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Standard Classification for Vinyl Chloride Plastics Used in Biomedical Application[1]

This standard is issued under the fixed designation F 665; 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 classification provides guidance to engineers and users in the selection of practical vinyl chloride plastics for medical applications and further provides a method for specifying these materials by use of a simple line call-out designation. This classification excludes vinyl chloride plastics used in long-term implants.

1.2 Use is made of a classification scheme based on the premise that the composition of vinyl chloride plastics, copolymers, fillers, plasticizers, stabilizers, and other additives in these systems can be arranged into characteristic material designations.

1.3 In all cases where the provisions of this classification system would conflict with those of the detailed specification for a particular device, the latter shall take precedence.

NOTE 1—For cases in which the vinyl chloride plastic may be used for purposes where the requirements are too specific to be completely described by this classification system, it is advisable for the purchaser to consult the supplier to secure adjustment of the properties to suit the actual conditions to which the device is to be subjected.

1.4 The biocompatibility of vinyl chloride plastics as a class of materials has not been established. Since many compositions and formulations fall under this class, it is essential that the fabricators/device manufacturers assure the safety and efficacy of the specific composition or formulation, in its intended application, using state-of-the-art test methods.

1.5 This classification is to assist the interface between the material supplier and the device manufacturer (fabricator) who purchases a formulated vinyl chloride plastic for a component. For those device manufacturers (fabricators) who do their own formulating, compounding, extrusion, molding, and so forth, this classification does not apply.

1.6 *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 ~~ac~~AC Loss Characteristics and Permittivity (Dielectric Constant) of Solid Electrical ~~Insulating Materials[2]~~Insulation

D 257 Test Methods for ~~de~~DC Resistance or Conductance of Insulating Materials

D 543 ~~Test Method~~ Practices for Evaluating the Resistance of Plastics to Chemical Reagents

D 570 Test Method for Water Absorption of Plastics

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

D 882 ~~Test Methods for Tensile Properties of Thin Plastic Sheeting[3]~~

~~D955Test Method of Measuring Shrinkage from Mold Dimensions of Molded Plastics[3]~~

~~D1898Practice for Sampling of Plastics~~ Test Method for Tensile Properties of Thin Plastic Sheeting

D 955 Test Method of Measuring Shrinkage from Mold Dimensions of Thermoplastics

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

F 748 ~~Practoce for Selecting Generic Biological Test Methods for Materials and Devices~~ Practice for Selecting Generic

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[1] This classification 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.

Biological Test Methods for Materials and Devices

F 1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices

2.2 *Other Standards:*

~~Title 21 Code of Federal Regulations~~

21 CFR Code of Federal Regulations[3]

2.3 *ISO Standard:*

ISO 10993 Biological Evaluation of Medical Devices[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *filler*—a relatively inert material added to a plastic to modify its strength, permanence, working properties, or other qualities, or to lower costs.

3.1.2 *plasticizer*—a substance incorporated into a material to increase its workability, flexibility, or distensibility.

3.1.3 *stabilizer*—a substance added to a plastic that will retard the deterioration of the plastic due to the effects of heat, light, or oxidation.

3.1.4 *vinyl chloride plastics*—plastics based on polymers of vinyl chloride or copolymers of vinyl chloride with other monomers, the vinyl chloride being the comonomer of the highest concentration by mass.

3.2 See Terminology F 1251 for additional terms relevant to polymers.

4. Significance and Use

4.1 This classification was developed to permit the addition of descriptive symbols and values for further new formulations with improved properties without complete reorganization of the standard and to facilitate the incorporation of future new test methods to keep pace with changing industry requirements.

5. Formulation Designation

NOTE 2—No judgment is made by ASTM as to the suitability of possible compounds classified by the following system to any specific biomedical use. Knowledge of formulation composition will only *aid* in evaluation of a composition for suitability.

5.1 A letter/number system ~~shall be used~~ that will give guidance to the engineer/user as to the nature of the formulation shall be used. A general knowledge of the types of additives employed will aid in the evaluation of a particular formulation's utility in a medical application.

5.2 *Homopolymer*—By definition, only one homopolymer is covered by this classification: poly(vinyl chloride).

5.3 *Copolymer*—The following is a representative list of major copolymers of poly(vinyl chloride). To specify ~~the~~a copolymer, use the prefix (A) followed by the number designation for the copolymer. In the event that more than one copolymer is present, separate the individual number designations by a comma.

~~[3] Annual Book of ASTM Standards, Vol 08.01.~~

[3] Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

~~[4] Discontinued; See 1997 *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.

Number Designation	Copolymer
1	none
2	vinyl acetate
3	vinylidene chloride
4	maleic ester
5	vinyl ether
6	propylene
7	ethylene
999	other

5.4 *Plasticizer*—The following is a representative list of primary monomeric and polymeric plasticizers with corresponding number designation and a list of secondary plasticizers with their corresponding letter designation. To specify the plasticizer system, use the prefix letter (B) followed by the secondary plasticizer number. In the event that there is more than one primary or secondary plasticizer, or both, separate the individual letter or number designations, or both, by a comma.

Letter Designation	Secondary Plasticizer
A	none
B	alkyl epoxy stearates
C	epoxidized tall oil
D	epoxidized soybean oil
E	epoxidized linseed oil
F	epoxidized sunflower oil
Z	other

Number	Primary Plasticizer
1	none
2	adipic acid derivatives
3	azelaic acid derivatives
4	benzoic acid derivatives
5	citric acid derivatives
6	isophthalic acid derivatives
7	myristic acid derivatives
8	phosphoric acid derivatives
9	phthalic acid derivatives
10	sebacic acid derivatives
11	terephthalic acid derivatives
12	polyethers
13	polyethylene glycols
14	polyesters
999	other

5.5 *Stabilizers*—Stabilization systems are usually composed of metal soap acceptors and auxiliary organic stabilizers. The metal soap acceptors are characterized by the metal(s) present. The following is a representative list of stabilizers. The designation is obtained by using the prefix (C) followed by the letter for the metal, followed by the number for the chelator used. In the event that more than one in each category is present, separate multiple letter or number designations, or both, by a comma.

Letter	Metal in Soap Acceptor
A	none
B	barium
C	calcium
D	cadmium
E	magnesium
F	lead
G	strontium
H	tin
I	zinc
Z	other

Number	Auxiliary Organic Stabilizer
1	none
2	organophospite
999	other

5.6 *Fillers*—The following is a representative list of fillers. The designation is obtained by using the prefix (D) followed by the number of the filler used. In the event that more than one is used, separate each number by a comma.

Number	Filler
1	none
2	clay
3	mica