

**UV Cure
Silicone
Elastomers**
For Long-Term Implants

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Silicone Elastomers for Long-Term Implants

Reliable

Silicone elastomers have a proven track record in the healthcare field due to their unique chemistry that provides the ideal foundation for long-term implants.

The secret to this success is found in the silicone chemistry, which provides inherent biocompatibility and hypoallergenic properties, making silicone elastomers ideal for a wide variety of medical applications which includes not only medical devices and short-term implants, but also long-term implants, combination devices, wearable devices, electronic encapsulation, and sensors.

Innovative

As a leading provider of silicones to the medical field, Momentive Performance Materials, Inc. has a long history of providing innovative solutions that help solve the toughest manufacturing challenges.

Momentive's ReliaSil UV product line combines the benefits of the ambient cure found in an RTV with the robust physical properties of a high-consistency silicone elastomer, redefining what is possible by offering new capability to proven technologies that will enable the next generation of long-term implants.



What if there was a silicone material that combined **low-temperature, UV cure** with **robust physical properties**, suitable for LTI applications?

Momentive's ReliaSil UV silicone elastomers bring UV Cure technology to the LTI market, creating the design flexibility that will open a whole new world of possibilities to medical design.

ReliaSil UV silicone elastomers utilize a unique UV catalyst system that enables command-cure flexibility, providing increased cure speeds at ambient temperatures, without sacrificing the physical properties that give silicone elastomers the performance advantage over RTVs and other room-temperature cure materials.

The result is a new world of medical device design: from creating new devices with active pharmaceutical ingredients (APIs) to encapsulating electronics with batteries and sensitive electronic components for the next generation of implantable devices.

ReliaSil UV elastomers create a new level of material performance that will allow the designer to redefine the limits of technology and reconsider what is possible, setting new expectations for material processing and challenging the perceived limitations of material capability and device performance.

Platinum-Cure Chemistry

High Purity

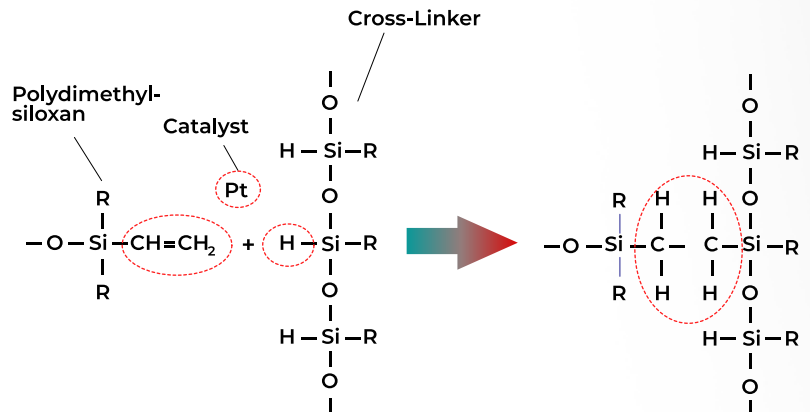
ReliaSil UV HCR is a platinum (Pt) cure silicone elastomer. Pt cure systems are also referred to as addition cure as the polymer matrix is formed through an addition reaction that avoids the formation of byproducts, making them preferred in applications where cleanliness and purity are required.

ReliaSil UV HCR ensures suitability for high purity applications with manufacturing operations that are located in a clean room environment. Additionally, each batch of ReliaSil UV HCR is tested for cytotoxicity and heavy metals at an outside laboratory to document the material purity and suitability for the demanding requirements of LTI applications.

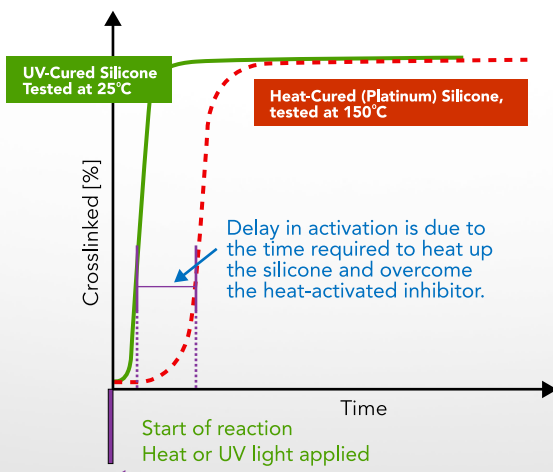
Proven Chemistry

ReliaSil UV HCR is a silicone high-consistency elastomer.

ReliaSil UV HCR is built on the proven Pt-cure (addition) reaction that has proven to be successful in medical applications. These materials have been used in many different healthcare applications: medical device, short-term implants, biopharmaceutical, and wound care.



Low-Temperature, UV Cure



ReliaSil UV HCR optimizes the addition-cure reaction with the incorporation of a UV-sensitive inhibitor that replaces the standard heat-sensitive inhibitor.

The result is a new generation of silicone elastomers that have revolutionized what is possible in the long-term market, specifically in applications with temperature limitations due to sensitive components or processing controls.

