

# Healthcare

Medical Adhesive Silicone, is a one-component, low-slump, translucent silicone material for bonding elastomers, synthetics and metals for part fabrication and medical devices.

### TYPICAL PROPERTIES

Specification these values are not intended for use in preparing specifications. Please contact your local Factor II sales representative prior to writing specifications on this product.

### FEATURES

- Cures at room temperature when exposed to atmospheric moisture
- Translucent paste
- Provided in ready-to-use containers
- Available sterile and non-sterile
- Easy to apply and use

### DESCRIPTION

Medical Adhesive Silicone, is a one-component, low-slump, translucent silicone used to permanently bond materials. It contains no solvents and cures at room temperature upon exposure to atmospheric moisture. During the curing process, the silicone adhesive releases acetic acid vapor as a by-product. After final cure, the resulting silicone elastomer possesses the appearance, texture and general composition of many conventional silicone elastomers.

### BENEFITS

- Solvent-free

### Properties

### HOW TO USE Surface preparation

Surfaces to be bonded or built-up with silicone adhesive should be cleaned thoroughly with non-oily cleaners or mild soap to remove possible surface contaminants. Rinse copiously with hot water and follow with a thorough rinse using distilled water. Allow surface to dry.

CTM <sub>1</sub>	AST M	Property	Unit	Value
0176		Appearance, uncured		Translucent paste
0098		Skin-over time at 55% R.H.	minutes	7-8
022	D742	Specific gravity at 25°C (77°F)		1.06
0099	D224	Durometer hardness, Shore A <sub>s</sub>		35
0137A	D412	Tensile strength <sub>s</sub>	MPa (psi)	3.3 (480)
0137A	D412	Elongation at break <sub>s</sub>	%	450

### How to apply

Apply Medical Adhesive Silicone, to one of the prepared surfaces, and then quickly cover with the other substrate to be bonded. Apply sufficient pressure to ensure full contact, without forcing the silicone out from between the pieces. For best results, maintain a bond thickness of at least 0.25mm.

Under ambient conditions, the adhesive forms a thin, tack-free outer skin for thick-section films within a few minutes after application. Any shaping of the uncured adhesive should be completed before the skin forms.

### Cure time

Curing or vulcanization time depends on the thickness of the silicone adhesive layer, the relative humidity and the accessibility of atmospheric moisture to the curing adhesive. Cure time is extended at lower humidity levels. Dry heat will not accelerate the cure and should not be used for at least the first 7 hours.

A 2mm thick sheet of silicone elastomer bonded to stainless steel requires approximately 24 hours for complete vulcanization. Bond strength, however, continues to increase for several days. A 6.4mm thick sheet of silicone elastomer bonded to stainless steel under the same conditions requires 48 to 96 hours for complete vulcanization.

If the relative humidity is greater than 60% when curing, a tacky surface may occur -especially with thin films. The tackiness can be removed by exposing the surface to a dry atmosphere.

### Dispersion

Medical Adhesive Silicone, Type A may be dispersed in moisture free aliphatic, aromatic or halogenated hydrocarbon solvents such as hexane or toluene. To disperse, the adhesive is added to the solvent and then agitated until a homogenous dispersion is obtained. A 10% concentration of Medical Adhesive Silicone, by weight will disperse in about 10 minutes when shaken by hand. The dispersion may be applied by brushing, dipping or spraying. A thin coat of cured silicone elastomer will result. Free films and membranes can be formed by coating the dispersion on suitable release sheets, such as polyethylene. If a release agent is needed, a one percent mild, non-oily soap solution may be used. The mild soap release agent may be removed after cure by repeated rinsing with water.

NOTE: When using any solvent, always provide adequate ventilation. When using flammable solvents, take precautions to prevent fire or explosion. Follow precautions on solvent container label.

### REGULATORY STATUS

A Drug Master File (DMF) for Medical Adhesive Silicone is on file with the U.S. Food and Drug Administration.

