Product Information
Healthcare

DOW CORNING

Silastic® Medical Adhesive Silicone, Type A

FEATURES & BENEFITS

- 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
- Solventless

COMPOSITION

- One-component adhesive/sealant

Silicone adhesive/sealant

APPLICATIONS

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

TYPICAL PROPERTIES

Specification Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office or your Global Dow Corning Connection before writing specifications on this product.

CTM[1]	ASTM[2]	Property	Unit	Value
0176		Appearance, uncured		Translucent paste
0098		Skin-over time, at 55% RH	Min	7-8
022	D742	Specific gravity, at 25°C (77°F)		1.06
0099	D2240	Durometer hardness [3]	Shore A	35
0137A	D412	Tensile Strength[3]	MPa Psi	3.3 480
0137A	D412	Elongation at break[3]	%	450

[1]CTM: Corporate Test Method, copies of CTMs are available on request.
[2]ASTM: American Society for Testing and Materials.
[3]Mechanical properties for adhesive cured a minimum of 72 hours in air at 23°C (73.4°F) and 50% relative humidity.

DESCRIPTION

Silastic Medical Adhesive Silicone, Type A is a one-component, low-slump, translucent silicone used to permanently bond materials. It is solventless 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.

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 with distilled water. Allow surface to dry.

How to Apply
Apply *Silastic* Medical Adhesive Silicone, Type A to one of the prepared surfaces, 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 0.25 mm.

Under ambient conditions, the adhesive forms a thin, without tackiness 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 upon 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 72 hours.**

A 2 mm 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 6.4 mm 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 percent 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
Silastic Medical Adhesive Silicone, Type A may be dispersed in moisture-free aliphatic, aromatic or halogenated hydrocarbon solvents such as hexane or toluene. *Dow Corning*® Q7- 9180 Silicone Fluid may also be used. To disperse, the adhesive is added to the solvent and then agitated until a homogenous dispersion is obtained. A 10 percent concentration of *Silastic* Medical Adhesive Silicone, Type A 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.

QUALIFICATION TESTING
The results of selected qualification tests are shown in Table 2. A summary of health data is available upon request.

ORDERING AND PRODUCT INFORMATION
For ordering and product information, contact your local Dow Corning Global Connection.

QUALITY ASSURANCE
Silastic Medical Adhesive Silicone, Type A is manufactured using appropriate principles of current Good Manufacturing Practice (cGMP). The Dow Corning Healthcare Industries Materials Site (HIMS) in Hemlock, MI, is dedicated to the production of silicone materials for healthcare applications. It is registered with the FDA (CFN 1816403) as a Drug Establishment. Dow Corning is globally registered to the ISO 9001 Quality Standard. Registration certificate number FM 10734 has been obtained through the British Standards Institution (BSI). Certification to ISO 9001 through an independent third party indicates that Dow Corning operates a quality management system in accordance with the standard, ensuring full documentation and traceability.

REGULATORY STATUS
A Drug Master File (DMF) for *Silastic* Medical Adhesive Silicone, Type A is on file with the U.S. Food and Drug Administration. Customers interested in authorization to reference the file must contact Dow Corning Corporation.

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 for implantation for up to 29 days, Dow Corning makes no end-use representation based on such testing. Nor does Dow Corning 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 IN THIS DOCUMENT. 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 ON THE DOW CORNING WEBSITE AT DOW CORNING.COM, OR FROM YOUR DOW CORNING SALES APPLICATION ENGINEER, OR DISTRIBUTOR, OR BY CALLING DOW CORNING CUSTOMER SERVICE.

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USABLE LIFE AND STORAGE

When stored at or below 100°C (212°F) in the original unopened containers, this product has a usable life of 24 months from the date of production.

Because the adhesive cures upon exposure to atmospheric moisture, tubes of *Silastic* Medical Adhesive Silicone, Type A 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.

PACKAGING INFORMATION

This product is available in 6 gram and 57 gram squeeze tubes, 340 gram cartridges, and 18 kilogram pails.

The *Silastic* Medical Adhesive Silicone, Type A supplied in the 6 gram tube is pre-sterilized. This tube size is for single use only. Once opened, resterilization 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 in order 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 shelf 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.

The tubes used to supply the 6 gram quantities of sterile *Silastic* Medical Adhesive Silicone, Type A have blind ends. 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.

The *Silastic* Medical Adhesive Silicone, Type A supplied in sizes other than the 6 gram tube is non-sterile in non-sterile packaging.

HEALTH AND ENVIRONMENTAL INFORMATION

To support Customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Product Safety and Regulatory Compliance (PS&RC) specialists available in each area.

For further information, please see our website, dowcorning.com or consult your local Dow Corning representative.

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 our 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.

Dow Corning's sole warranty is that our products will meet the 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.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

DOW CORNING DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

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Table 2: Selected Qualification Data for *Silastic* Medical Adhesive Silicone, Type A

Test	Samples tested	Summary Result
Cell Culture[1]	Cured adhesive	No cytopathic effect
	Cell culture medium extract of cured adhesive	No cytopathic effect
USP Pyrogen	Saline extract of cured adhesive (cured and autoclaved at 121°C for 20 min)	Non-pyrogenic
Skin sensitization[1]	• Cured adhesive • Saline extract of cured adhesive • Acetone extract of cured adhesive	No sensitization
Mutagenicity	• Acetone extract of cured adhesive • Saline extract of cured adhesive	No evidence of genetic activity or cytotoxicity in the bacterial reverse mutation assay.
USP Class V • Systemic Toxicity • Intracutaneous Reactivity[1]	• Saline extract of cured adhesive • Extract of cured adhesive in 5% ethanol/ 95% saline • PEG 400 extract of cured adhesive • Cottonseed oil extract of cured adhesive	Nonirritating and nontoxic relative to controls
Implant	Cured adhesive	Reaction equivalent to or less than negative control at 7, 30 and 90-days post-implantation

[1]Tests meet ISO 10993-1 requirements for Surface Devices with "limited" (<24 hours) or "prolonged" (1 to 30 days) contact duration.