

Healthcare
Solutions

DOW CORNING

Dow Corning[®] brand
Class VI Elastomers for
General Healthcare
Fabrication

*Appropriate
Cost-Effective
Advantageous*

DOW CORNING
C6-135
ELASTOMER, PART A
NET WT. 454 g

DOW CORNING
C6-515
LIQUID SILICONE RUBBER, PART B
NET WT. 454 g

BATCH 0001602042

BATCH 0001356250

C6-135

C6-515

Dow Corning Class VI Elastomers

Dow Corning® Class VI elastomers are designed for fabrication of products for the healthcare industry, including devices that will be implanted in humans for *no more than 29 days*. They are also appropriate for pharmaceutical processing, veterinary, food contact and other applications. Dow Corning Class VI elastomers complement the industrial and BioMedical Grade materials to form a comprehensive product line.

Appropriate:

*Exactly what you need ...
no more, no less.*

Dow Corning Class VI elastomers were developed to give you a practical, competitive choice of materials for healthcare fabrication while also offering the level of assurance you need. More appropriately manufactured, tested and supported for healthcare applications than typical industrial grade materials, they reflect the commitment, outstanding quality and superior processing capabilities associated with the Dow Corning brand name.

The table *Evaluating Materials for Healthcare Applications* provides a comparison of Dow Corning Class VI elastomers with our Silastic® BioMedical Grade and industrial materials.

Class VI elastomer materials from Dow Corning have been tested in accordance with **USP** (*United States Pharmacopeia*) plastics requirements. In addition, select tests from **Ph. Eur.** (*European Pharmacopoeia* or “EP”) and **ISO** (*International Organization for Standardization*) guidelines have been completed. Dow Corning Class VI qualification tests include:

USP Class VI

- USP Class V Extractables
 - Intracutaneous Reactivity
 - Acute Systemic Toxicity
- 7-day Implant¹
- 30-day Implant¹

EP 3.1.9.

- Substances soluble in hexane
- Volatile matter

ISO 10993-1 Surface Devices

- Cytotoxicity
- Skin Sensitization
- Intracutaneous Reactivity
- Systemic Toxicity

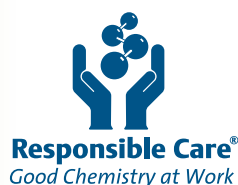
¹ This exceeds the 5-day USP Class VI implant test requirement.

Benefits

- Broad range of elastomers
- Two-part platinum-catalyzed or one-part uncatalyzed silicone elastomer (peroxide initiator selected by customer and added at point of use)
- Cost-effective
- Can be post-cured to stabilize properties
- No phthalates or organic plasticizers
- Heat-stable and autoclavable
- High gas permeability compared with most thermoset elastomers and thermoplastics
- Available in a range of hardnesses
- Special purpose elastomer with enhanced properties also available

| The following Dow Corning Class VI materials are offered: | | |
|-----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| LSRs Liquid Silicone Rubbers | Dow Corning® C6-515 Liquid Silicone Rubber, Parts A & B Dow Corning® C6-530 Liquid Silicone Rubber, Parts A & B Dow Corning® C6-540 Liquid Silicone Rubber, Parts A & B Dow Corning® C6-550 Liquid Silicone Rubber, Parts A & B Dow Corning® C6-560 Liquid Silicone Rubber, Parts A & B Dow Corning® C6-570 Liquid Silicone Rubber, Parts A & B | Platinum-Catalyzed |
| | Dow Corning® C6-135 Elastomer, Parts A & B Dow Corning® C6-150 Elastomer, Parts A & B Dow Corning® C6-165 Elastomer, Parts A & B Dow Corning® C6-180 Elastomer, Parts A & B | |
| HCRs High Consistency Rubbers | Dow Corning® C6-350LH Elastomer, Parts A & B | Special Purpose |
| | Dow Corning® C6-235 Elastomer Dow Corning® C6-250 Elastomer Dow Corning® C6-265 Elastomer | Uncatalyzed (Peroxide-Initiated) |

Dow Corning Class VI elastomers are **manufactured to ISO 9001** quality standards utilizing appropriate principles of Good Manufacturing Practice (GMP) regulations **in accordance with Dow Corning Responsible Care® practices.** (*Responsible Care* is a program of the American Chemistry Council that Dow Corning has adopted worldwide to help us manage environmental, health and safety issues that could affect you.)



