage and Dielectric Strength of Solid Electrical Insulating Materials at Commercial Power Frequencies²

D 256 Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics³

D 570 Test Method for Water Absorption of Plastics³

D 638 Test Method for Tensile Properties of Plastics³

D 648 Test Method for Deflection Temperature of Plastics Under Flexural Load in the Edgewise Position³

D 696 Test Method for Coefficient of Linear Thermal Expansion of Plastics Between – 30°C and 30°C with a Vitreous Silica Dilatometer³

D 883 Terminology Relating to Plastics³

D 955 Test Method of Measuring Shrinkage from Mold Dimensions of Molded Plastics³

D 1238 Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer³

D 1505 Test Method for Density of Plastics by the Density-Gradient Technique³

D 1898 Practice for Sampling of Plastics⁴

D 3750 Practice for Determination of Number-Average Molecular Weight of Polymers by Membrane Osmometry⁵

F 619 Practice for Extraction of Medical Plastics⁶

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices⁶

2.2 Code of Federal Regulations:

Title 21 CFR Subpart 177.1655⁷

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 Practice D 3750 or an equivalent method. The weight average

² Annual Book of ASTM Standards, Vol 10.01.

³ Annual Book of ASTM Standards, Vol 08.01.

⁴ Discontinued; See 1997 Annual Book of ASTM Standards, Vol 08.01.

⁵ Discontinued; See 1990 Annual Book of ASTM Standards, Vol 08.03.

⁶ Annual Book of ASTM Standards, Vol 13.01.

⁷ Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.