

Factor II, Inc.

MEDICAL GRADE ELASTOMER

A-103

DESCRIPTION

Medical Grade Elastomer is a pourable two-component product which, when combined, cures to a translucent silicone rubber at room temperature or slightly elevated temperatures. The elastomer component consists of a dimethylsiloxane polymer, a reinforcing silica and a platinum catalyst. The curing agent component consists of a dimethylsiloxane polymer, an inhibitor and a siloxane crosslinker. Medical Grade Elastomer is made to exacting specifications to meet high quality standards for medical applications.

Advantages of this product include:

Room-temperature and heat-accelerable cure

Good thick section cure

Excellent dielectric properties

Essentially no shrinkage when cured at room temperature

is designed for use in medical device

APPLICATIONS

encapsulating and moldmaking applications where cure is at room temperature or slightly elevated temperatures. It has, for example, been used as a flexible mold to facilitate the encapsulation of electronic components of biomedical devices. It can also be used as a drug matrix for controlled release drug delivery systems. The purchaser should thoroughly test products made in part or otherwise incorporating Medical Grade Elastomer to determine the acceptability of the product's performance in a specific application.

INSTRUCTIONS FOR USE

Mixing

Thoroughly mix one part of curing agent with 10 parts by weight of the base elastomer. The viscosity of the mix will be about one-half of the original base viscosity. During mixing, care should be taken to minimize entrapment of air.

De-Airing

If a void-free finished part is desired, the entrapped air must be removed from the mixed materials. Exposure to a vacuum of about 28 inches of mercury for approximately 30 minutes is usually adequate. Release of the vacuum several times during the early phase will help break the bubbles that form. After de-airing, if the materials are to be cured at elevated temperatures, let the material stand for 10 minutes to allow the remaining traces of gasses to escape from the material. The container holding the material should be at least four times the volume of the mixture to allow for expansion.

Curing

A cure of approximately 24 hours at 23°C (73°F) is required for the material to be sufficiently cured for handling. Full cure is achieved in

Table I: Compatibility of Medical Grade Elastomer

Test	Results
Pyrogenicity.....	Nonpyrogenic*
Intracutaneous Injection.....	.Nonirritating*
SystemInjection	Nontoxic*
Skin Sensitization	Nonsensitizing*
Intramuscular Implant	
10 days	Nonreactive*
30 days	Nonreactive*
90days	Nonreactive*
Cell Tissue Culture	No Cytopathic effect

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications

about three days at room temperature. The cure may be accelerated with any of the following schedules:

- 5 hours.....40°C (104°F)
- 2 hours.....55°C (131°F)
- 30 minutes 75°C (167°F)
- 15 minutes 100°C (212°F)

Large parts with thick cross sections may require a longer time to compensate for the time needed to heat the entire part to the desired curing temperature.

Thin films of Medical Grade Elastomer may cure more slowly at room temperature. Slight heating will accelerate the cure of these films.

Use of Silicone Fluid to Modify Properties

The consistency of Medical Grade Elastomer may be lowered by adding *Factor II*® 360 Medical Fluid (100 cs viscosity). The fluid may be premixed with either the base or the curing agent. The addition of *Factor II* 360 Medical Fluid will lengthen working and vulcanization times and result in lower physical properties. **Caution:** The added fluid can be readily extracted with solvents and may impart a slightly oily surface.

Cure Compatibility

Medical Grade Elastomer will cure in contact with many materials. However, exceptions that have been noted are chlorinated and butyl rubbers, some RTV silicone rubbers, and the unreacted components of some plastics. Often, troublesome substrates that inhibit the proper curing of Medical Grade Elastomer can be made compatible by solvent washing or by heating.

Bonding and Release

Medical Adhesive Silicone A can be used to bond cured Medical Grade Elastomer to other silicone elastomers and many other materials.

