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Standard Guide for
Silicone Elastomers, Gels, and Foams Used in Medical Applications Part I—Formulations and Uncured Materials[1]

This standard is issued under the fixed designation F2038; 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 guide is intended to educate potential users of silicone elastomers, gels, and foams relative to their formulation and use. It does not provide information relative to silicone powders, fluids, and other silicones. The information provided is offered to guide users in the selection of appropriate materials, after consideration of the chemical, physical, and toxicological properties of individual ingredients or by-products. This guide offers general information about silicone materials typically used for medical applications. Detail on the crosslinking and fabrication of silicone materials is found in Part II of this guide.

1.2 Fabrication and properties of elastomers is covered in the companion document, F604, Part II. This monograph addresses only components of uncured elastomers, gels, and foams.

1.3 Silicone biocompatibility issues can be addressed at several levels, but ultimately the device manufacturer must assess biological suitability relative to intended use.

1.4 Biological and physical properties tend to be more reproducible when materials are manufactured in accordance with accepted quality standards such as ANSI ISO 9001 and current FDA Quality System Regulations/Good Manufacturing Practice Regulations.

1.5 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

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.* Users are also advised to refer to Material Safety Data Sheets provided with uncured silicone components.

2. Referenced Documents

2.1 *ASTM Standards:*[2]
D1566 Terminology Relating to Rubber
F813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices

2.2 *Sterility Standards:*[3]
ANSI/AAMI ST41 Good Hospital Practice: Ethylene Oxide Sterilization and Sterility Assurance
ANSI/AAMI ST50 Dry Heat (Heated Air) Sterilizers
ANSI/AAMI ST29 Recommended Practice for Determining Ethylene Oxide in Medical Devices
ANSI/AAM1 ST30 Determining Residual Ethylene Chlorohydrin and Ethylene Glycol in Medical Devices
AAMI 13409-251 Sterilization of Health Care Products—Radiation Sterilization—Substantiation of 25kGy as a Sterilization Dose for Small or Infrequent Production Batches
AAMI TIRS-251 Microbiological Methods for Gamma Irradiation Sterilization of Medical Devices

2.3 *Quality Standards*[4]:
ANSI/ASQC Q9001 Quality Systems—Model for Quality Assurance in Design, Development Production, Installation, and Servicing
21 CFR 820 Quality System Regulation (current revision)
21 CFR 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General (current revision)
21 CFR 211 Current Good Manufacturing Practice for Finished Pharmaceuticals (current revision)

3. Terminology

3.1 Additional pertinent definitions can be found in Terminology D1566.

[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.

[4] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

3.2 *Definitions:*

3.2.1 *silicone polymer*—polymer chains having a backbone consisting of repeating silicon-oxygen atoms where each silicon atom bears two organic groups. The organic groups are typically methyl, but can be vinyl, phenyl, fluorine, or other organic groups.

3.2.2 *cyclics and linears*—low molecular weight volatile cyclic siloxane species are referred to using the "D" nomenclature which designates the number of Si-O linkages in the material (usually D_4-D_{20}); species from D_7 to D_{40} (or more) may be called "macrocyclics". Linears are straight chain oligomers that may be volatile or of higher molecular weight, depending on chain length; they are designated by "M" and "D" combinations, where "M" is R_3Si-O, and D is as explained above; "R" is usually methyl. (For example, MDM is $(CH_3)_3SiOSiOSi(CH_3)_3$). Low molecular weight species are present in silicone components to varying degrees depending on process and storage. The levels of macrocyclics that can be removed from silicone polymers by vacuum, high temperature stripping, or oven post-cure is dependent on the conditions used.

3.2.3 *catalyst*—a component of a silicone elastomer formulation that initiates the crosslinking reaction when the material is vulcanized.

3.2.4 *crosslinker or crosslinking agent*—a component of a silicone elastomer that is a reactant in the crosslinking reaction that occurs when an elastomer is vulcanized.

3.2.5 *inhibitor*—a component of a silicone elastomer added to moderate the rate of the crosslinking reaction.

3.2.6 *filler*—a finely divided solid that is intimately mixed with silicone polymers during manufacture to achieve specific properties. The fillers used in silicone elastomers are one of two types:

3.2.6.1 *reinforcing fillers*—usually have high surface areas and are amorphous in nature such as fumed or precipitated silica. Such fillers impart high strength and elastomeric physical properties to the elastomer.

