

October 2017

SILBIONE® BIOMEDICAL LSR M300 SERIES

Implant Grade Liquid Silicone Rubber

Description **Silbione® BIOMEDICAL LIQUID SILICONE RUBBERS (LSRs)** are two-component platinum-catalyzed silicone elastomers designed for liquid injection molding 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.

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- Advantages**
- Excellent mold release for shorter cycle times.
 - Superior clarity.
 - High performance physicals – high tear and elongation.
 - 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 in equal parts using standard liquid injection molding 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.

Typical Properties
As supplied:

<i>Typical properties</i>	ASTM	LSR M301	LSR M305	LSR M310	LSR M325	LSR M330	LSR M340	LSR M350	LSR M360	LSR M370
Appearance	TP 038	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear
Extrusion Rate, <i>g/min</i>	TP 001	550	545	275	135	100	90	85	95	70
Specific Gravity	TP 013	1.07	1.07	1.09	1.11	1.11	1.12	1.12	1.12	1.14

Press Cure, 5 minutes, 177°C (350°F)

<i>Typical properties</i>	ASTM	LSR M301	LSR M305	LSR M310	LSR M325	LSR M330	LSR M340	LSR M350	LSR M360	LSR M370
Hardness, Shore A	D2240	1	5	10	23	30	40	50	60	70
Tensile strength, Psi (<i>N/mm²</i>)	D412	270 (1.9)	480 (3.3)	850 (5.8)	1250 (8.6)	1340 (9.2)	1250 (8.6)	1225 (8.4)	1275 (8.8)	1250 (8.6)
Elongation, %	D412	1100	1050	1020	970	800	660	600	480	440
Tear strength, Ppi (<i>N/mm</i>)	D624 Die B	45 (7.8)	65 (11.5)	115 (20)	180 (32)	185 (32)	230 (40)	270 (47)	240 (42)	230 (40)
Modulus, 100%, Psi (<i>N/mm²</i>)	D412	12 (0.1)	19 (0.1)	32 (0.2)	59 (0.4)	83 (0.6)	157 (1.1)	277 (1.9)	380 (2.6)	540 (3.7)

Post-Cured, 4 hours, 200°C (392°F)

<i>Typical properties</i>	ASTM	LSR M301	LSR M305	LSR M310	LSR M325	LSR M330	LSR M340	LSR M350	LSR M360	LSR M370
Hardness, Shore A	D2240	2	4	10	26	31	40	50	61	72
Tensile strength, Psi (<i>N/mm²</i>)	D412	219 (1.5)	450 (3.1)	750 (5.1)	1198 (8.2)	1350 (9.3)	1250 (8.6)	1275 (8.8)	1250 (8.6)	1200 (8.3)
Elongation, %	D412	800	1000	1060	1035	750	605	530	430	440
Tear strength, Ppi (<i>N/mm</i>)	D624 Die B	35 (6.1)	60 (10)	125 (22)	168 (29)	205 (36)	285 (50)	290 (51)	235 (41)	200 (35.1)
Modulus, 100%, Psi (<i>N/mm²</i>)	D412	32 (0.2)	20 (0.1)	28 (0.2)	72 (0.5)	200 (1.4)	200 (1.4)	340 (2.3)	400 (2.8)	580 (4.0)

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BIOMEDICAL LSR M300 SERIES

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.

Safety

Please consult the Safety Data Sheets of **Silbione® BIOMEDICAL LSRs**.

Packaging

Silbione® BIOMEDICAL LSRs are available in multiple packages, please check with our team.

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.

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Warning to the users

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