ReliaSil UV HCR

Potential Applications for UV Technology

Temperature-Sensitive Additives

Reliasil UV HCR offers a distinct advantage when considering formulations with temperature-sensitive components such as active pharmaceutical ingredients (APIs).

ReliaSil UV HCR provides a unique combination of low-temperature, UV cure with robust physical properties in a command-cure package that is activated by UV light (365 nm).

These distinctive properties enable applications where the direct addition of the API to the device will allow for enhanced performance. Applications typically involve a requirement for a precise loading of the API or a secondary process with solvent impregnating is undesirable or not possible.

Benefits

- Low temperature cure for compatibility with temperature sensitive ingredients.
- Localized drug delivery can reduce the necessary dosage levels which may lead to a lower incidence of potential side effects.
- Direct loading enables a precise process for a stable mass ratio and accurate demonstration of efficacy of the drug additives.
- Direct loading eliminates secondary processes, solvent baths, and the uncertainty that is inherent to a swelling/ impregnation process.

Considerations:

- The cure reaction initiates with exposure to UV light (centered on 365 nm)
- Additives may impact the cure reaction, requiring longer cycle times and/or increased catalyst levels.
- Depending on the API concentration and/or primary mode of action, devices may be classified as combination medical devices or drug delivery devices.

Please consult the FDA for proper designation and corresponding requirements.

Temperature-Sensitive Components

Implants that incorporate temperature sensitive components are often limited in material choices that offer low temperature cure and strong physical properties. One of the more sensitive components can often be batteries, which typically have an upper temperature range of 80°C.

RTVs meet the necessary curing temperatures, but lack the robust properties (tear, tensile, elongation, etc.) of a silicone elastomer.

Medical devices that are designed with ReliaSil UV HCR harness the robust physical properties of a silicone elastomer while curing well under the upper temperature limits of the battery, optimizing battery life and enabling designers to create new, more robust solutions.

Applications

Implantable electronics | Wearable devices

Considerations:

- The UV cure reaction will proceed at room temperature
- The rate of cure can be accelerated with low levels of heat
- Processing temperatures of 40-50°C provide the optimum conditions for achieving the fastest cure speed and cycle times

ReliaSil UV HCR 241-60

Product Description

ReliaSil UV HCR 241-60 silicone rubber is a two component UV-cured silicone elastomer with a standard mix ratio of 100:0.5 (rubber base: catalyst), which offers high-speed cure at room temperature for extrusion and compression molding. This ratio may be modified depending on application and may need to be adjusted to allow the successful incorporation of APIs or other temperature sensitive ingredients. UV-cured high-consistency elastomers are extruded using standard equipment and cured with UV light source that is often less than 1 m in length, eliminating the need for large, high-temperature ovens, maximizing efficiency and energy savings.

Key Features and Typical Benefits

- long-term implantation*, > 29 days
- Cure on-demand by UV light
- Low-temperature cure
- Reduced shrinkage compared to heat-cured materials
- Compatible with existing silicone extruders

*Subject to written approval in accordance with Momentive's Healthcare policy.

Biocompatibility

Summary of Biocompatibility Studies:

- Determination of Extractability - ISO 10993-12
- Analytical Screening of Metals By ICP/MS - ICH - (QED)
- Kligman Maximization Test – ISO 10993-10
- 28-Day Systemic Toxicity in Rats via Intramuscular Implantation (ISO 10993-6,-11)
- Rabbit Blood Hemolysis Test - ASTM
- Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay - ISO 10993-3
- Mouse Lymphoma Mutagenesis Assay with Confirmation – ISO 10993-3
- Rabbit Pyrogen Test (Material Mediated) – ISO 10993-11
- L929 MEM ELUTION TEST - ISO 10993-5
- L929 AGAR DIFFUSION TEST (DIRECT CONTACT) - ISO 10993-5
- CLASS VI TEST – USP <88>; ISO 10993-6,-11,-23 : Acute Systemic Toxicity, Intracutaneous Reactivity, 2 Week Muscle Implant

Contact your sales representative to request a Toxicology summary and/or LoA (letter of access).

FDA Master File for Devices

Submission Number: MAF3797

Device: ReliaSil UV HCR 241-60

Typical Physical Properties

Typical Properties (from the trial batch)		
Appearance	A-Component	B-Component
	Translucent	Translucent

The pot-life of the mixture of the two components (closed vessel) at 20 C is seven days. Increased temperature and/or exposure to UV light reduces the pot-life.

Typical properties of the vulcanizate:

Mixing ratio of components A : B = 100 : 0.5

Vulcanization conditions: exposed to UV light for 2 min UV-irradiation at 60mW/cm²

Density	DIN 53 479 A	g/cm ³	1.18
Hardness	DIN 53 505	Shore A	60
Tensile Strength	DIN 53 504 S2	N/mm ²	11.1
Elongation at break	DIN 53 504 S2	%	615
Tear Strength	ASTM D 624, Die B	N/mm ²	57

Typical properties are based on averages and are not to be used to develop specifications.



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