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Standard Specification for Polysulfone Resin for Medical Applications[1]

This standard is issued under the fixed designation F702; 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.

1. Scope

~~1.1This specification covers polysulfone resin (poly(oxy-*p*-phenylenesulfonyl- *p*-phenyleneoxy-*p*-phenyleneisopropylidene-*p*-phenylene)) for medical applications (as defined in Terminology D883). 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.~~

~~1.2As 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.~~

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

~~1.4The 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.~~

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

~~1.6~~

1.1 This specification covers polysulfone resin (poly(oxy-1,4-phenylenesulfonyl-1,4–phenylene (dimethylmethylene)-1,4–phenylene)) as defined in ISO 25137–1, supplied by a vendor in virgin form (pellets, powder, fabricated forms and so forth) for medical applications. This specification provides requirements and associated test methods for this thermoplastic when it 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 the production of a specific part or device. Therefore, properties of fabricated forms of this resin should be evaluated using test methods which are appropriate to ensure safety and efficacy as agreed upon by the vendor, purchaser, and regulating bodies.

1.3 The standard allows for designation of polysulfone resin for all medical applications. The actual extent of performance and suitability for a specific application must be evaluated by the vendor, purchaser, and regulating bodies.

1.4 The properties included in this specification are those applicable for unfilled polysulfone (PSU) polymers with the addition of colorants and processing aids. Indicated properties are for injection molded forms. Forms containing fillers or other additives, as well as polymer blends which contain PSU, or reclaimed materials, are not covered by this specification.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 When evaluating material in accordance with this specification, hazardous materials, operations, and equipment may be involved. *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.*

[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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2. Referenced Documents

2.1 *ASTM Standards:*[2] ~~*D149Test Method for Dielectric Breakdown Voltage and Dielectric Strength of Solid Electrical Insulating Materials at Commercial Power Frequencies*~~

D256 Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics ~~D570Test Method for Water Absorption of Plastics~~

D638 Test Method for Tensile Properties of Plastics

D648 Test Method for Deflection Temperature of Plastics Under Flexural Load in the Edgewise Position

~~D696Test Method for Coefficient of Linear Thermal Expansion of Plastics Between 30C and 30C with a Vitreous Silica Dilatometer~~

792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement

~~D883Terminology Relating to Plastics~~

~~D955Test Method of Measuring Shrinkage from Mold Dimensions of Thermoplastics~~

~~D1238Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer~~

~~D1505Test Method for Density of Plastics by the Density-Gradient Technique~~

~~D1898Practice for Sampling of Plastics~~

~~D3750Practice for Determination of Number-Average Molecular Weight of Polymers by Membrane Osmometry~~

~~F619Practice for Extraction of Medical Plastics~~ 6394 Specification for Sulfone Plastics (SP)

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

2.2 ~~*Code of Federal Regulations:*~~ *ISO Standards:*[3]

~~Title 21CFR Subpart 177.1655~~ ISO 10993 Biological Evaluation of Medical Devices

ISO 17025 General Requirements for the Competence of Testing and Calibration Laboratories

ISO 25137–1 Plastics—Sulfone Polymer Moulding and Extrusion Materials—Part I: Designation System and Basis for Specifications

3. ~~Chemical Requirements~~

~~3.1The 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 24000. The molecular weight shall be determined by osmotic pressure in monochlorobenzene using the method described in Practice D3750 or an equivalent method. The weight average molecular weight shall be equal to or greater than two times the number average molecular weight.~~

~~3.2Polysulfone 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)**~~Significance and Use

3.1 This specification is designed to recommend test methods to establish a reasonable level of confidence concerning the performance of unfilled polysulfone resins for use in medical devices. The properties listed should be considered in selecting material according to specific end-use requirements.

3.2 Polysulfones may be evaluated in implantable medical devices as well as in non-implant medical applications. Polysulfone resins intended for use in implant applications are manufactured with more rigorous use of manufacturing and/or testing controls, to assure consistency of properties, cleanliness and biocompatibility. This is further elaborated in 4.1.

~~3.3The 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~~

4. Classification

4.1 Polysulfone resin may be designated for either implant or non-implant medical applications. Designation of resins for implant applications implies that the resins are manufactured in compliance with relevant aspects of GMP (Good Manufacturing Practices), use of process validation, enhanced controls, testing in a laboratory accredited to ISO 17025, and compliance testing to ISO 10993:5 (cytotoxicity) and ISO 10993:18 (physiochemical testing).

NOTE 1—Implant uses are medical applications implanted in the human body and devices that are in contact with bodily fluids or tissues for greater than 24 h, that is, either prolonged or permanent exposure. Non-implant uses are medical applications in contact with bodily fluids or tissues for 24 h or less, that is, limited exposure.

