

## Liquid Silicone Rubber – Injection Molding Guide

Injection molding of silicone parts has enabled producers to achieve higher levels of automation and productivity than ever before. Molders and OEMs can now manufacture articles for a variety of devices and components with very demanding performance specifications.

This document is intended to illustrate the basics of injection molding of **Silbione® Liquid Silicone Rubber** and troubleshooting. Additional sources of information are the tool and injection molding machine manufacturers who are involved in the injection molding process.

Contact your Bluestar Silicones Representative for additional information on specific products and for information beyond the contents of this document.

### BLUESTAR SILICONES – DELIVERING YOUR POTENTIAL

#### High Performance Physical Properties

**Silbione® LSRs** are designed to give the highest physical properties on the market right out of the mold. These high strength products require no post-curing. If the application does require post-curing, the percent change in physical properties is minimal. With high clarity, high resiliency, and low compression set, **Silbione® LSRs** are ideal for demanding healthcare applications.

#### Ease of Processing

The manufacture of **Silbione® LSRs** is tightly controlled, providing good lot-to-lot consistency to the molder. With low viscosities, matching A/B extrusion rates and lot-to-lot consistency, fewer process adjustments are required during molding and between lot change-over.

#### Improved Productivity

**Silbione® LSR 43xx Series** is formulated to give good release from the mold with no sticking. Combine this with the ability to fill cavities faster (low viscosity = lower injection pressures), fast cure rates, and lower part flashing, and the molder now has the right combination to improve injection molding productivity rates.

#### Technical & Regulatory Support

Bluestar Silicones is committed to its customers and to providing fast, high-quality service in the marketplace. Our team of silicone experts can offer the assistance needed to help you mold the **Silbione® LSR** successfully.

#### Product Development

Bluestar Silicones works closely with customers to develop new products and new opportunities for growth. Contact your Bluestar Silicones Representative for more information on Research and Development project.



## General Information

### General

For many years, silicones have been used in a wide range of application areas including aerospace, automotive, electrical, construction, industrial, medical and healthcare. The unique properties of silicones make them ideal for very demanding applications.

The injection molding of **Silbione® Liquid Silicone Rubber (LSR)** offers the user ease of processing, high-volume molding, improved productivity, and consistent part quality.

### Why use silicones in healthcare applications?

- Excellent biocompatibility
- Inert, odorless, tasteless, stain resistant
- Extreme temperature applications (from -50C to + 200C continuous)
- Hypo-allergenic
- Can be steam or radiation sterilized. Dishwasher safe.
- Easy to clean
- Flexible and durable
- Resistance to ozone and corona
- Resistance to weathering and oxidation
- Excellent resistance to many chemicals, including low water absorption
- Superior dielectric and insulation characteristics
- High clarity and transparency
- Low compression set and good resiliency
- Long work and shelf life
- Low Shrinkage (no cure by products)

### Benefits of LSRs over HCRs

- **Molding Cycle Time:** Fast cycle times that are typically measured in seconds. Temperature = ~170 °C to 200°C, Cycle time = ~4 to 6s/mm.
- **Secondary Operation:** Molds can be designed to be flashless, eliminating the need for secondary operations.
- **Contamination:** Packaged in a closed system; less chance of contamination because an operator does not physically touch the material, and the material is not in contact with the atmosphere.
- **Labor:** LSR injection equipment and tooling can be set up to run automatically with only minimal labor to monitor the system and change drums.
- **Scrap:** LSR does not generate scrap from excess flash to the same degree as high consistency rubber. LSR molds can be designed to run flashless.
- **Part Configuration:** Because of the flow properties of LSRs, they are ideal for small intricate parts where maintaining tight tolerances is important.



## Limitations

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 its original un-opened packaging, at a temperature of 24°C (77°F), may be stored for a minimum of 6 months (12 months for most products) from the date of manufacture. Beyond this date, Bluestar Silicones no longer guarantees that the product meets the sales specifications.

