

## SILASTIC® MDX4-4210 BioMedical Grade Elastomer

### FEATURES

- Room temperature and heat accelerable cure
- Good thick section cure
- Excellent dielectric properties
- Essentially no shrinkage when cured at room temperature
- Contains no peroxides, peroxide by-products, chlorophenyls or PCBs
- Contains no organic plasticizers, phthalates or latex additives
- Non-blooming
- Pigmentable

### BENEFITS

- Qualified to address the tests described in ISO 10993-1 for “limited” (≤ 24 h) and “prolonged” (≤ 30 d) contact duration:
  - Meets or exceeds acceptance criteria for Cytotoxicity, Sensitization, Irritation/Intracutaneous reactivity, Systemic toxicity (acute) and Subchronic toxicity (as tested by implantation)
  - Meets requirements of screening tests described by specific ISO standards for Hemocompatibility and Genotoxicity
- Meets or exceeds testing requirements of:
  - United States Pharmacopeia (USP) Class VI
  - European Pharmacopoeia (Ph. Eur. or ‘EP’) silicone elastomers for closures and tubing—“Substances soluble in hexane” and “Volatile matter”
- Batch-to-batch consistency

### COMPOSITION

- Two-part silicone elastomer

### APPLICATIONS

- SILASTIC MDX4-4210 BioMedical Grade Elastomer is designed for use in medical device 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.
- Can be used for general prototyping, molding and fabrication of medical device components. Can also be used as a drug matrix for controlled release drug delivery systems.

### 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>	ASTM <sup>2</sup>	Property	Unit	Value
<b>As supplied</b>				
0050	D1084	Base viscosity	Pa.s	115
		Viscosity <sup>3</sup>	Pa.s	
0050	D1084	- Initial <sup>4</sup>		60
0050	D1084	- After 2 hours		110
<b>Cured<sup>5</sup></b>				
0063		Color		Translucent
		Relative density <sup>6</sup>		1.11
		Durometer hardness	Shore A	30
0137A	D412	Tensile strength	MPa	5.0
			psi	730
0137A	D412	Elongation	%	470
0274		Tissue culture		No CPE
0114	D149	Dielectric strength	volts/mil	575
0249	D257	Volume resistivity	Ohm-cm	2x10 <sup>15</sup>
0112	D150	Dielectric constant at 100Hz		3.01
0112	D150	Dielectric constant at 100kHz		3.00
0112	D150	Dissipation factor 100Hz		9x10 <sup>-4</sup>
0112	D150	Dissipation factor 100kHz		10x10 <sup>-4</sup>
0249	D257	Surface resistivity	ohm	>7x10 <sup>16</sup>

1. CTM: Corporate Test Method, copies of CTMs are available on request.

2. ASTM: American Society for Testing and Materials.

3. With 10pph curing agent added.

4. Approximately 10 minutes.

5. When 100 parts of SILASTIC MDX4-4210 BioMedical Grade Elastomer and 10 parts of the curing agent are mixed, de-aired, press-cured for 3 minutes at 150°C (302°F), post-cured one hour at 150°C (302°F) and stabilized for three hours at room temperature, the typical properties will be obtained on a 0.075-inch slab.

6. Press-cured only.

## DESCRIPTION

SILASTIC MDX4-4210 BioMedical Grade Elastomer is a pourable two-component product which, when combined, cures to a translucent silicone rubber over several hours at room temperatures, but may be more rapidly cured by application of heat (see Curing). 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. SILASTIC MDX4-4210 BioMedical Grade Elastomer is made to exacting specifications to meet high quality standards for medical applications.

## HOW TO 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 710mm Hg (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 4 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 about 3 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 SILASTIC MDX4-4210 BioMedical Grade Elastomer may cure more slowly at room temperature. Slight heating will accelerate the cure of these films.

**CAUTION:** The cure may be inhibited by traces of amines, sulfur, nitrogen oxide, organotin 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 some room temperature vulcanized and peroxide-cured silicone elastomers may also inhibit cure.

### Use of silicone fluid to modify properties

The consistency of SILASTIC MDX4-4210 BioMedical Grade Elastomer may be lowered by adding DOW CORNING® 360 Medical Fluid (100cSt viscosity). The fluid may be premixed with either the base or the curing agent. The addition of DOW CORNING 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.

## Bonding and release

SILASTIC® Medical Adhesive Silicone Type A can be used to bond cured SILASTIC MDX4-4210 BioMedical Grade Elastomer to other silicone elastomers and many other materials.