4.2 Classes and grades of unfilled polysulfone plastics are described in Table SP, Group 1 of Specification D6394. For example, the material designation Specification D6394 SP0112 specifies a material from group 01 (polysulfone), class 1 (general purpose), and grade 2 (5 to 9 melt flow rate grade) with mechanical properties as specified in Table SP of Specification D6394.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

~~[3] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.~~

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

5. Properties and Sampling

5.1 Specification D6394 defines a sulfone plastic as an aromatic polymer containing diphenyl sulfone in the backbone of the repeat unit, and polysulfones as a member of sulfone plastics. Specification D6394 and ISO 25137–1 describe the chemical structure for polysulfone resin. The chemical structure for polysulfone is further shown in Appendix X1, and includes benzene rings joined by diphenyl sulfone and ether linkages, and includes a isopropylidene (CH3CH3C) group.

5.2 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**~~

~~4.1Polysulfone 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.~~

~~4.2Except for nonvolatile content and melt flow, the properties listed in~~). The infrared spectrum, as used in this specification, is to identify the polysulfone present and does not necessarily indicate an acceptable degree of material purity. The presence of additional bands in the IR spectrum of a sample may indicate a different sulfone polymer, such as polyether sulfone or polyphenylsulfone, or impurities, or both.

5.3 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**~~

~~5.1The material shall be sampled in accordance with the procedure described in Practice D1898 or equivalent.~~ are determined from specimens injection molded in accordance with the resin supplier's process recommendations and per Specification D6394. Additional or different treatments and processing steps (such as extrusion, molding, machining, sterilization, and so forth) may alter the material properties. Table 1 lists typical properties of non-sterilized fabricated forms.

5.4 Sampling shall be statistically adequate to satisfy the requirements of 7.3. The material shall be sampled with commonly accepted sampling procedures or other sampling techniques as agreed upon between the customer and the supplier.

6. ~~Inspection, Marking, and Packaging~~Inspection

6.1 The resin shall be inspected for particulate foreign matter contamination using the following or equivalent procedure suitable only for transparent material. Specimen plaques 2.67 ± 0.25 ~~mm (0.105 ± 0.010 in.)~~mm thick shall be injection molded

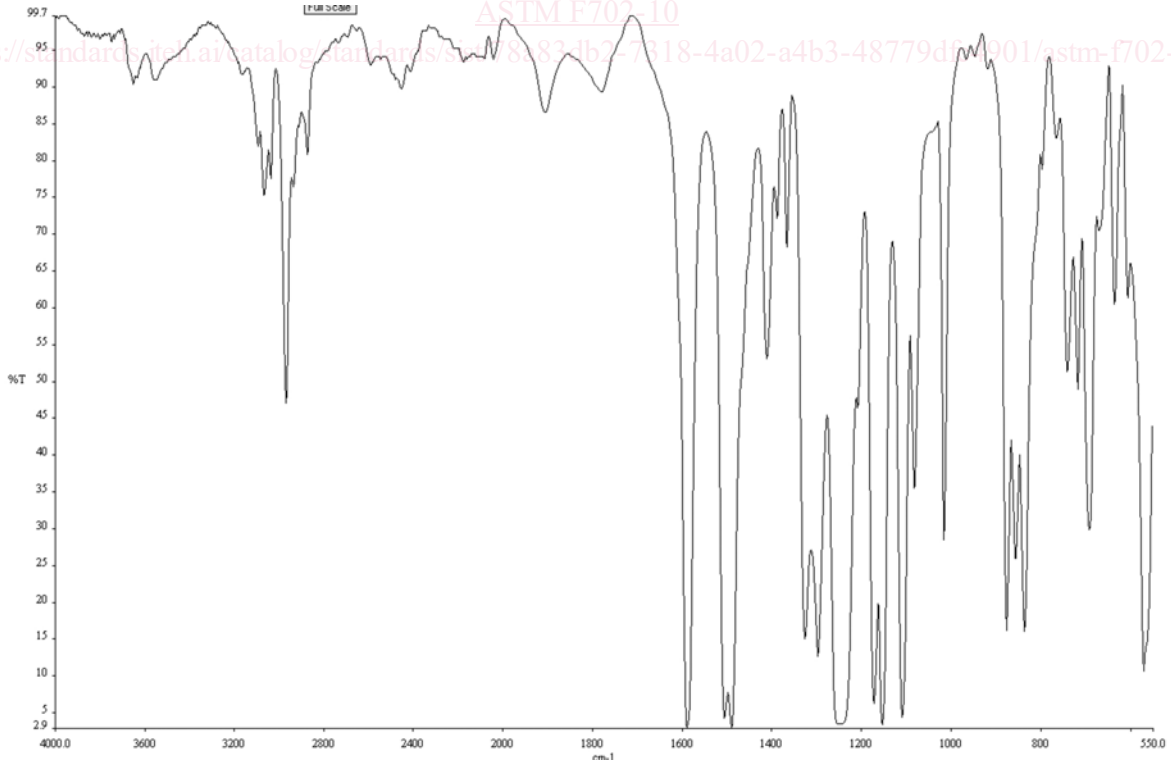

FIG. 1 Polysulfone Infrared Spectrum—Percent Transmittance