### IMPORTANT INFORMATION

#### THE USER'S ATTENTION IS IN PARTICULAR DRAWN TO THE FOLLOWING STATEMENT:

It is the User's responsibility to ensure the safety and efficacy of this material for all intended uses. While this material has passed screening tests that are applicable to products intended or implantation for up to 29 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 for applications of greater than 29 days of implantation in the human body.

### HANDLING PRECAUTIONS

Product safety information required for safe use is not included. Before handling, read product and safety data sheets and container labels for safe use, physical and health hazard information.

### USABLE LIFE AND STORAGE

When stored at or below 32°C (90°F) in the original unopened containers, this product has a usable life of 24 months from

## PACKAGING

This product is available in 90 gram tubes and 6 ounce Semco cartridges.

The Medical Adhesive Silicone, once opened, sterilization of the tube and its uncured contents is not recommended. The exterior of the tube and cap are non-sterile. They must be sterilized in a secondary packaging operation using either gamma irradiation or ethylene oxide to maintain product sterility during opening the tube. If irradiation is used, it is the user's responsibility to evaluate the effects of sterilization on the physical properties and usable life of the adhesive. If ethylene oxide sterilization is used, the gas will not penetrate the adhesive tube and will have no effect on the contents. It is the user's responsibility to validate either sterilization method to ensure sterility of the exterior and cap. **DRY HEAT OR STEAM STERILIZATION MUST NOT BE USED AS THEY WILL MELT THE CAP.**

Once sterilized, only the cap supplied with the adhesive should be used to open the blind end tube. Using the piercing pin side of the cap, push the pin straight into the tube. Remove the pin/cap and dispense the amount of adhesive

desired. **TO AVOID CONTAMINATION, USE ONLY THE CAP PROVIDED WITH THE ADHESIVE AND PUSH THE PIERCING PIN STRAIGHT IN.**

## QUALIFICATION TESTING

The results of selected qualification tests are shown in Table 1. A summary of health data is available upon request.

## ORDERING AND PRODUCT INFORMATION

For ordering and product information, contact Factor II, Inc.

## QUALITY ASSURANCE

Medical Adhesive Silicone is manufactured using appropriate principles of current Good Manufacturing Practice (GMP). Factor II operates a quality management system in accordance with the standard, ensuring full documentation and traceability.

For further information, please see our website, [www.factor2.com](http://www.factor2.com) or contact representative at Factor II, Inc.

## LIMITED WARRANTY INFORMATION PLEASE READ CAREFULLY

The information contained herein is

offered in good faith and is believed to be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customers' tests to ensure that Factor II's products are safe, effective, and fully satisfactory for the intended end use.

Suggestions of use shall not be taken as inducements to infringe any patent.

Factor II's sole warranty is that the product will meet the Factor II sales specifications in effect at the time of shipment.

Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

**FACTOR II SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.**

**FACTOR II DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.**

Table 1: Selected Qualification Data for Medical Adhesive Silicone, <sup>1</sup>

Test Samples tested Summary result

Cell culture<sup>2</sup> Cured adhesive No cytopathic effect

Cell culture medium extract of cured adhesive No cytopathic effect USP Pyrogen Saline extract of cured adhesive Non-pyrogenic

Skin sensitization<sup>3</sup> • Cured adhesive Saline extract of cured adhesive No sensitization

Acetone extract of cured adhesive

Mutagenicity • Acetone extract of cured adhesive No evidence of genetic activity or cytotoxicity

Saline extract of cured adhesive in the bacterial reverse mutation assay USP Class V • Saline extract of cured adhesive

Systemic toxicity • Extract of cured adhesive in 5% ethanol/95% saline Non-irritating and non-toxic relative to

Intracutaneous reactivity<sup>3</sup> • PEG 400 extract of cured adhesive controls

• Cottonseed oil extract of cured adhesive

Prior to testing cured adhesive was sterilized @ 120 degrees C for 20 mins @ 15 psi

Because the adhesive cures upon exposure to atmospheric moisture, tubes of Medical Adhesive Silicone, must be kept tightly closed when not in use. A plug of cured material may form in the tip of the tube or cartridge during storage. The plug is easily removed and does not affect the remaining contents