

## DOW CORNING® 7-9600 Soft Filling Elastomer Parts A & B

### FEATURES

- Transparent before and after curing
- Low viscosity before curing for easy processing
- Platinum-catalyzed
- Versatile cure cycles
- No cure by-products

### BENEFITS

- Adhesion to polyurethane film
- Pigmentable
- Non-sensitizing

### COMPOSITION

- 2-part filler-free silicone elastomer

### Two Part Filler-Free Elastomer

#### APPLICATION

- 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 representative prior to writing specifications on this product.

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

1. CTM: (Corporate Test Method) corresponds to American Standard Test Methods (ASTM). Copies of CTM's are available upon 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 polydimethylsiloxane 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 will double within 1 to 3 hours at 25°C (77°F). 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 (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. 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. Before handling, read product and 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 [www.dowcorning.com](http://www.dowcorning.com). You can also obtain a copy from your local Dow Corning sales representative or Distributor or by calling your local Dow Corning Global Connection.

## 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

This product is available in 908g (2 lb) and 30kg (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, [www.dowcorning.com](http://www.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 Dow Corning'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.

Dow Corning's sole warranty is that the product will meet the Dow Corning 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.**

<i>Test</i>	<i>Samples tested</i>	
Cell culture with neutral red uptake	Elastomer	No cytopathic effect (morphology changes)
	Cell culture medium extract of elastomer	No cytopathic effect (morphology changes); ≥75% viability
Ames Bacterial Reverse Mutagenicity	Acetone extract of elastomer	No evidence of genetic activity or cytotoxicity
	Saline extract of elastomer	No evidence of genetic activity or cytotoxicity
Hemolysis	Elastomer	Non-hemolytic
	Saline extract of elastomer	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	Non-irritating and non-toxic relative to controls
	Cottonseed oil extract of elastomer	Non-irritating and non-toxic relative to controls
	Elastomer	No sensitization
Skin sensitization	Saline extract of elastomer	No sensitization
	Ethanol or acetone extract of elastomer	No sensitization
	Elastomer	Reaction equivalent or lesser than negative control