

Dow Corning® QP1 Liquid Silicone Rubber Materials

Product Range

The Dow Corning® brand QP1 LSR product offering includes eight products ranging in Shore A hardness from 20 to 75.

Features

- ▶ Contains no peroxides, peroxide by-products, chlorophenyls or PCBs
- ▶ No organic plasticizers, phthalates or latex additives
- ▶ Solventless
- ▶ Non-blooming
- ▶ Can be post-cured
- ▶ Pigmentable
- ▶ Formulated to meet FDA 21 CFR 177.2600 requirements for food contact applications

Benefits

- ▶ Suitable for healthcare applications, including short-term implantation and insert
- ▶ Available in a range of Shore A hardness from 20 to 75
- ▶ United States Pharmacopeia (USP) Class VI
- ▶ Warranted for tissue culture
- ▶ FDA food grade compliant by formulation
- ▶ Notification provided on changes to process and formulation
- ▶ Manufactured in facilities audited by Dow Corning Healthcare representatives to help ensure quality
- ▶ Fast cure
- ▶ Batch-to-batch consistency
- ▶ Easy processing



Dow Corning offers more choice for healthcare device and component fabrication

An Expanded LSR Offering

With Dow Corning® QP1 LSR, Dow Corning has broadened our existing offering of elastomers for medical device and component fabrication, giving you the choice to select the most appropriate product to meet your liquid injection molding needs. Dow Corning® QP1 LSR materials can be used in a variety of healthcare applications, including:

- ▶ Short-term implant – wound drains, gastric feeding tubes, in place for 29 days or fewer
- ▶ Non-implant – needleless access valves
- ▶ Surgical suite – anesthesia masks, surgical instrumentation
- ▶ Consumer healthcare – dental applications, nasal aspirators

Dow Corning® QP1 LSR materials are two-part platinum-catalyzed silicone elastomers, supplied in a kit (Part A and Part B). They are available in a range of nominal hardness, from

20 to 75 Shore A durometer. When cured, the elastomers are heat stable to 204°C (400°F), and they can be autoclaved. They also exhibit high gas permeability compared to most thermoset elastomers and thermoplastics.

Reliable Quality and Supply

When you choose Dow Corning® QP1 LSR materials, you are assured high quality and reliable supply. Our materials are manufactured in accordance with the ISO 9001 Quality Management System. Documentation includes a regulatory summary and certificate of Class VI testing.

Dow Corning® QP1 LSR materials are manufactured in Midland, Michigan, U.S.A. and Wiesbaden, Germany.



Compare LSR Materials from Dow Corning

Dow Corning offers a range of liquid silicone rubber materials. The following table offers a brief comparison of *Dow Corning*[®] QP1 LSR materials, *Dow Corning*[®] brand Class VI Elastomers and S Series LSR materials and *Dow Corning*[®] brand BioMedical Grade (BMG) Elastomers and E Series LSR materials.

	<i>Dow Corning</i> [®] QP1 LSR	<i>Dow Corning</i> [®] C6/S Series LSR	<i>Dow Corning</i> [®] BMG/E Series LSR
Applications	<ul style="list-style-type: none"> ▶ Non long-term implant ▶ Suitable for medical insert ▶ Suitable for selected short-term implant (<30 days) ▶ Suitable for non-implant ▶ Food contact application <ul style="list-style-type: none"> • 21 CFR 177.2600 (food grade) 	<ul style="list-style-type: none"> ▶ Non long-term implant ▶ Suitable for medical insert ▶ Suitable for selected short-term implant (<30 days) ▶ Suitable for non-implant ▶ Food contact application <ul style="list-style-type: none"> • 21 CFR 177.2600 (food grade) 	<ul style="list-style-type: none"> ▶ Long-term implant (>30 days, indemnification needed) ▶ Suitable for medical insert ▶ Suitable for selected short-term implant (<30 days) ▶ Suitable for non-implant ▶ Food contact application <ul style="list-style-type: none"> • 21 CFR 177.2600 (food grade)
Quality System	▶ ISO 9001 Quality Management System	▶ ISO 9001 Quality Management System ▶ Produced in GMP facility*	▶ ISO 9001 Quality Management System ▶ Produced in GMP facility*
Documentation	▶ Regulatory summary ▶ Certificate of Class VI testing	▶ Regulatory summary ▶ Summary of Health Data	▶ Regulatory summary ▶ Summary of Health Data ▶ EU Technical File/US Drug Master File**
Testing	<ul style="list-style-type: none"> ▶ USP Class V and VI ▶ Select ISO 10993 <ul style="list-style-type: none"> • Cytotoxicity • 7-day implant 	<ul style="list-style-type: none"> ▶ USP Class V and VI ▶ Select ISO 10993 <ul style="list-style-type: none"> • Cytotoxicity • 30-day implant • Hemolysis • Skin sensitization ▶ Select EP 3.1.9 <ul style="list-style-type: none"> • Volatile matter • Substance soluble in hexane (SSH) 	<ul style="list-style-type: none"> ▶ USP Class V and VI ▶ Select ISO 10993 <ul style="list-style-type: none"> • Cytotoxicity • 30-day and 90-day implant • Hemolysis • Skin sensitization • Mutagenicity/Genotoxicity • Pyrogenicity (USP) ▶ Select EP 3.1.9 <ul style="list-style-type: none"> • Volatile matter • Substance soluble in hexane (SSH)
Other	<ul style="list-style-type: none"> ▶ Shore A, hardness 20-75 ▶ Notification for change ▶ Manufactured in Midland, Michigan U.S.A. and Wiesbaden, Germany 	<ul style="list-style-type: none"> ▶ Shore A, hardness 30-70 ▶ Dow Corning Healthcare Industries Materials Site (HIMS) change notification policy ▶ Manufactured at HIMS (U.S.A.) 	<ul style="list-style-type: none"> ▶ Shore A, hardness 30-70 ▶ Dow Corning HIMS change notification policy ▶ Manufactured at HIMS (U.S.A.)

* Following principles of 21 CFR 820 (Medical Device Quality System Regulation/Good Manufacturing Practices)

** Only for *Dow Corning*[®] BMG products

How can we help you today?

When you need innovation, Dow Corning can help. *Dow Corning*[®] brand solutions are dedicated to meeting your needs for specialty materials, collaborative problem solving and innovation support. Learn how we can help you **GO BEYOND** at dowcorning.com/healthcare.

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