Commercially available RTV primers have been used to enhance the adhesion of SILASTIC MDX4-4210 BioMedical Grade Elastomer to some metal and plastic surfaces; however, Dow Corning has not conducted tests of these primers for biomedical applications. In molding applications, SILASTIC MDX4-4210 BioMedical Grade Elastomer will normally release well from smooth, unprimed surfaces other than glass. A release agent may be used to ensure trouble-free releases.

## CAUTION

### Cure Inhibition

The cure of SILASTIC MDX4-4210 BioMedical Grade Elastomer may be inhibited by traces of amines, sulfur, 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.

## QUALIFICATION TESTING

The results of selected qualification tests are shown in Table 1. Summaries of Qualification Data are available upon request.

Each production batch of SILASTIC MDX4-4210 BioMedical Grade Elastomer is tested for the absence of cytopathic effects using a tissue culture test (direct contact method).

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

## QUALITY

SILASTIC® BioMedical Grade Elastomers are manufactured using appropriate principles of Good Manufacturing Practice (GMP) requirements. 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

SILASTIC BioMedical Grade Elastomers, when fully cured and thoroughly cleansed may be used in accordance to the requirements of FDA regulation 21CFR177.2600, "Rubber Articles Intended For Repeated Food Contact".

## FDA MASTER FILE

A Master File for SILASTIC MDX4-4210 BioMedical Grade Elastomer have been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the file must contact Dow Corning Corporation.

## 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 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.***

## ORDERING AND PRODUCT INFORMATION

For ordering and product information, contact your local Dow Corning Global Connection.

## 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 properly stored at ambient conditions in the original, unopened containers, this product has a usable life of 24 months from date of production.

## PACKAGING

This product is available in 11 and 44 lb (4.9 and 19.9kg) kits, which contain an elastomer and a curing agent in the ratio required for mixing. A one-pound (454g) sample kit is also available. All weights are net.

## 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: Selected qualification data for SILASTIC MDX4-4210 BioMedical Grade Elastomer**

<i>Test<sup>1</sup></i>	<i>Samples tested<sup>2</sup></i>	<i>Summary Results</i>
Cell culture	<ul style="list-style-type: none"> <li>• Elastomer</li> <li>• Minimum Essential Medium extract of elastomer</li> </ul>	Non-cytotoxic
Skin sensitization	<ul style="list-style-type: none"> <li>• Elastomer</li> <li>• Saline extract of elastomer</li> <li>• 80% Ethanol extract of elastomer</li> </ul>	No sensitization
USP Class V <ul style="list-style-type: none"> <li>• Systemic toxicity</li> <li>• Intracutaneous reactivity</li> </ul>	<ul style="list-style-type: none"> <li>• Saline extract of elastomer</li> <li>• Extract of elastomer in 5% ethanol/95% saline</li> <li>• PEG 400 extract of elastomer (diluted in saline)</li> <li>• Cottonseed oil extract of elastomer</li> </ul>	No significant reaction greater than controls
Implant	<ul style="list-style-type: none"> <li>• Elastomer</li> </ul>	Reaction comparable to negative control at 7, 30, and 92 days postimplantation
USP Pyrogen	<ul style="list-style-type: none"> <li>• Saline extract of elastomer</li> </ul>	Non-pyrogenic
Mutagenicity	<ul style="list-style-type: none"> <li>• Saline extract of elastomer</li> <li>• Acetone extract of elastomer</li> </ul>	No evidence of genetic activity or cytotoxicity in the bacterial reverse mutation assay
Hemolysis	<ul style="list-style-type: none"> <li>• Elastomer</li> <li>• Saline extract of elastomer</li> </ul>	Non-hemolytic
European Pharmacopoeia <sup>3</sup> <ul style="list-style-type: none"> <li>• Substances soluble in hexane</li> <li>• Volatile matter</li> </ul>	<ul style="list-style-type: none"> <li>• Hexane extract of elastomer</li> <li>• Elastomer</li> </ul>	≤3% residue ≤2% weight loss

1. The requirements specified in ISO 10993-1 for medical devices with limited and prolonged exposure (not exceeding 30 days) are addressed by the tests listed here. European Pharmacopoeia testing is not a component of ISO 10993.
2. Unless otherwise noted, SILASTIC MDX4-4210 BioMedical Grade Elastomer Base and Curing Agent were mixed, press-cured 3 minutes at 150°C (302°F) and post-cured 1 hour at 150°C (302°F).
3. European Pharmacopoeia monograph 3.1.9. Silicone Elastomer for Closures and Tubing. The elastomer was post-cured 2 hours at 177°C (350°F) for European Pharmacopoeia tests