

**Frequently Asked Questions
About *Dow Corning*[®] brand
Class VI Elastomers**

Dow Corning Healthcare

Q: What new product line is Dow Corning offering?

A: Dow Corning is offering a range of silicone elastomer products focused on two primary applications within our Healthcare Industries business:

- Fabrication of medical devices with possible body contact (or implantation) of up to 29 days or less duration
- Pharmaceutical processing

These materials are referred to as *Dow Corning®* brand Class VI (C6) elastomers.

Q: What individual products are offered?

A: Dow Corning expanded its initial offering of four platinum-catalyzed high-consistency rubber elastomers (HCRs) to include six new liquid silicone rubbers (LSRs), as well as a special purpose medium hardness HCR with enhanced physical properties. We also introduced three uncatalyzed elastomers that permit customers to formulate with their choice of peroxide initiator.

These products meet a battery of testing requirements including USP Class VI, and key elements of ISO and European Pharmacopoeia (Ph. Eur. or “EP”) standards. Dow Corning Class VI materials are offered under the following brand name and product nomenclature:

LSRs	<i>Dow Corning®</i> C6-515 Liquid Silicone Rubber, Parts A & B		Platinum-Catalyzed
	<i>Dow Corning®</i> C6-530 Liquid Silicone Rubber, Parts A & B		
	<i>Dow Corning®</i> C6-540 Liquid Silicone Rubber, Parts A & B		
	<i>Dow Corning®</i> C6-550 Liquid Silicone Rubber, Parts A & B		
	<i>Dow Corning®</i> C6-560 Liquid Silicone Rubber, Parts A & B		
	<i>Dow Corning®</i> C6-570 Liquid Silicone Rubber, Parts A & B		
HCRs	<i>Dow Corning®</i> C6-135 Elastomer, Parts A & B		
	<i>Dow Corning®</i> C6-150 Elastomer, Parts A & B		
	<i>Dow Corning®</i> C6-165 Elastomer, Parts A & B		
	<i>Dow Corning®</i> C6-180 Elastomer, Parts A & B		
	<i>Dow Corning®</i> C6-350LH Elastomer, Parts A & B	Special Purpose	
	<i>Dow Corning®</i> C6-235 Elastomer	Uncatalyzed (Peroxide-Initiated)	
	<i>Dow Corning®</i> C6-250 Elastomer		
	<i>Dow Corning®</i> C6-265 Elastomer		

Q: What do you mean by special purpose HCR with enhanced physical properties?

A: We introduced an HCR with “enhanced” physical properties. *Dow Corning* C6-350LH Elastomer is a platinum-catalyzed material of approximately 50-durometer that has low hysteresis loss. Hysteresis occurs in a silicone when a strain is induced to the material. The strain reduces the number of effective crosslinks and liberates heat energy. Hysteresis is typically accompanied by a shift in which strain lags behind stress. In this respect, this special purpose material can offer improved performance versus typical platinum-catalyzed high consistency silicone elastomers. A potential use is longer-lasting roller-pump tubing.

Q: What does USP Class VI mean?

A: The United States Pharmacopeia (USP) is a private (non-governmental) organization that “*promotes the public health by establishing state-of-the-art standards to ensure the quality of medicines and other health care technologies.*” Those standards include *in vivo* animal biological reactivity tests for “*elastomers, plastics and other polymeric material with direct or indirect patient contact.*” USP monograph (88) describes the classification of plastics into six classes based on responses to a series of *in vivo* tests for which extracts, materials and routes of administration are specified.

Class VI requires the most stringent testing of the six classes. Extracts of the test material are prepared in saline, alcohol in saline, polyethylene glycol (PEG 400), and vegetable oil. The extracts (diluted in the case of the PEG extract) and blanks are injected into mice and rabbits, which are observed several times over a 72-hour period. The animals’ response to the sample extracts and the blank are compared to determine test passage. These tests of extracts are called the *Systemic Injection Test* and the *Intracutaneous Test*. Materials that pass these two tests are compliant with USP Class V.