As Supplied

CTM ¹	ASTM Test	Value
0050	D 1084 Base Viscosity, poise	1150
	Viscosity ² , poise	
0050	D 1084 Initial ³	600 0050
D 1084	After 2 hours	1100
When 100 parts of Medical Grade Elastomer and 10 parts of the curing agent are mixed, de-aired, press-cured for three minutes at 150°C (302°F), post-cured one hour at 150°C (302°F) and stabilized for three hours at room temperature, the following typical properties will be obtained on a 0.075-inch slab:		
As Cured		
CTM	ASTM Test	Value
0063	Color	Translucent 0022
D 792	Specific Gravity ⁴ , at 25°C (77°F)	1.10 0099 D
2240	Durometer Hardness, Shore A, points	27 0137A D 412
	Tensile Strength, psi	650 0137A D 412
	Elongation, percent	500 0274 –
	Tissue Culture	No CPE 0114 D 149
	Dielectric Strength, volts per mil	575 0249 D 257
	Volume Resistivity, ohm-cm	2 x 10 ¹⁵
	Dielectric Constant	
0112	D 150 100 Hz	3.01 0112 D 150
100kHz		3.00
	Dissipation Factor	
0112	D 150 100 Hz	9 x 10 ⁻⁴
0112	D 150 100 kHz	10 x 10 ⁻⁴
0249	D 257 Surface Resistivity	>7 x 10 ¹⁶

Specification Writers: Please obtain a copy of the Factor II's Sales Specification for this product and use it as a basis for your specifications. It may be obtained from any Factor II Sales Office, or from Factor II's Customer Service .

CAUTION

Commercially available RTV primers have been used to enhance the adhesion of to some metal and plastic surfaces; however, Factor II has not conducted tests of these primers for biomedical applications. In molding will normally release well from smooth unprimed surfaces other than glass. A release agent may be used to ensure Trouble-free releases. One useful release agent consists of a two to five percent water solution of a mild soap such as *Ivory Liquid*

Cure Inhibition
The cure of may be inhibited by traces of amines, sulphur, nitrogen oxide, organo-tin compounds and carbon monoxide. Because organic rubbers often contain these substances, they should not come in Contact with the uncured elastomer and curing agent. Catalyst residues from silicone elastomers that have

been catalyzed by tin salts or peroxides may also inhibit cure.

BIOCOMPATIBILITY

Biocompatibility tests, which meet or exceed current USP Class VI tests, have been performed on MDX44210 Medical Grade Elastomer and are shown in Table I.

Using a tissue culture test (direct contact method), every production lot of elastomer is tested for the absence of cytopathic effects.

Testing for levels of trace metals is also performed on each lot.

SHIPPING LIMITATIONS

None.

STORAGE AND SHELF LIFE

When properly stored at ambient conditions in the original, unopened containers, Medical Grade Elastomer has a shelf life of 24 months from date of manufacture.

PACKAGING

Medical Grade Elastomer is available in 1, 11-, 55- and 440-lb (5-, 25- and 200-kg) kits, which contain an elastomer and a curing agent in the ratio required for mixing. All weights are net.

ORDERING

To order this product, call 1-928-537-8387.

IMPORTANT INFORMATION

These tests are intended only to provide an initial biocompatibility screen for this material. It is the user's responsibility to ensure the safety and efficacy of this material for all intended uses. While this material has passed certain biocompatibility screening tests that are applicable to products intended to be implanted for fewer than 30 days, Factor II makes no end-use representation based on such testing. Nor does Factor II make any representation concerning the suitability of this product intended to be implanted for 30 or more days.

SAFE HANDLING INFORMATION

PRODUCT SAFETY INFORMATION REQUIRED FOR SAFE USE IS NOT INCLUDED. BEFORE HANDLING, READ PRODUCT AND MATERIAL SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE MATERIAL SAFETY DATA SHEET IS AVAILABLE FROM YOUR FACTOR II REPRESENTATIVE, OR DISTRIBUTOR, OR BY WRITING TO FACTOR II CUSTOMER SERVICE, OR BY CALLING 928-537-8387

LIMITED WARRANTY – PLEASE READ CAREFULLY

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