Cost-Effective:
*Enhance your efficiency,
reduce your costs.*

With *Dow Corning* Class VI elastomers, you can enhance the efficiency of your operations and reduce your costs.

- The superior processability typical of *Dow Corning* elastomers can **optimize production rates**, resulting in potential **cost savings**.
- Our formal change control process **keeps formulation and process changes in check** ... changes that could impact your manufacturing process or your product's performance and consequently cost you money.
- Because *Dow Corning* Class VI elastomers are appropriate for both healthcare and non-healthcare use, you can use them for multiple applications, which can **increase your fabrication flexibility** and **reduce your inventory costs**.
- *Dow Corning* Class VI elastomers provide a **competitively-priced alternative** to *Silastic®* BioMedical Grade materials from Dow Corning **for general healthcare fabrication**.

Advantageous:
*Reduce your risks,
add to your success.*

The healthcare market is intensely competitive. You cannot afford to pay more than necessary for your raw materials.



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Neither can you afford to take unnecessary risks with your product's end-use performance.

- *Dow Corning* Class VI elastomers have been extensively tested to USP and select EP and ISO guidelines, allowing you to **better manage your risk**.
- They are also subject to **strict contamination control procedures** that further help reduce your risk of product adulteration or failure.

In addition to reducing your risks, *Dow Corning* Class VI elastomers can contribute to your success by lending **the recognized value of the *Dow Corning* name** to your product ... the value that comes from more than 50 years of experience and expertise in the development of silicon-based materials.

Class VI elastomers from Dow Corning can help you grow sales, increase your market share and improve your profitability.

Learn more about them today.

Why Choose Silicone?

Silicones are among the most extensively tested biomaterials. Compared with other plastics, silicone materials from Dow Corning have unique strengths that make them the materials of choice for many healthcare applications.

- Not a source for organism growth
- Inherent flexibility
- Minimal *in vivo* reactivity
- No phthalates or other processing additives that could be released
- A long history and extensive documentation in healthcare applications