USP Class VI includes the tests of USP Class V plus an *implantation test* wherein strips of the test material and a negative control are implanted in rabbits for a period of *not less than 120 hours*. Hemorrhage, necrosis, discolorations, and infections are macroscopically observed and degree of encapsulation is scored and compared with the negative control to determine test passage. Note that the 7- and 30-day implantation test protocols utilized by Dow Corning exceed the 5-day (120-hour) USP Class VI implantation minimum requirement.

Although USP Class VI testing is widely used and accepted in the medical products industry, some view it as the minimum requirement a raw material must meet to be considered for use in health care applications. USP Class VI testing does not fully meet any category of ISO 10993-1 testing guidelines currently used by the US FDA (General Program/Bluebook Memorandum G95-1) for medical device approval. In addition, developers of finished products still bear the responsibility to determine the suitability of a raw material for its end use.

Q: Are Dow Corning Class VI (C6) elastomers tested to USP Class VI requirements?

A: *Dow Corning* Class VI (C6) products meet Class VI testing requirements as defined above.

Dow Corning has performed USP Class V extractables testing, as well as 7-day and 30-day* implant tests. The benefit to Dow Corning customers is that our Class VI materials are subjected to a more rigorous implant test, yet are available in the same price range as Class VI materials with 5- to 10-day implant studies from other suppliers. In short, the result is optimal performance and affordable solutions for our customers.

*In some cases, 8- and 31-day implant tests may be conducted.

Q: What are the ISO 10993-1 guidelines you referred to?

A: The most influential guideline for biocompatibility is the ISO 10993-1 standard. The standard was developed for medical device and dental materials by the International Organization for Standardization, a worldwide federation of national standards bodies. Three types of contact categories are defined for devices: Surface, External Communicating and Implant. These device categories are further divided into three exposure periods: Limited (<24 hours), Prolonged (24 hours to 30 days) and Permanent Contact (>30 days).

Q: Are Dow Corning Class VI (C6) elastomers tested to ISO 10993-1 requirements?

A: *Dow Corning* Class VI (C6) products meet the requirements defined in ISO 10993-1 for Surface Devices with “limited” (<24 hours) or “prolonged” (1 to 30 days) contact duration.

Q: Does the European Pharmacopoeia provide guidelines for silicone elastomers used in medical applications?

A: Yes, the EP includes monograph 3.1.9. Silicone Elastomer for Closures and Tubing, which applies to functionalized and crosslinked polysiloxanes prepared using peroxide initiator or platinum catalyst. The standard includes identification tests and several chemical assays, the most important of which are generally recognized to be “Substances soluble in hexane” and “Volatile matter.”

Q: Are Dow Corning Class VI (C6) elastomers tested to EP guidelines?

A: *Dow Corning* Class VI products have been tested against two key tests from EP 3.1.9. The “Substances soluble in hexane” test measures the amount of residue resulting from hexane extraction. The “Volatile matter” test measures weight loss after extensive heating.

Q: Can we get summaries of qualification test results for specific products?

A: Yes, qualification data summaries are available upon request.

Q: Why did Dow Corning introduce Class VI materials?

A: Drug and device manufacturers are facing the reality of managed care, downward price pressure, shrinking profit margins and liability for products they bring to market. Historically, Dow Corning only had one offering for our

medical device and pharmaceutical processing customer base, regardless of application, functionality or needs from the customer’s perspective. Under this approach, it was often difficult for Dow Corning to meet customer needs without over-delivering in terms of extensive and costly biotesting.

The introduction of *Dow Corning* Class VI (C6) elastomers demonstrates our ongoing commitment to the healthcare industry and the direction and trends we see in the marketplace.

By expanding our offering, we are better able to position Dow Corning’s Healthcare Industries business to more appropriately meet the functional and general needs of our targeted customers. This approach also helps us contain raw material costs as our customers face the price pressures of the marketplace.

