INTERNATIONAL

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Standard Guide for Evaluation of Thermoplastic Polyurethane Solids and Solutions for Biomedical Applications[1]

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1. Scope

1.1 This guide covers the evaluation of thermoplastic polyurethanes in both solid and solution form for biomedical applications. The polymers have been reacted to completion and require no further chemical processing.

1.2 The tests and methods listed in this guide may be referenced in specification containing minimum required values and tolerances for specific end-use products.

1.3Test values shall be stated in SI units with inch-pound units in parentheses.

1.4Standard 1.3 Standard tests for biocompatibility are included to aid in the assessment of safe utilization in biomedical applications. Compliance with these criteria shall not be constructedconstrued as an endorsement of implantability. Since many compositions, formulations, and forms of thermoplastic polyurethanes in solid and solution forms are within this material class, the formulator or fabricator must evaluate the biocompatibility of the specific composition or form in the intended use and after completion of all manufacturing processes including sterilization.

1.54 Purchase specifications may be prepared by agreement between the buyer and seller by selection of appropriate tests and methods from those listed applicable to the specific biomedical end use.

1.61.5 *This standard does not purport to address all of the safety 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:*[2]

D 149 Test Method for Dielectric Breakdown Voltage and Dielectric Strength of Solid Electrical Insulating Materials at Commercial Power Frequencies
D 150 Test Methods for acAC Loss Characteristics and Permittivity (Dielectric Constant) of Solid Electrical Insulating Materials[2]Insulation
D 257 Test Methods for dcDC Resistance or Conductance of Insulating Materials
D 395 Test Methods for Rubber Property—Compression Set
D 412 Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers-Tension[3] Test Methods for Vulcanized Rubber and Thermoplastic ElastomersTension
D 570 Test Method for Water Absorption of Plastics
D 575 Test Methods for Rubber Properties in Compression
D 671 Test Method for Flexural Fatigue of Plastics by Constant-Amplitude-of-Force
D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials
D 792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement
D 1238 Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer
D 1242 Test Methods for Resistance of Plastic Materials to Abrasion
D 1434 Test Method for Determining Gas Permeability Characteristics of Plastic Film and Sheeting
D 1544 Test Method for Color of Transparent Liquids (Gardner Color Scale)
D 1638 Methods of Testing Urethane Foam Isocyanate Raw Materials[3]

[1] This guide 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* , Vol 10.01.volume information, refer to the standard's Document Summary page on the ASTM website.
[3] Withdrawn.

D 2124 Test Method for Analysis of Components in Poly(Vinyl Chloride) Compounds Using an Infrared Spectrophotometric Technique
D 2240 Test Method for Rubber Property—Durometer Hardness
D 2857 ~~Test Method~~ Practice for Dilute Solution Viscosity of Polymers
D 2990 Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics
D 3137 Test Method for Rubber Property—Hydrolytic Stability
D 3418 ~~Test Method for Transition Temperatures of Polymers by Thermal Analysis[3]~~ Test Method for Transition Temperatures and Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry
E96~~Test Methods for Water Vapor Transmission of Materials~~
F619~~Practice for Extraction of Medical Plastics~~ 96/E 96M Test Methods for Water Vapor Transmission of Materials
F 748 ~~Practice for Selecting Generic Biological Test Methods for Materials and Devices[11]~~ Practice for Selecting Generic Biological Test Methods for Materials and Devices

2.2 *ISO Standard:*
ISO 10993 Biological Evaluation of Medical Devices[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *chain extender*—(*1*) an active hydrogen containing a compound such as a diol or diamine used to increase the molecular weight of an isocyanate-terminated prepolymer by chemical reaction; (*2*) a diisocyanate used to extend a polyol-terminated polyurethane by chemical reaction.

3.1.2 *chain terminating agent*—an active hydrogen containing a compound such as a monofunctional alcohol, amine, or acid that reacts with the isocyanate group of a prepolymer to prevent further chain growth.

3.1.3 *linear polyurethane*—a polymer whose backbone consists of urethane groups joined by hydrocarbon chains with little or no crosslinking.

3.1.4 *segmented polyurethane*—A family of polymers in which ester or ether groups, connected by hydrocarbon chains, occur as blocks that are coupled by urethane and urea groups.

3.1.5 *thermoplastic polyurethane*—linear or segmented polyurethanes that can be melted for processing without significant crosslinking or degradation. They are most frequently synthesized by reacting diols with diisocyanates.

4. Significance and Use

4.1 This guide is intended to aid device fabricators in the selection of proper commercially available polyurethane solids and solutions for their application.

4.2 The polyurethanes covered by this guide may be thermoformed or solution cast into biomedical devices for use as surgical aids or for implantation as determined to be appropriate, based on supporting biocompatibility and physical test data.

5. Descriptive Chemical Information

5.1 *Diols*—Diols that can be used for biomedical applications are as follows:
5.1.1 Poly(oxypropylene).
5.1.2 Poly(oxytetramethylene).
5.1.3 Poly(caprolactone).
5.1.4 Poly(ethylene adipate).
5.1.5 1,4-dihydroxybutane.
5.1.6 Mixture of the above diols.
5.2 *Difunctional Diisocyanates* —Difunctional diisocyanates that can be used are:
5.2.1 Diphenylmethane 4,4-diisocyanate (MDI).
5.2.2 2,4-tolylene diisocyanate (TDI).
5.2.3 1,5-naphthalene diisocyanate.
5.2.4 1,6-hexamethylene diisocyanate (HMDI).
5.3 *Chain Extenders*—Chain extenders that can be used are:
5.3.1 Water.
5.3.2 Glycols.
5.3.3 Aliphatic and aromatic diamines.
5.4 *Chain-Terminating Agents*—Chain-terminating agents suitable for use are:
5.4.1 Monofunctional alcohols, such as methanol or ethanol.
5.4.2 Monofunctional amines, such as dibutylamine or diethylamine.

[4] ~~Annual Book of ASTM Standards, Vol 08.01.~~
[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.