## Safety

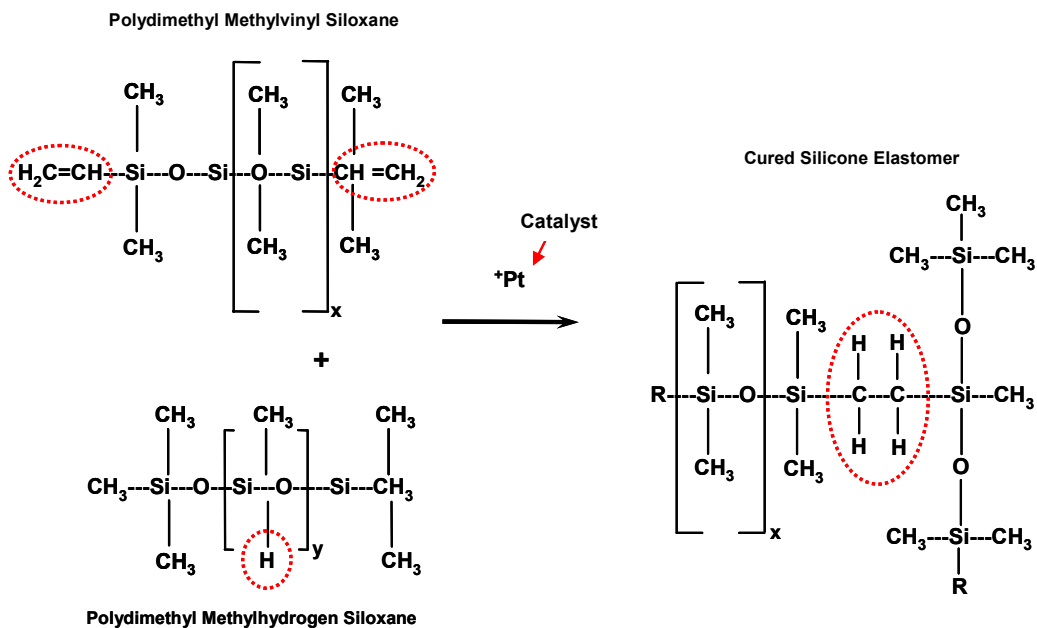
Please read the container labels for **Silbione® LSRs** or consult the Material Safety Data Sheet (MSDS) before handling for safe use, physical and health hazard information. The MSDS is not included with the product packaging, but can be obtained by contacting Bluestar Silicones at 866-474-6342 or consult your Bluestar Silicones representative.

## Packaging

**Silbione® LSRs** are available in 18 kg (40 lb) pail kits or 200 kg (440 lb) drum kits.

## LSR Chemistry

**Silbione® Liquid Silicone Rubbers (LSRs)** are two-component platinum-catalyzed silicone elastomers. The Part A component contains vinyl functional polymer(s) and the platinum catalyst. The Part B component contains the hydride crosslinker and inhibitor.



## Product Portfolio

### ■ TYPICAL PROPERTIES

Low durometer, rapid cure, high strength				
<i>As Supplied</i>	<i>LSR 4301</i>	<i>LSR 4305</i>	<i>LSR 4310</i>	<i>LSR 4325</i>
Appearance	clear	clear	clear	clear
Viscosity, cps	55,000	60,000	110,000	
Extrusion Rate, g/min			270	130
Specific Gravity, g/cm	1.07	1.07	1.08	1.12
<i>Press Cured (1) 5 min., 177°C</i>				
	<i>LSR 4305</i>	<i>LSR 4310</i>	<i>LSR 4325</i>	
Hardness, Shore A	1	5	10	23
Tensile Strength, psi (N/mm <sup>2</sup> )	254 (1.75)	450 (3.1)	750 (5.1)	1198 (8.2)
Elongation, %	1090	1100	1060	950
Tear Strength, ppi (N/mm)	60 (10)	60 (10)	115 (19.2)	168 (29)
Modulus, 100%, psi (N/mm <sup>2</sup> )		15 (0.1)	28 (0.2)	54 (0.4)
Resiliency, %			35	41

### ■ BIOCOMPATIBILITY DATA

<i>Biocompatibility Tests (1)(2)</i>				
	<i>LSR 4301</i>	<i>LSR 4305</i>	<i>LSR 4310</i>	<i>LSR 4325</i>
Cytotoxicity	•	•	•	•
Skin Sensitization	•	•	•	○
Intracutaneous Toxicity	•	•	•	○
Systemic Toxicity			•	○
Mutagenicity			•	○
Hemolysis				
Mucosal Irritation			•	
Pyrogenicity			•	
7-Day Implant				○
USP Class VI	•	•	•	○
FDA Master File (MAF)				
<i>Extraction Tests (2)</i>				
		<i>LSR 4305</i>	<i>LSR 4310</i>	<i>LSR 4325</i>
FDA 21 CFR 177.2600		Water extraction only		
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)

