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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

1.1 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~~ safety, health, and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D256 Test Methods for Determining the Izod Pendulum Impact Resistance 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
D792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement
D6394 Specification for Sulfone Plastics (SP)
D7474 Practice for Determining Residual Stresses in Extruded or Molded Sulfone Plastic (SP) Parts by Immersion in Various Chemical Reagents
F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

2.2 *ISO Standards:*[3]

ISO ~~10993~~10993–1 Biological Evaluation of Medical ~~Devices~~Devices—Part 1: Evaluation and Testing Within a Risk Management Process

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

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. 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.

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).~~ per recommendations of ISO 10993–1.

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.

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). 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 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.

5.5 The quality of fabricated parts can be affected by residual stress from typical processing methods. Reduction of chemical resistance of Polysulfone parts is a well-known effect of high residual stress. Fabricators and end-users may use Practice D7474 as a reference on evaluation of fabricated parts to help optimize processing parameters and improve environmental stress crack resistance.

5.5.1 The use of Practice D7474 to improve resistance to environmental stress cracking does not necessarily ensure a clinically acceptable degree of performance. Therefore pre-clinical testing should be performed under conditions that simulate the in vivo environment, including environment and mechanical factors.

6. 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 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 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 of any contaminant specks present. A total level of contamination greater than a count of 12 specks shall be cause for rejection of the material. It may not be possible to evaluate foreign matter contamination by this method for opaque materials.