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

This standard is issued under the fixed designation F665; 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]

D149 Test Method for Dielectric Breakdown Voltage and Dielectric Strength of Solid Electrical Insulating Materials at Commercial Power Frequencies

D150 Test Methods for AC Loss Characteristics and Permittivity (Dielectric Constant) of Solid Electrical Insulation

D257 Test Methods for DC Resistance or Conductance of Insulating Materials

D543 Practices for Evaluating the Resistance of Plastics to Chemical Reagents

D570 Test Method for Water Absorption of Plastics

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

D882 Test Method for Tensile Properties of Thin Plastic Sheeting

D955 Test Method of Measuring Shrinkage from Mold Dimensions of Thermoplastics

D2124 Test Method for Analysis of Components in Poly(Vinyl Chloride) Compounds Using an Infrared Spectrophotometric Technique

D2240 Test Method for Rubber Property—Durometer Hardness

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

F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices (Withdrawn 2012)[3]

2.2 *Other Standards:*

21 CFR Code of Federal Regulations[4]

2.3 *ISO Standard:*

ISO 10993 Biological Evaluation of Medical Devices[5]

3. Terminology

3.1 *Definitions:*

[1] This classification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devicesand 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] The last approved version of this historical standard is referenced on www.astm.org.

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

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

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 F1251 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 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 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.

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
4	talc
5	diatomaceous earth
6	titanium dioxide
7	calcium carbonate
8	carbon black
9	conductive carbon black
10	barium sulfate
11	Bi_2O_3

999	other

5.7 *Colorants*—The following is a representative list of colorants. The designation is obtained by using the prefix (E) followed by the number. In the event that more than one is used, separate each number by a comma.

Number	Colorant
1	none
2	titanium dioxide
3	ultramarine blue
4	phthalocyanines
5	benzidines
6	quinacridones
7	oxynaphthoic reds
8	FD & C colorants
999	other

5.8 *Lubricants*—The following is a representative list of lubricants. The designation is obtained by using the prefix (F) followed by the number. In the event that more than one is used, separate each number by a comma.

Number	Lubricant
1	none
2	stearic acid and derivatives
3	metal stearates
4	waxes
5	low molecular weight polyethylene
6	silicones
7	stearamides
999	other

5.9 *Example*—As an example of how this materials designation would be used, suppose there was a vinyl chloride plastic formulation with the following ingredients: PVC, 2 ethyl hexyl phthlate, expoxidized soybean oil, lead stearate, ultramarine blue, and stearic acid. This entire system would be characterized by the following designation: BD9CF1D1E3F2.

5.10 Many ingredients are cited by the FDA in the Food Additive Regulations (21 CFR). Since there is a very long list of possible additives to vinyl chloride plastics, it would serve as a starting point to know if all components to the formula are suitable for food contact applications. This can be designated as (Y) or (N) for yes or no at the end of the above example.

6. Main Number Designation

6.1 The main number shall define the basic physical properties of the plastic compound and shall include hardness (Shore A), tensile strength, and elongation (%). Other properties and requirements shall be covered by a suffix code.

6.1.1 *Hardness*—The first number shall define the hardness of the plastic compound by the first number of the nominal ±5 point range:

Designation	Hardness (Shore A, Test Method D2240)
0	below 5
1	10 ± 5
2	20 ± 5
3	30 ± 5
4	40 ± 5
5	50 ± 5
6	60 ± 5
7	70 ± 5
8	80 ± 5
9	See special note for special range requirement.

6.1.2 *Elongation*—The second set will be a two-digit code which shall define the minimum elongation in percent as follows:

Code	Elongation, min, % (Test Methods D882)
10	100
29	290
99	990
00	See special note for special range requirement.

6.1.3 *Tensile Strength*—The second group shall be a three-digit code which shall designate the minimum allowable tensile strength in megapascals as follows:

Code	Tensile Strength, min, MPa (psi) (Test Methods D882)
007	0.7 (100)
035	3.5 (500)
070	7.0(1000)
105	10.5(1500)
000	See special note for special range requirement.

7. Chemical, Mechanical, and Biological Properties

7.1 The specific chemical, mechanical, and biological properties shall be determined by a purchaser-seller agreement based on end use.

7.2 The following is a representative list of referee tests that may be employed to determine those properties:

Specific gravity	D792
Durometer	D2240
Tensile strength	D882
Percent elongation	D882
Modulus at specified elongation	D882
Dielectric strength	D149
Dielectric constant	D150
Volume resistivity	D257
Surface resistivity	D257
IR analysis of components	D2124
Resistance to Chemical Reagents	D543
Water Absorption	D570
Molding Shrinkage	D955

8. Biocompatibility

8.1 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 fabricator assure the safety and efficacy of the specific composition or formulation, in its intended application, using state-of-the-art test methods.

8.2 Biological tests are appropriate to determine biological and tissue reaction depending on the end-use application. These tests should be conducted when indicated for specific applications according to Practice F748 and ISO 10993.

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

9. Keywords

9.1 plastic surgical devices/application; vinyl chloride plastics

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 This classification provides definitions and a standard description for vinyl chloride plastics for biomedical applications. The guide enumerates relevant test methods and describes generic criteria which should assist in developing more specific specifications for implantable devices containing vinyl chloride plastics with values and limits covering end-use applications.

X2. BIOCOMPATIBILITY

X2.1 The suitability of these materials from a human implant perspective is dependent on the specific application. The biologic tests appropriate for the specific site, such as recommended in Practice F748 and ISO 10993 should be used as a guideline.

X2.2 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 compositions and formulations of this material class referred to in this standard has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.