

Silbione® Liquid Silicone Rubbers for Healthcare (4305, 4310, & 4325)

Distributed By
Freeman Manufacturing & Supply Co.
www.freemansupply.com 800-321-8511



Liquid Silicone Rubber

Description

Silbione® Liquid Silicone Rubbers (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 05 to 25 durometer Shore A, Bluestar Silicones' **Silbione® LSRs** offer the distinctive advantages of easy processing and easy release combined with high performance physical properties.

Designed specifically for healthcare applications, **Silbione® 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 device use of less than 30 days duration. See Table 2.

Features

- Easy processing and convenient 1:1 mix ratio
- Excellent mold release for shorter cycle times
- Superior clarity
- High performance physicals – high tear and elongation; can be molded into thin-walled parts
- Rebound resilience characteristics – cushioning and non-tacky
- Rapid cure at elevated temperatures
- Can be post-cured, but post cure is not necessary to achieve desired physicals
- Easily pigmented
- Soft, skin-like feel when molded

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 less than 30 day implantation
- Skin contact parts like liners
- Balloons
- Cushioning applications

Instructions for use

Silbione® 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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Table 1. - Typical Properties

<i>As Supplied</i>	CTM	LSR 4305	LSR 4310	LSR 4325
Appearance	TP 038	clear	clear	clear
Viscosity, cps	TP 005	45,000	110,000	
Extrusion Rate, g/min	TP 031		275	135
Specific Gravity, g/cm	TP 013	1.07	1.08	1.12

<i>Press Cured</i> (1) 5 min., 177°C	ASTM	LSR 4305	LSR 4310	LSR 4325
Hardness, Shore A	D 2240	5	10	23
Tensile Strength, psi (N/mm²)	D 412	450 (3.1)	750 (5.1)	1198 (8.2)
Elongation, %	D 412	1000	1060	1035
Tear Strength, Ppi (N/mm)	D 624, Die B	60 (10)	125 (22)	168 (29)
Mod@,100%, psi (N/mm²)	D 412	15 (0.1)	28	54
Resiliency, %	D 2632		35	41

<i>No Post Cured</i>	LSR 4305	LSR 4310	LSR 4325
Elongation, %	1080	1010	986
Tensile, psi	547	732	1284
Mod@100%	19	27	59
Mod@200%	31	47	107
Mod@300%	48	75	172
Tear, ppi	66	105	185

<i>2 Hr. Post Cure. @,200°C</i>	LSR 4305	LSR 4310	LSR 4325
Elongation, %	5	10	23
Tensile, psi	450 (3.1)	750 (5.1)	1198 (8.2)
Mod@100%	1000	1060	1035
Mod@200%	60 (10)	125 (22)	168 (29)
Mod@300%	15 (0.1)	28	54
Tear, ppi		35	41

<i>4 Hr. Post Cure. @,200°C</i>	LSR 4305	LSR 4310	LSR 4325
Hardness, Shore A	5	10	23
Tensile Strength, psi (N/mm²)	450 (3.1)	750 (5.1)	1198 (8.2)
Elongation, %	1000	1060	1035
Tear Strength, Ppi (N/mm)	60 (10)	125 (22)	168 (29)
Mod@,100%, psi (N/mm²)	15 (0.1)	28	54
Resiliency, %		35	41

(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 4305	LSR 4310	LSR 4325
Cytotoxicity	●	●	○
Skin Sensitization	●	●	○
Intracutaneous Toxicity	●	●	○
Systemic Toxicity		●	○
Mutagenicity			○
Hemolysis			
Mucosal Irritation		●	
Pyrogenicity		●	
7-Day Implant			○
USP Class VI	●	●	○
FDA Master File (MAF)			
Extraction Tests (2)			
	LSR 4305	LSR 4310	LSR 4325
FDA 21 CFR 177.2600	<i>Water extraction only</i>		
FDA 7117.11 Nitrosamines	●		

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

● = Indicates test performed on the material, successfully passed

(1) - The biocompatibility testing listed addresses the categories of evaluation specified in ISO 10993 for device use of less than 30 days duration.