3.2.6.2 *extending fillers*—typically have lower surface area and lower cost than reinforcing fillers. They include crystalline forms of silica and diatomaceous earths. While they provide some reinforcement, because they are relatively inexpensive, they are used primarily to extend the bulk of the silicone.

3.2.7 *additives*—a component of a silicone elastomer used in relatively small amounts to perform functions such as marking, coloring, or providing opacity to the elastomer.

3.2.8 *silicone base*—a uniformly blended mixture of silicone polymers, fillers, and additives which does not contain crosslinkers or catalyst.

3.2.9 *uncured elastomer*—a silicone base which contains crosslinker and/or catalyst but has not been vulcanized.

3.2.10 *silicone elastomer*—an uncured elastomer that has been subjected to conditions which cause it to become crosslinked. Elastomers may be either high consistency rubbers, low consistency rubbers, or RTVs (see below).

3.2.10.1 *high consistency rubbers (HCRS)*—are materials which cannot be pumped by conventional pumping equipment. They normally must be processed using high shear equipment such as a two-roll mill and parts are typically fabricated using compression or transfer molding techniques.

3.2.10.2 *low consistency rubbers or liquid silicone rubbers (LSRS)*—are normally flowable materials which can be readily pumped. They can be mixed by pumping through static mixers and parts can be fabricated using injection molding techniques.

3.2.10.3 *RTVs (room temperature vulcanization)*— are one-part elastomers which cure in the presence of atmospheric moisture. Little, if any, acceleration of cure rate is realized by increasing temperature. Because cure is dependent upon diffusion of water into the elastomer, cure in depths greater than 0.25 in. (0.635 cm) is not recommended.

3.2.10.4 *gels*—are lightly crosslinked materials having no or relatively low levels of reinforcement beyond that provided by the crosslinked polymer. They are usually two-part formulations utilizing a platinum catalyzed addition cure system. The hardness of the gel can be adjusted within wide limits. The material is not usually designed to bear heavy loads but rather to conform to an irregular surface providing intimate contact. As a result, loads are distributed over a wider area. These materials may also be used to provide protection from environmental contaminants.

3.2.10.5 *foams*—are crosslinked materials which have a component added to them that generates a volatile gas as the material is being vulcanized. This results in a material with a very low density. These are usually two-part formulations utilizing a platinum catalyzed addition cure system. They conform to an irregular surface as they expand to provide intimate contact and protection from the environment but are more rigid and provide more strength than gels. Since foams are expanded elastomers, on a weight basis they are highly crosslinked relative to gels. Most cure conditions will result in a closed cell foam.

3.2.11 *lot or batch*—a quantity of material made with a fixed, specified formulation in a single, manufacturing run carried out under specific processing techniques and conditions.

3.2.12 *vulcanization*—an irreversible process in which covalent chemical bonds are formed between silicone polymer chains. During vulcanization, the material changes from a flowable or moldable compound to an elastomeric material which cannot be reshaped except by its physical destruction.

3.2.13 *types of cure*—based upon the cure chemistry employed, silicone elastomers used in medical applications fall into one of three categories: condensation cure, peroxide cure, and addition cure.

3.2.13.1 *condensation cure*—these materials liberate an organic leaving group during curing and are normally catalyzed by an organometallic compound.

one-part—material supplied ready to use in an air tight container which cures upon exposure to atmospheric moisture. The material cures from the surface down and cure depths of greater than about 0.25 inches (0.635 cm) are not practical.

two-part—material supplied in two separate containers which must be intimately mixed in the prescribed proportions shortly before use. Because they do not rely upon dispersion of atmospheric moisture into the silicone, the cure depth is not limited.

3.2.13.2 *peroxide cure*—one-part formulations vulcanized by free radicals generated by the decomposition of an organic peroxide.

3.2.13.3 *addition cure*—two-part elastomers which must first be mixed together and then cure by addition of a silylhydride to a vinyl silane in the presence of a platinum catalyst.

3.2.14 *dispersion*—an uncured silicone elastomer dispersed in a suitable solvent to allow application of a thin layer of elastomer to a substrate by either dipping or spraying.

4. Significance and Use

4.1 This guide is intended to provide guidance for the specification and selection of silicone materials for medical device applications.

4.2 Silicone manufacturers supplying materials to the medical device industry should readily provide information regarding non-proprietary product formulation to their customers either directly, or through the US FDA master file program.

5. Formulation

5.1 Elastomers, gels, and foams shall be manufactured using formulations containing combinations of the following raw materials.