## ■ TYPICAL PROPERTIES

Rapid cure, high strength								
<i>As Supplied</i>	<b>LSR 4330</b>	<b>LSR 4340</b>	<b>LSR 4340 FC</b>	<b>LSR 4340 SL</b>	<b>LSR 4350</b>	<b>LSR 4360</b>	<b>LSR 60</b>	<b>LSR 4370</b>
<b>Appearance</b>	<i>clear</i>	<i>clear</i>	<i>clear</i>	<i>opaque</i>	<i>clear</i>	<i>clear</i>	<i>clear</i>	<i>clear</i>
<b>Viscosity</b>								
Shear rate 1/sec, <i>Pa.s</i>	550	1,800	1,800	1,800	2000	2000	<i>Not tested</i>	2000
Shear rate 10/sec, <i>Pa.s</i>	270	650	650	650	700	700		700
<b>Extrusion Rate, <i>g/min</i></b>	105	90	90	100	80	75	100	70
<b>Specific Gravity, <i>g/cm</i></b>	1.11	1.12	1.12	1.10	1.12	1.13	1.13	1.14
<b>Press Cured<sup>(1)</sup> 5 min., 177°C</b>	<b>LSR 4330</b>	<b>LSR 4340</b>	<b>LSR 4340 FC</b>	<b>LSR 4340 SL</b>	<b>LSR 4350</b>	<b>LSR 4360</b>	<b>LSR 60</b>	<b>LSR 4370</b>
<b>Hardness, Shore A</b>	30	40	40	34	50	60	59	68
<b>Tensile Strength, <i>psi (N/mm<sup>2</sup>)</i></b>	1400 (9.7)	1230 (8.5)	1230 (8.5)	942 (6.5)	1225 (8.4)	1300 (9.0)	1380 (9.5)	1300 (9.0)
<b>Compression Set, %</b>	35	35	35	<i>Not tested</i>	35	30	<i>Not tested</i>	30
<b>Elongation, %</b>	790	615	615	580	570	480	415	450
<b>Tear Strength, <i>Ppi (N/mm)</i></b>	195 (34)	250 (43)	250 (43)	237 (40)	265 (45)	250 (43)	190 (33)	240 (41)
<b>Modulus, 100%, <i>psi (N/mm<sup>2</sup>)</i></b>	190 (1.3)	200 (1.4)	200 (1.4)	200 (1.4)	350 (2.4)	425 (3.0)	360 (2.5)	530 (3.7)
<b>Resiliency, %</b>	62	62	62	56	63	63		63
<b>Post Cured<sup>(1)</sup> 4 hrs., 200°C</b>	<b>LSR 4330</b>	<b>LSR 4340</b>	<b>LSR 4340 FC</b>	<b>LSR 4340 SL</b>	<b>LSR 4350</b>	<b>LSR 4360</b>	<b>LSR 60</b>	<b>LSR 4370</b>
<b>Hardness, Shore A</b>	31	40	40		50	61		70
<b>Tensile Strength, <i>psi (N/mm<sup>2</sup>)</i></b>	1350 (9.3)	1250 (8.6)	1250 (8.6)		1275 (8.8)	1250 (8.6)		1200 (8.3)
<b>Compression Set, %</b>	10	10	10		12	15		25
<b>Elongation, %</b>	750	605	605	<i>Not tested</i>	530	430		400
<b>Tear Strength, <i>ppi (N/mm)</i></b>	205(36)	285 (50)	285 (50)		290 (51)	235 (41)		200 (35.1)
<b>Modulus, 100%, <i>psi (N/mm<sup>2</sup>)</i></b>	200 (1.4)	200 (1.4)	200 (1.4)		340 (2.3)	400 (2.8)		580 (4.0)
<b>Resiliency, %</b>	60	52	52		57	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.



