Product Information
Healthcare

DOW CORNING

Dow Corning® 7-9600 Soft Filling Elastomer Parts A&B

FEATURES & BENEFITS

- Transparent before and after curing
- Low viscosity before curing for easy processing
- Platinum-catalyzed
- Versatile cure cycles
- No cure by-products
- Adhesion to polyurethane film
- Pigmentable
- Non-sensitizing

COMPOSITION

- Two-part filler-free silicone elastomer

Two-Part, Filler-Free Elastomer

APPLICATIONS

- Commonly used to fill devices such as external prostheses and pressure cushions.

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.

Test*	Property	Unit	Result
CTM 0176	Appearance		Clear
CTM 0050	Viscosity Part A	mPa.s	400
CTM 0050	Viscosity Part B	mPa.s	400
	Penetration after cure	mm/10	245–275
CTM 0055	Cure Rate (1 hour)	mPa.s	>1500
CTM 1228	Penetration after cure	mm/10	245–275

*CTM: Corporate Test Method, copies of CTM's are available on request.

DESCRIPTION

Dow Corning® 7-9600 Soft Filling Elastomer is a 2-part, platinum-catalyzed silicone elastomer useful in producing a cohesive and soft feeling material for biomedical applications. This adhesive elastomer is based on a platinum-catalyzed polydimethysiloxane composition that will cure at a variety of temperatures, from ambient to 140°C (284°F), without the formation of by-products. The elastomer is supplied as a two-component kit (Part A and Part B), equal portions (by weight) of which must be thoroughly blended together prior to use.

HOW TO USE

Mixing

Thoroughly mix the desired amount of part A and part B in a 1: 1 ratio by weight. One-shot blending systems or continuous static mixers can be used. During mixing, care should be taken to minimize entrapment of air. Airless mixing, metering and dispensing equipment is recommended for large production processing.

De-airing

If a void-free finished part is desired, the entrapment air must be removed from the mixed materials. Exposure to a residual pressure of 45 Torr (28 inches of mercury) for approximately 2 minutes is usually adequate.

Release of the vacuum several times during the early phase will help break the bubbles that form. The container holding the material should be at least four times the volume of mixture to allow for expansion.

Curing
The cure reaction will begin once the two parts have been mixed. The initial viscosity can double within 1 to 3 hours depending on the temperature. If the material is not processed within this time frame, it can no longer be molded, coated or cast. Refrigeration and/or freezing may extend the pot life, but care must be taken to avoid any moisture contamination due to condensation. The cure reaction will occur at room temperature, however heating will accelerate the process. Cure conditions will depend upon the amount and thickness of elastomer to be cured.

Cleaning
To remove uncured elastomer, *Dow Corning*® Q7-9180 (0.65cSt) Silicone Fluid, isopropyl alcohol, ethyl acetate, xylene, or heptane can be used. When the elastomer is cured, the greater part should be removed with a paper towel or spatula, and the remaining material should be removed with one of the above solvents.

MANUFACTURING ENVIRONMENT
Dow Corning® Healthcare Products are manufactured under strict quality control guidelines. The Healthcare Industries Materials Site (RIMS) 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. The site quality system is based on principles of current Good Manufacturing Practices for both Bulk Pharmaceutical Products and Medical Devices. The site has been ISO registered with BSI since 1990.

BIOCOMPATIBILITY
The results of selected biocompatibility tests are shown in Table 1. Samples were sterilized by autoclaving before testing. Toxicological Summaries are available upon request.

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. Dow Corning makes no end-use representation regarding any safety testing we may have conducted on this material. The product is not designed for, intended for and therefore not suitable for implantation of any duration 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 DOWCORNING.COM, OR FROM YOUR DOW CORNING SALES APPLICATION ENGINEER, OR DISTRIBUTOR, OR BY CALLING DOW CORNING CUSTOMER SERVICE.

USABLE LIFE AND STORAGE
When stored at or below room temperature in the original unopened containers, this product has a usable life of 12 months from the date of production.

PACKAGING INFORMATION
This product is available in 908 g (2 lb) and 30 kg (65 lb) kits, each containing equal portions of Part A and B.

LIMITATIONS
These products are neither tested nor represented as suitable for long-term implantation of greater than 29 days in the human body.

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 customer's 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.

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Table 1: Results of selected biocompatibility tests for *Dow Corning*® 7-9600 Soft Filling Elastomer.

Test	Samples Tested	
Cell culture with neutral red uptake	Elastomer Cell culture medium extract of elastomer	No cytopathic effect (morphology changes) No cytopathic effect (morphology changes); ≥75% viability
Ames Bacterial Reverse Mutagenicity	Acetone extract of elastomer Saline extract of elastomer	No evidence of genetic activity or cytotoxicity No evidence of genetic activity or cytotoxicity
Hemolysis	Elastomer Saline extract of elastomer	Non-hemolytic Non-hemolytic
USP Pyrogen	Saline extract of elastomer	Non-pyrogenic
USP Class V extractables	Saline extract of elastomer	Non-irritating and non-toxic relative to controls
System toxicity	5% ethanol in saline extract of elastomer	Non-irritating and non-toxic relative to controls
Intracutaneous reactivity	Polyethylene glycol (PEG 400) extract of elastomer Cottonseed oil extract of elastomer	Non-irritating and non-toxic relative to controls Non-irritating and non-toxic relative to controls
Skin sensitization	Elastomer Saline extract of elastomer Ethanol or acetone extract of elastomer	No sensitization No sensitization No sensitization
90-Day implant	Elastomer	Reaction equivalent or lesser than negative control