Q: Does this product line displace the existing *Silastic* BioMedical Grade elastomers from Dow Corning?

A: No, in fact we have made a substantial investment in *Silastic*® BioMedical Grade high consistency elastomers and liquid silicone rubbers, and we will continue to make them available for customers who need and value these materials. *Silastic* BioMedical Grade high consistency rubbers and liquid silicone rubbers remain available. These products and related offerings are being repositioned to our medical device customers focused on long-term implant applications (defined as >29-day human implantation). Dow Corning’s pricing, channel and promotion strategy are being modified to better focus these materials for implant applications. To learn more about our policy regarding materials for long-term implantation devices, please read on. The policy is described below.

Q: How do *Dow Corning* Class VI (C6) products differ from *Silastic* BioMedical Grade products?

A: A comparison chart is available to help you evaluate these materials. Refer to *Dow Corning*® *Class VI Elastomers for General Healthcare Fabrication* available at <http://www.dowcorning.com> or from your Dow Corning representative.

Q: What if I am using *Silastic* BioMedical Grade elastomers for a non-implant application; do I still have access to these materials?

A: Yes. *Silastic* BioMedical Grade elastomers continue to be available to our entire customer base. As always, Biomedical Grade products are supported by more extensive testing, services and different procedures than the *Dow Corning* Class VI (C6) products. (Differences between the two product lines are summarized in the comparison chart described in the preceding answer.)

For non-implant applications, and short-term applications of no longer than 29 days of body contact duration, customers are free to choose from either product line according to the testing and services they value. Customers with long-term implant applications of greater than 29 days duration are required to purchase the elastomers from the *Silastic* BioMedical Grade product line. (Dow Corning policy places limitations regarding supply to certain parties and applications.)

Q: Is Dow Corning changing its policy on implant applications?

A: Although continuously under review, at the current time, our policy allows the sale of materials into long-term (>29 day) implant applications if appropriate contractual protections, including indemnification are in place. *Silastic* BioMedical materials are the ONLY Dow Corning elastomers that may be appropriate for long-term implant applications. Of course, the implant manufacturer is responsible for determining the suitability of the material for their specific device.

For customers that have different functional and general needs other than long-term implant customers, the *Dow Corning* Class VI solution set was designed to best meet these needs without delivering unnecessary testing and services.

Q: What package sizes does Dow Corning offer?

A: The following package sizes are available:

<u>HCRs (Pt)</u>	<u>LSRs</u>	<u>Uncatalyzed HCRs</u>
908 g sample kit	908 g sample kit	454 g sample
13.6 kg kit	36 kg kit	11.3 kg
408.2 kg kit	400 kg kit	408.2 kg

Q: Under what standards are these materials produced?

A: Dow Corning produces the materials in an ISO-certified facility, using the critical elements of cGMP regulations (21 CFR 820). These critical elements incorporate strict practices such as contamination control, change control and traceability.

Q: Where can customers purchase Dow Corning Class VI (C6) elastomers?

A: These and other silicone elastomers for healthcare are available directly from Dow Corning. Contact your local Dow Corning representative or Service Center.

Q: What literature is available on these materials?

A: The following literature pieces provide additional information about the Dow Corning Class VI silicone elastomer product line:

- *DOW CORNING*® Class VI Elastomers for General Healthcare Fabrication
- *DOW CORNING*® Class VI Elastomers (C6-135, C6-150, C6-165, C6-180) Parts A & B
- *DOW CORNING*® Class VI Uncatalyzed Elastomers (C6-235, C6-250, C6-265)
- *DOW CORNING*® Class VI Elastomer (C6-350LH) Parts A & B
- *DOW CORNING*® Class VI Liquid Silicone Rubber Elastomers (C6-515, C6-530, C6-540, C6-550, C6-560, C6-570) Parts A & B

Q: Who can provide additional information?

A: Please contact the local Dow Corning Service Center or your local Dow Corning technical service representative.

Dow Corning Service Centers:

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