## ■ BIOCOMPATIBILITY DATA

<b>Biocompatibility Tests (1)(2)</b>								
	<b>LSR 4330</b>	<b>LSR 4340</b>	<b>LSR 4340 FC</b>	<b>LSR 4340 SL (3)</b>	<b>LSR 4350</b>	<b>LSR 4360</b>	<b>LSR 60</b>	<b>LSR 4370</b>
<b>Cytotoxicity</b>	●	●	●	○	●	●	●	●
<b>Skin Sensitization</b>	●	●	○	○	○	○	●	●
<b>Intracutaneous Toxicity</b>	●	●	○	○	●	○	●	●
<b>Systemic Toxicity</b>	●	●	○	○	●	○	●	●
<b>Mutagenicity</b>	●	●	○	○	●	○	●	●
<b>Hemolysis</b>		●	○					
<b>Mucosal Irritation</b>								
<b>Pyrogenicity</b>		●	○					●
<b>7-Day Implant</b>	●				●	○		
<b>28-Day Implant</b>		●	○	○				
<b>90-Day Implant</b>							●	
<b>USP Class VI</b>	●	●	○	○	●	○	MAF	●
<b>FDA Master File (MAF)</b>							●	
<b>Extraction Tests (2)</b>								
	<b>LSR 4330</b>	<b>LSR 4340</b>	<b>LSR 4340 FC</b>	<b>LSR 4340 SL (3)</b>	<b>LSR 4350</b>	<b>LSR 4360</b>	<b>LSR 60</b>	<b>LSR 4370</b>
<b>FDA 21 CFR 177.2600</b>		●	○		●	○	See note (4)	○
<b>FDA 7117.11 Nitrosamines</b>		●	○		●			

○ = 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).

(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.

## Injection Molding

### Injection Pressure

The injection velocity and pressure depend on the viscosity of the silicone and the design of the runner system. Cavities are typically filled in 0.5 – 3 seconds. Pressures range from 250 psi to 2000 psi.

During the start-up of a new tool, the injection pressure should be set high enough that the silicone will be completely injected into the mold before the cure of the silicone can begin in order to prevent premature curing at the injection point. A mold filling study is typically done during the start-up to monitor the balance of the cavities and to ensure that, upon complete filling, the mold is not over-loaded.

The point at which the injection is completed and the curing time begins is referred to as the switch over.

### Holding Time / Pressure

Silicone expands as its temperature increases. Holding pressure is required to prevent the silicone from flowing back into the injection nozzles when this expansion occurs. Typically, 0.5 – 4 seconds is a sufficient holding time.

### Cavity Pressure

The slow expansion of the curing silicone causes the cavity pressure to gradually increase. To prevent excessive flashing and back-rind, each cavity should be filled to 98-99% of capacity.

### LSR Supply

The **Silbione® LSR** is dispensed from a pressurized pumping unit at a ratio of 1:1. This meter-mix system is typically a double-acting pneumatically driven reciprocating pump with follower plates that move the silicone from the 200 kg drums or 18 kg pails through flexible pipes to the static mixer.

### Mixing

The **Silbione® LSR** and any other additives (typically a pigment/polymer masterbatch) are delivered through a static mixer that will thoroughly mix the components while not imparting additional frictional heat. Some injection molding machines include a dynamic mixer near the end of the screw to achieve additional mixing. Although a dynamic mixer provides additional mixing of the components, it can also impart frictional heat into the silicone shortening the pot life of the material after this point.

### Injection Unit

The pressure of the LSR drops to approximately 400 – 1000 psi as the material is delivered from the pumps to the screw (injection unit). The rotational speed of the screw should be high enough to deliver the silicone into the mold so as not to prolong the cycle time but not so high that the temperature of the **Silbione® LSR** is increased causing partial curing.

Leakage can occur at the non-return valve if the valve closing does not occur immediately or if the valve does not close completely.