5.1.1 *silicone polymer*—any polymer of medium or high molecular weight of the structure shown in Fig. 1 where R is a methyl, an unsaturated alkyl group or a hydroxy group, R is generally a methyl or an unsaturated alkyl group but may also be a phenyl, trifuoropropyl, or other hydrocarbon radical, and x and y are integers greater than or equal to zero. At least 2.0 alkenyl groups must exist per chain if R is not a hydroxy group.

5.1.2 *catalyst*—an organometallic complex of platinum or tin bonded to ligands made of any suitable combination of elements such as carbon, hydrogen, oxygen, fluorine and silicon.

5.1.2.1 *platinum*—this catalyst may be dispersed in a silicone polymer of the structure shown in Fig. 1 having a viscosity low enough that the resulting dispersion is easily pourable. Platinum catalysts can be used in the range of 5 to 20 ppm of active platinum but typically are present at about 7.5 ppm.

5.1.2.2 *tin*—one-part condensation cure formulations will typically contain from 0.1 to 0.5 wt percent of an organotin compound. Two-part condensation cure formulations will typically contain from 0.5 to 2.0 weight percent organotin compound. The ligands attached to tin will be some combination of alkyl groups, alkoxy groups, or the anions of a carboxylic acid.

5.1.3 *Crosslinker or crosslinking agent:*

5.1.3.1 *Two-part, addition cure formulation*—the crosslinker is a polymer of the structure shown in Fig. 2 where R is generally a methyl or a hydrogen group such as to provide at least 2.0 SiH groups per chain and x and y are integers greater than or equal to zero. In order to avoid chain extension, the functionality of either the vinyl-containing polymer or the SiH-containing crosslinker must be at least 3.0.

Because of the limitless possibilities for the structure of both the crosslinker and the functional (vinyl containing) polymer, it would be meaningless to define a weight range for the level of crosslinker in a formulation. However, the amount of crosslinker will typically be sufficient to provide a stoichiometric excess of SiH groups over the amount of unsaturated alkyl groups when the 2 components (parts) of the addition cure silicone elastomer are mixed together in the manufacturer's recommended ratio.

5.1.3.2 *One-part RTVs and two-part addition cure formulations*—the crosslinker may be an organosilane monomer of the general formula:

$$R_xSi(OR')_{4-x} \quad (1)$$

where:

R = organic group excluding phenyl
OR' = hydrolyzable group such as alkoxy, acetoxy, ketoximo, etc.

5.1.3.3 *Peroxide vulcanized elastomers*—organic peroxides comprise a third type of crosslinking agent which participates in the crosslinking reaction that does not become directly incorporated into the crosslinked network. Peroxide levels range from less than a percent to as high as a couple of weight percent in the total formulation. These peroxides decompose, at a rate which is dependent upon the temperature, to form radicals which then abstract hydrogen atoms from some of the alkyl groups attached to the silicone backbone. Recombination of these radicals results in the formation of a crosslinked silicone network. One commonly used peroxide is 2,4,-dichlorobenzoyl peroxide. Decomposition of this peroxide results in the formation of small amounts of polychlorinated biphenyls and other catalyst decomposition by-products which must be, and are, removed from the cured elastomer during post-curing.

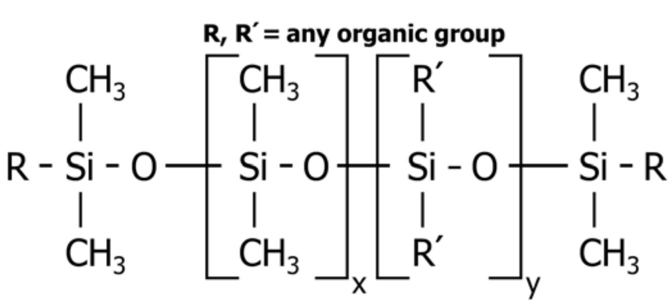

FIG. 1 Typical Polymeric Silicone Dispersing Agent

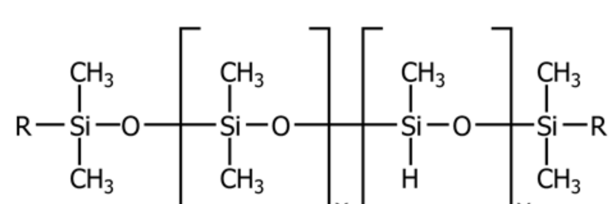

FIG. 2 Typical Polymeric Crosslinker Agent