

Silbione® BIOMEDICAL LSR M100 SERIES

October 2017

Liquid Silicone Rubber – Long-Term Implant

Description

Silbione® BIOMEDICAL LIQUID SILICONE RUBBERS (LSRs) are two-component platinum-catalyzed silicone elastomers designed for liquid injection molding and casting medical parts, including selected long-term implant (30 days or more) applications.

Available in a full range of hardnesses from 01 to 70 durometer – Shore A, Elkem Silicones' **Silbione® BIOMEDICAL LSRs** offer the distinctive advantages of easy processing and easy release combined with high performance physical properties.

Advantages

- Flowable and self-levelling.
- Rapid cure at elevated temperatures.
- Can be post-cured, but post cure is not necessary to achieve desired physical properties.

Processing

Silbione® BIOMEDICAL LSRs are supplied as kit-matched products. Parts A and B components are designed to be mixed with standard liquid injection molding or casting processing equipment and techniques. Airless mixing, metering and dispensing equipment are recommended.

Cure:

Cure is initiated once the two-part A and part B components are mixed and can be accelerated by heating the mixed elastomer. Cure is dependent upon molding temperature and part size.

Special care must be taken to assure clean molds and a clean work area with no organic rubbers used on the same processing equipment.

Caution: Traces of foreign materials can poison the catalyst and inhibit the cure. All metering and mixing equipment should be thoroughly cleaned. Polymer systems, which contain traces of amines, sulfur, nitrogen oxide, organotin compounds and carbon monoxide can interfere with the cure of this product and should be avoided.

Note: Kit matching, accurate measuring and complete mixing are essential factors in obtaining consistent results.

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Typical Properties

As supplied:

<i>Typical properties</i>	ASTM	LSR M125	LSR M140	LSR M125 10:1	LSR M130 10:1	LSR M140 10:1
Appearance	TP 038	Clear	Clear	Clear	Clear	Clear
Mix Ratio	-	1:1	1:1	10:1	10:1	10:1
Viscosity Part A, cP	TP 001	75,000	85,000	85,000	90,000	100,000
Viscosity Part B, cP	TP 001	70,000	65,000	2,200	550	300
Specific Gravity	TP 013	1.08	1.09	1.08	1.08	1.09

Press cure, 5 minutes, 177°C (350°F):

<i>Typical properties</i>	ASTM	LSR M125	LSR M140	LSR M125 10:1	LSR M130 10:1	LSR M140 10:1
Hardness, Shore A	D2240	27	41	28	31	40
Tensile strength, Psi	D412	800	975	770	650	975
Elongation, %	D412	550	385	480	480	350
Tear strength, Ppi	D624 Die B	70	145	76	70	140
Work Life hr	D412	>2	>4	>2	>2	>4

Please note: The typical properties listed in this bulletin are not intended for use in preparing specifications for any particular application of **Silbione®** silicone materials.

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Storage and shelf life

For shelf life, please refer to the expiry date (to be used before « month-year ») marked clearly on the packaging. Comply with the storage instructions and expiry date marked on the packaging.

Beyond this date, Elkem Silicones no longer guarantees that the products meet the sales specifications.

**Silbione®****BIOMEDICAL LSR M100 SERIES****Safety**Please consult the Safety Data Sheets of **Silbione® BIOMEDICAL LSRs**.**Regulation**Bio-compatibility Testing

Designed specifically for long-term implant applications, **Silbione® BIOMEDICAL** brand materials have been tested according to, or are substantially equivalent to materials that have been tested according to ISO 10993/USP Class VI for:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation (ISO 10993)
- Intracutaneous Toxicity (USP)
- Systemic Toxicity
- Mutagenicity
- Hemolysis
- Pyrogenicity (USP)
- 12-Week Implant

FDA Master Files

Master Files (MAFs) in support of **Silbione® BIOMEDICAL** brand products are on file with the U.S.FDA. Customers interested in referencing these files must contact Elkem Silicones representative.

Limitation

Elkem Silicones selectively supports the sales of these **Silbione® BIOMEDICAL LSRs** to customers involved in manufacturing and assembling approved medical devices for 30 days or more implantation. The purchaser has the sole responsibility to select a particular Elkem Silicones product and determine its application suitability. The purchaser also has the sole responsibility to comply with all applicable statutory, regulatory and industry requirements and standards for compatibility, extractability, testing, safety, efficacy and labelling.

Packaging**Silbione® BIOMEDICAL LSRs** are available in multiple packages, please consult with our team.**Silbione®** is a registered Trademark of **Elkem SILICONES****Warning to the users**

The information contained in this document is given in good faith based on our current knowledge. It is only an indication and is in no way binding, particularly as regards infringement of or prejudice to third party rights through the use of our products. Elkem SILICONES guarantees that its products comply with its sales specifications. This information must on no account be used as a substitute for necessary prior tests which alone can ensure that a product is suitable for given use. Users are responsible for ensuring compliance with local legislation and for obtaining the necessary certifications and authorizations. Users are requested to check that they are in possession of the latest version of this document and Elkem SILICONES is at their disposal to supply any additional information.