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Standard Specification for Polycarbonate Resin for Medical Applications[1]

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1. Scope

1.1 This specification covers polycarbonate resin and provides requirements and associated test methods for this thermoplastic when it is to be used in the manufacture of 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, assembly, 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 those test methods that are appropriate to assure safety and efficacy.

1.3 The properties included in this specification are those applicable for polycarbonate only. The biocompatibility of plastic compounds made up of polycarbonate resin containing colorants, fillers, processing aids, or other additives, as well as polymer blends which contain polycarbonate, should not be assumed. The biocompatibility of these modified polycarbonates must be established by testing the final (end-use) compositions using the appropriate methods of evaluation. In addition, the biocompatibility of the material depends to a large degree on the nature of the end-use application. It is, therefore, necessary to specify a set of biocompatibility test methods for each new and distinct application.

1.4 *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]

D256 Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics

D570 Test 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

D790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials

D792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement

D883 Terminology Relating to Plastics

D955 Test Method of Measuring Shrinkage from Mold Dimensions of Thermoplastics

D1003 Test Method for Haze and Luminous Transmittance of Transparent Plastics

D1238 Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer

D1600 Terminology for Abbreviated Terms Relating to Plastics

D1898 Practice for Sampling of Plastics (Withdrawn 1998)[3]

D3892 Practice for Packaging/Packing of Plastics

D3935 Specification for Polycarbonate (PC) Unfilled and Reinforced Material

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

2.2 *Underwriter's Laboratories Document:*

UL Standard 94 Tests and Flammability of Plastic Materials for Parts in Devices and Appliances[4]

2.3 *Code of Federal Regulations:*

Title 21 CFR Subpart 177.1580[5]

2.4 *ISO Standard:*

ISO 10993 Biological Evaluation of Medical Devices[6]

3. Significance and Use

3.1 This specification is designed to recommend physical, chemical, and biological test methods to establish a reasonable

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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] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from Underwriters Laboratories (UL), 333 Pfingsten Rd., Northbrook, IL 60062-2096, http://www.ul.com.

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

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

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level of confidence concerning the performance of unfilled polycarbonate resins for use in medical devices. The properties listed should be considered in selecting material according to the specific end-use requirements.

4. Classification

4.1 Types of polycarbonate plastics, molding, and extrusion grades are described in Specification D3935.

5. General Requirements

5.1 Polycarbonate resin may be processed by most techniques available for thermoplastic polymers. Medical devices and components of medical devices made of polycarbonate may be sterilized. Methods used successfully include steam, ethylene oxide, and irradiation. Repeated sterilization may weaken parts molded of any plastic material. The number of times a given part may be sterilized safely without fear of subsequent breakage depends on a number of factors, for example, the design of the part, the method of manufacture, the method of sterilization, the application or use of the part. Therefore, it is imperative that the manufacturer test the part to determine the maximum number of sterilization cycles to which it can be safely subjected. The function of the part should be very carefully evaluated if repeated sterilization is desired.

5.2 Polycarbonate resin is the thermoplastic carbonic-acid polyester of bisphenol-A (BPA), or 4,4′-isopropylidenediphenol, or as defined in Terminology D883.

5.3 Polycarbonate resins used in medical applications may comply with the Food and Drug Administration (FDA) Regulation 21 CFR 177.1580 which covers both wet and dry food contact applications.

5.4 The formulated compound may contain optional adjuvant substances required in the production of the polymer or in the fabrication or intended use of the end product. The biocompatibility of these adjuvant substances shall be established on the finished product in accordance with Practice F748 or ISO 10993.

6. Physical Properties

6.1 The physical properties of polycarbonate may be determined by the following: Test Methods D256, Test Method D570, Test Method D638, Test Method D648, Test Methods D790, Test Methods D792, Terminology D883, Test Method D955, Test Method D1003, Test Method D1238, Terminology D1600, and UL Standard 94.

7. Biocompatibility

7.1 Biocompatibility shall be determined in accordance with Practice F748 or ISO 10993, unless otherwise agreed upon by the supplier and consumer.

7.1.1 Biocompatibility testing should be performed on specimens that have been processed and sterilized per the methods intended for the final device.

7.1.2 Residual BPA has been implicated as a potential health risk. At present, there is no censensus on the allowable amount of BPA for medical devices, but it is suggested that steps be taken to control and minimize it. For applications in which biocompatibility testing would not be appropriate or would not discover potentially harmful levels of BPA, the concentration of residual BPA should be determined by a validated analytical technique.

8. Sampling

8.1 The material should be sampled in accordance with standard sampling procedures, such as those described in Practice D1898, or other sampling techniques unless otherwise agreed upon between consumer and supplier.

9. Packaging and Labeling

9.1 Packaging material shall meet the standards set forth in Practice D3892, unless otherwise agreed upon by packager and consumer.

10. Keywords

10.1 plastics (thermoplastic); plastic surgical devices/applications; polycarbonate (PC) plastics; polymers-surgical applications; resins-polycarbonate; seals

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 This specification was established to provide guidance in the testing of polycarbonate resins intended for use in medical device applications. It recommends test methods for the measurement of chemical, physical, and mechanical properties of unfilled resins. Tests should be selected according to end-use applications. It is intended that biocompatibility be established on the finished product by the appropriate procedures, after it has gone through all processing steps and after all adjuvant substances have been incorporated.

X2. BIOCOMPATIBILITY

X2.1 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long-term clinical experience of use of specific formulations and grades of this material referred to in this specification has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

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