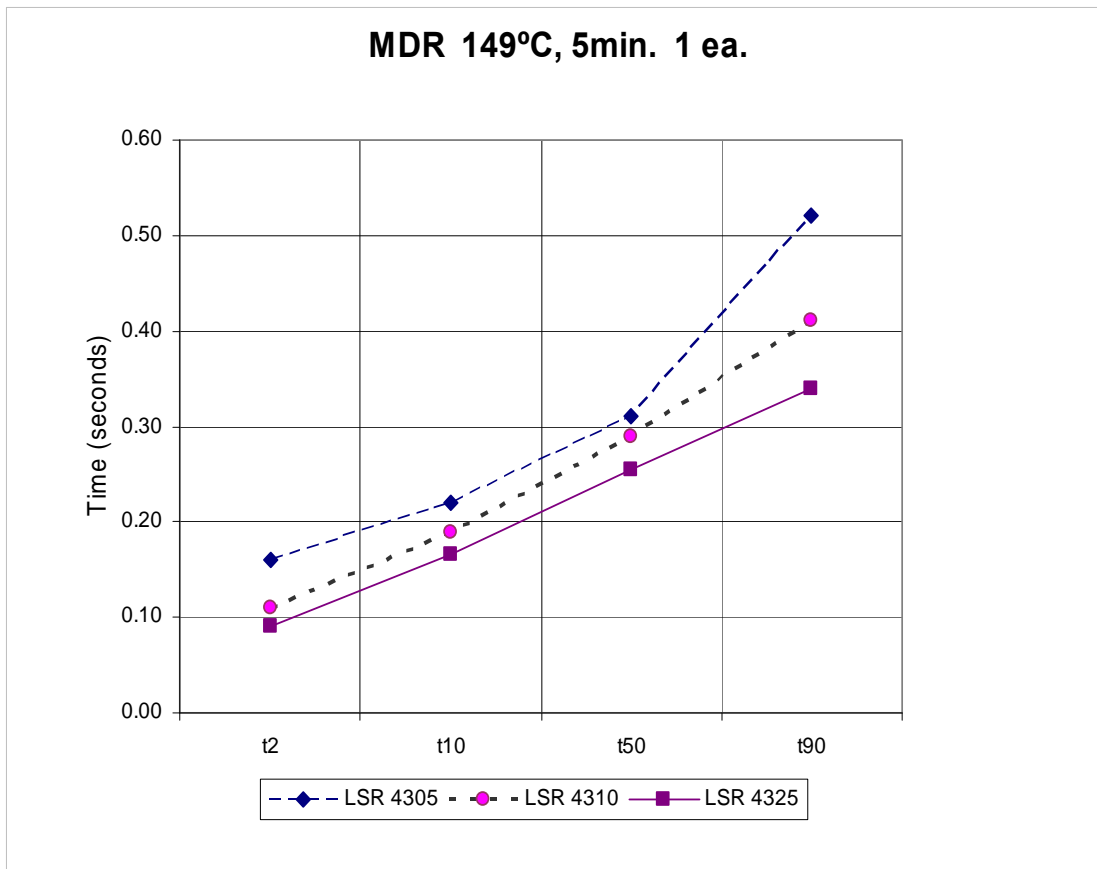
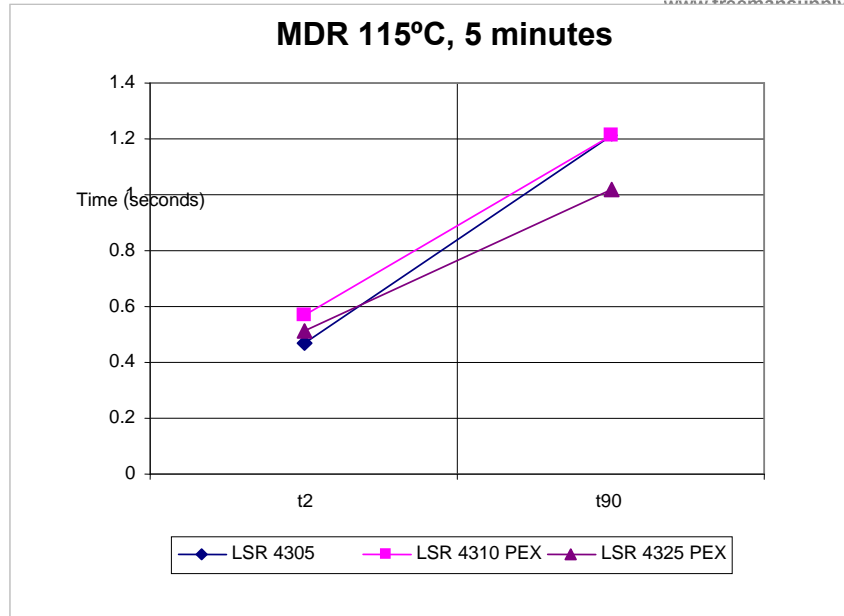
(2) - Tests conducted on final product (A+B)

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Table 3. – Rheological Test Data

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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® LSRs , when stored in original unopened packaging, at a temperature of 24°C (77°F), may be stored for 12 months from the date of manufacture. Beyond this date, Bluestar Silicones no longer guarantees that the product meets the sales specifications.
Handling and Safety	Prior to handling, read container labels and material safety data sheets for safe use, physical and health hazard information. Material safety data sheets are available on the Bluestar Silicones website at www.bluestarsilicones.com or can be obtained by contacting Bluestar Silicones at 866-474-6342.
Packaging	Silbione® LSRs are supplied in 36 kg (79.4 lb.) pail or 400 kg (881.8 lb.) drum kits.

Silbione® is a registered Trademark of **BLUESTAR SILICONES**

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