SILBIONE® High Performance – High Durometer LSRs

Liquid Silicone Rubber

Description

SILBIONE® High Performance – High Durometer LSRs are two-component platinum-catalyzed silicone elastomers designed for liquid injection molding healthcare and medical devices, including applications of less than 30-day implantation in the human body.

Available in 30 to 70 durometer Shore A, Bluestar Silicones' **SILBIONE® High Performance – High Durometer LSRs** offer the distinctive advantages of easy processing and easy release combined with high performance physical properties.

Designed specifically for healthcare applications, **SILBIONE® High Performance – High Durometer LSRs** meet or exceed testing requirements of United States Pharmacopoeia (USP) Class VI. Biocompatibility testing addresses the categories of evaluation for cytotoxicity, skin sensitization and skin irritation specified in ISO 10993 for skin contact or device use of less than 30-day implantation.
See Table 2.

Features

- Easy processing
- 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 physicals

Applications

The easy processing and high performance physical properties of the **SILBIONE® LSRs** make them suitable for a broad range of applications including:

- Fabrication of healthcare and medical devices, including skin contact or less than 30-day implantation
- Skin contact parts like masks and goggles
- Infant care products
- Overmolding (Silbione® LSR 60)

Instructions for use

SILBIONE® High Performance – High Durometer 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.

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

Cure

Cure is initiated 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.

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.

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Limitation	Bluestar Silicones supports the sales of these products to customers involved in manufacturing and assembling approved medical devices for less than 30-day implantation. The purchaser has the sole responsibility to select a particular Bluestar 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 labeling.
Storage and shelf life	**SILBIONE® High Performance – High Durometer LSRs**, when stored in original unopened packaging, may be stored at temperatures between 5ºC - 32ºC (40ºF - 90ºF) for 12 months from the date of manufacture. Beyond this date, Bluestar Silicones no longer guarantees that the product meets the sales specifications
Safety	Please read the container labels for **SILBIONE® High Performance – High Durometer LSRs** or consult the Material Safety Data Sheet (MSDS) before handling for safe use, physical and health hazard information. The MSDS is not included with the product packaging, but can be obtained by contacting Bluestar Silicones at 866-474-6342 or consult your Bluestar Silicones representative.
Packaging	**SILBIONE® High Performance – High Durometer LSRs** are supplied in 36 kg pail or 400 kg drum kits.

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Table 1: TYPICAL PROPERTIES

As Supplied	CTM	*LSR* 4360	*LSR* 4365	*LSR* 60	*LSR* 4370
Appearance	TP 038	*clear*	*clear*	*clear*	*clear*
Viscosity					
Shear rate 1/sec, Pa.s		2000			
Shear rate 10/sec, Pa.s		700			
Extrusion Rate, *g/min*	TP 001	95	72	140	70
Specific Gravity, *g/cm*	TP 013	1.12	1.14	1.12	1.14
Press Cured (1) *5 min.,177°C*	**ASTM**	***LSR* 4360**	***LSR* 4365**	***LSR* 60**	***LSR* 4370**
Hardness, *Shore A*	D 2240	60	65	59	68
Tensile Strength, *psi (N/mm²)*	D 412	1,225 (8.4)	1270 (8.8)	1330 (9.1)	1250 (8.6)
Compression Set	D395B	50			40
Elongation,%	D 412	450	470	440	440
Tear Strength, *Ppi (N/mm)*	D 624, Die B	230 (40)	250 (43)	190 (33)	230 (40)
Modulus,100%, *psi (N/mm2)*	D 412	380	560	334	540
Resiliency, %	D 2632	63			63
Post Cured (1) *4 hrs.,200°C*	**ASTM**	***LSR* 4360**	***LSR* 4365**	***LSR* 60**	***LSR* 4370**
Hardness, *Shore A*		61			70
Tensile Strength, *psi (N/mm²)*	D 2240	1,250 (8.6)			1200 (8.3)
Compression Set	D395B	25			
Elongation,%	D 412	430			400
Tear Strength, *Ppi (N/mm)*	D 624, Die B	235 (41)			200 (35.1)
Modulus,100%, *psi (N/mm²)*	D 412	400 (2.8)			580 (4.0)
Resiliency, %	D 2632	60			60

(1) Slab 6" x 6" x 0.07"

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. Please contact our Technical Service Department for assistance in writing specifications.

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Table 2: BIOCOMPATIBILITY DATA

Biocompatibility Tests (1)(2)				
	***LSR* 4360**	***LSR* 4365**	***LSR* 60**	***LSR* 4370**
Cytotoxicity	●	○	○	●
Skin Sensitization	●	○	○	●
Intracutaneous Toxicity	●	○	○	●
Systemic Toxicity	●	○	○	●
Mutagenicity	○	○	●	●
Hemolysis				
Mucosal Irritation				
Pyrogenicity	○	○		●
7-Day Implant	○	○	○	●
28-Day Implant				
90-Day Implant			●	
USP Class VI or ISO 10993	●	○	●	●
FDA Master File (MAF)			●	
Extraction Tests (2)				
	***LSR* 4360**	***LSR* 4365**	***LSR* 60**	***LSR* 4370**
FDA 21 CFR 177.2600	See note (4) ○	See note (4) ○	See note (4)	○
FDA 7117.11 Nitrosamines				

● = Indicates test performed on the material, successfully passed

○ = Indicates test not performed on the material, however, it is substantially equivalent to another tested Bluestar Silicones LSR

(1) - The biocompatibility testing listed addresses the categories of evaluation specified in ISO 10993 for device use of less than 30 days duration.
(2) - Tests conducted on final product (A+B)
(3) - Equivalent to LSR 4340 with a healthcare grade self lubricating additive
(4) - Supported by testing meeting European Pharmacopoeia section 3.1.9 hexane extraction