Evaluating Materials for Healthcare Applications: A Comparison

| | Silastic BioMedical Grade Silicone Elastomers | Dow Corning Class VI Grade Silicone Elastomers | Dow Corning Industrial Elastomers | | | | | | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Material Testing | | | | | | | | | | | |
| Qualification Testing Including Biologic and Other Compendial Testing: | <p>All supporting biotesting is performed in compliance with Good Laboratory Practices (GLPs), which specify audits and quality assurance procedures.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Biotesting under GLPs</th> <th style="text-align: center;">Other Testing</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"> <i>90-day Implant¹</i> <i>Hemolysis</i> <i>USP Intracutaneous Reactivity</i> <i>USP Acute Systemic Toxicity</i> <i>Cell Culture</i> <i>Mutagenicity</i> <i>USP Pyrogen</i> <i>Skin Sensitization</i> </td> <td style="text-align: center;"> <i>EP substances soluble in hexane</i> <i>EP volatile matter</i> </td> </tr> </tbody> </table> | Biotesting under GLPs | Other Testing | <i>90-day Implant¹</i> <i>Hemolysis</i> <i>USP Intracutaneous Reactivity</i> <i>USP Acute Systemic Toxicity</i> <i>Cell Culture</i> <i>Mutagenicity</i> <i>USP Pyrogen</i> <i>Skin Sensitization</i> | <i>EP substances soluble in hexane</i> <i>EP volatile matter</i> | <p>All supporting biotesting is performed in compliance with GLPs, which specify audits and quality assurance procedures.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Biotesting under GLPs</th> <th style="text-align: center;">Other Testing</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"> <i>7-day Implant²</i> <i>30-day Implant²</i> <i>USP Intracutaneous Reactivity</i> <i>USP Acute Systemic Toxicity</i> <i>Cell Culture</i> <i>Skin Sensitization</i> </td> <td style="text-align: center;"> <i>EP substances soluble in hexane</i> <i>EP volatile matter</i> </td> </tr> </tbody> </table> | Biotesting under GLPs | Other Testing | <i>7-day Implant²</i> <i>30-day Implant²</i> <i>USP Intracutaneous Reactivity</i> <i>USP Acute Systemic Toxicity</i> <i>Cell Culture</i> <i>Skin Sensitization</i> | <i>EP substances soluble in hexane</i> <i>EP volatile matter</i> | <p><i>Dow Corning</i> industrial elastomers are not intended for medical or pharmaceutical application. They are neither tested nor represented as suitable for medical or pharmaceutical uses.</p> <p>ISO 9001 has no requirements for material biotesting; ISO 9001 quality requirements are less rigorous than GLPs.</p> |
| Biotesting under GLPs | Other Testing | | | | | | | | | | |
| <i>90-day Implant¹</i> <i>Hemolysis</i> <i>USP Intracutaneous Reactivity</i> <i>USP Acute Systemic Toxicity</i> <i>Cell Culture</i> <i>Mutagenicity</i> <i>USP Pyrogen</i> <i>Skin Sensitization</i> | <i>EP substances soluble in hexane</i> <i>EP volatile matter</i> | | | | | | | | | | |
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| Manufacturing Procedures and Process | | | | | | | | | | | |
| Manufacturing Standards and Mindset: | Products are manufactured to the standards of ISO 9001, <i>following principles of 21 CFR 820 (Medical Device QSR/GMP³)</i> , and are <i>intended</i> for the <i>healthcare industry</i> . | Products intended for use in <i>multiple industries</i> are manufactured in facilities that <i>are ISO 9001 certified and committed to Dow Corning Responsible Care practices</i> , with added emphasis on <i>contamination control</i> . Furthermore, <i>Dow Corning Class VI materials</i> are manufactured using appropriate principles of current GMP regulations. | Products intended for use in <i>multiple industries</i> are manufactured in facilities that <i>are ISO 9001 certified and committed to Dow Corning Responsible Care practices</i> . | | | | | | | | |
| Quality Responsibilities: | A <i>Dedicated Quality Unit</i> is responsible for supporting the application of appropriate medical device QSR/GMP procedures and practices throughout the entire process. | A <i>Dedicated Quality Unit</i> supports the application of Dow Corning quality system procedures and practices to the manufacturing process. <i>Management is responsible</i> for ensuring that ISO 9001 quality system requirements are established and implemented. | <i>No dedicated quality unit requirements. Management is responsible</i> for ensuring that ISO 9001 quality system requirements are established and implemented. | | | | | | | | |
| Process Controls: | Documented product formulation and process change control procedures address impact on product properties, chemistry and impurity profile. Impact assessment based on <i>FDA guidelines</i> . <i>Quality Assurance approves all material used on site</i> regarding potential product contamination. Written procedures ensure <i>control of contamination</i> from airborne dust, microorganisms, static electricity, etc. <i>Equipment</i> used in any aspect of material processing is <i>appropriately designed, adequately sized and properly</i> located to facilitate intended <i>use, cleaning and maintenance</i> . | Documented product formulation and process change control procedures address impact on product properties, chemistry and impurity profile. Impact assessment based on <i>performance and chemical testing and Dow Corning Responsible Care</i> practices. <i>Manufacturing reviews production area materials</i> regarding potential contamination. <i>Dow Corning quality practices</i> ensure defined area is <i>clean and sanitary</i> with special attention to airborne dust, microorganisms, static electricity, etc. Equipment involved in processing product is properly situated for <i>use, cleaning and maintenance</i> . | Product and process change control procedures document the modification, the reasons and the impact of the change on product specifications. Impact assessment is based on <i>performance testing and Dow Corning Responsible Care</i> practices. ISO 9001 requires use of <i>suitable working environment and suitable production and installation equipment</i> , but does not specify/define <i>contamination control</i> or <i>cleaning and maintenance requirements</i> . | | | | | | | | |
| Disposition of Non-Conforming Materials: | Rework activities, <i>including a determination of any adverse effect on the product</i> , are documented. <i>Nonconformances require documentation of root cause analysis</i> . | Rework and re-evaluation activities are documented in product history records. | Nonconforming product is reviewed and re-work documented if performed. <i>Nonconforming product may be accepted with or without repair, by concession</i> . | | | | | | | | |
| Lot-to-Lot Consistency: | Products meet specification requirements as well as conform to various environmental and process controls intended to maintain the form, fit and function of devices made from these materials. | Products meet specification requirements as well as conform to certain environmental and process controls. | Products meet specification requirements only. | | | | | | | | |
| Services | | | | | | | | | | | |
| Records: | Legible quality records (including those that address validation, scale-up, equipment, training, control and distribution) are maintained <i>in a dedicated record center for several years beyond product shelf life</i> . | Quality records are legible, retrievable and include those for validation, scale-up, equipment, training, control and distribution. Retention times are typically <i>7 years</i> . | Legible and retrievable quality records are maintained to demonstrate conformance to the quality system. <i>Retention times are established and recorded</i> . | | | | | | | | |
| Traceability: | Raw material <i>and direct-contact packaging components</i> are traceable relative to identification, storage, <i>handling, sampling, testing</i> and approval or rejection. Traceability also extends to the equipment and personnel involved, and any related <i>cleaning or environmental monitoring</i> . | <i>ISO 9001</i> requirements address traceability of raw material receipt, identification, storage and approval or rejection, and traceability of product to equipment used and manufacturing personnel involved. | <i>ISO 9001</i> requirements address traceability of raw material receipt, identification, storage and approval or rejection, and traceability of product to equipment used and manufacturing personnel involved. | | | | | | | | |
| Sample Retention and Audits: | <i>Raw material</i> and <i>product</i> retainer samples <i>are kept (for shelf life + 1 year)</i> in case of a quality issue. Customer audits are <i>available upon request</i> , at Dow Corning's discretion. | <i>Product</i> retainer samples <i>may be kept</i> , typically for <i>6–18 months</i> . Customer audits may be <i>negotiable</i> . | <i>No parallel requirement in ISO 9001</i> for sample retention. Customer audits are <i>not specifically addressed</i> in ISO 9001. | | | | | | | | |
| Regulatory and Technical Support: | <i>FDA Device and Drug Master File access</i> may be available upon request. Technical support <i>based on product performance and regulatory filings/approvals</i> . | <i>Master File access is not a Dow Corning or ISO 9001 requirement</i> . Technical support <i>based on product performance</i> . | <i>Master File access is not a requirement</i> of ISO 9001. <i>No ISO requirement</i> for technical support. | | | | | | | | |
| Change Control Notification: | <i>Written notification</i> (of changes that could impact the properties, quality, purity or functionality of finished product) is provided to customers <i>in advance of the change</i> . | <i>Written notification</i> (due to significant change in product specification and/or composition) is provided to customers <i>at the time of the change</i> . | <i>Customer notification is not specifically addressed in ISO 9001</i> . | | | | | | | | |

¹In some cases 91- or 92-day Implant; 90-day Implant studies typically also include intermediate intervals. ²In some cases 8- and 31-day Implant. ³QSR = Quality System Regulation; GMP = Good Manufacturing Practices

For More Information:

Contact your Dow Corning representative, or call the Dow Corning Global Connection nearest you.

Dow Corning has sales offices, manufacturing sites, as well as science and technology laboratories around the globe. Telephone numbers of locations near you are available on the world wide web at www.dowcorning.com.

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It is the user's responsibility to ensure the safety and efficacy of these materials for all intended uses. While these materials have passed Class VI testing requirements, Dow Corning makes no end-use representation based on such testing. This product is not designed for, intended for or suitable for implantation for more than 29 days in the human body. Dow Corning reserves the right to not sell these materials for selected applications.

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 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.

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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