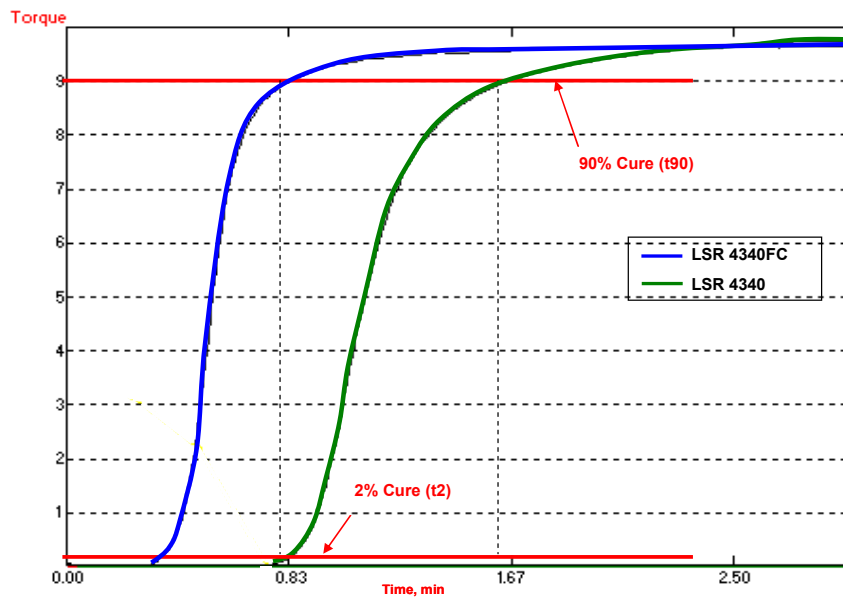
Back pressure should be set at approximately 70 – 500 psi.



## Curing

The reaction between the vinyl and hydride-functional components takes place very slowly at room temperature but is rapidly accelerated with heat. This fast and efficient addition-cure reaction can be measured on a rheometer. The graph shows cure of the silicone plotted as a function of torque versus time at a given temperature. As the temperature of the sample increases in the testing chamber of the rheometer, the polymerization of the silicone begins. The  $t_2$  value is the time at which 2% of the maximum torque is reached, indicating the beginning of silicone cure. The  $t_{90}$  value is the time at which 90% of the maximum torque is reached, indicating the point in an injection molding process that the silicone reaction is approaching completion and demolding is now possible.

Cure Rate measured with MDR 2000 at 115°C



Recommended molding temperature (actual temperature inside the mold) is 150°C - 200°C. At these temperatures, the LSR cures very rapidly. The exact rate of reaction of the LSR depends on the following factors:

- chemical formulation of the **Silbione® LSR**
- temperature of the mold
- temperature of the **Silbione® LSR** when it enters the cavity
- surface area of the part being molded versus the volume of the part

For planning purposes, the cure time can be estimated assuming 4 – 6 sec/mm. As the part thickness gets larger, this factor will also increase due to the poor heat transfer characteristics of silicone.

During the start-up of a new tool, the cure time of the article can be decreased until deforming or stickiness occurs. This cure time represents the “edge” of the process and the curing time should then be increased by 5 – 10% to guarantee a safe operating range.

For ways to increase productivity after your current process has been optimized, contact your Bluestar Silicones Technical or Sales Representative.





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<b>Demolding</b>	<p><b>Silbione® LSR 43xx</b> series products are designed to provide excellent mold release properties and high hot tear resistance. These features allow for high productivity, and automated removal of articles from the hot mold.</p>
<b>Cavity Surface Finish</b>	<p>The LSR duplicates exactly the surface of the cavity. Polished steel or polished chrome plated surfaced molds should be used to achieve highly transparent parts. <b>Silbione® LSR 43xx</b> series products are formulated to provide excellent release from any cavity surface finish.</p> <p>LSRs adhere more to polished surfaces. A rough surface finish on a mold will provide less adhesion with the silicone and easier demolding when using a LSR that is not designed for good mold release.</p> <p>A PTFE/Nickel surface coating on the mold provides easier demolding of the cured silicone article. This coating will wear over time and the tool will need to be resurfaced.</p> <p>A Titanium/Nickel surface coating offers a very high wear resistance.</p>
<b>Shrinkage</b>	<p>Linear shrinkage of articles molded with <b>Silbione® LSR</b> is typically 1.5 – 2.5%. Exact shrinkage depends on the following factors:</p> <ul style="list-style-type: none"><li>■ chemical formulation of the <b>Silbione® LSR</b></li><li>■ molding temperature</li><li>■ cavity pressure</li><li>■ where the shrinkage measurement is made (shrinkage is usually slightly higher in the direction of the material flow than perpendicular to the direction of flow).</li><li>■ dimension of the part (thicker parts shrink less than thinner parts)</li><li>■ post curing causes an additional 0.3 – 0.5% shrinkage.</li></ul>
<b>Production Shut-down</b>	<p>Unless otherwise stated, mixed <b>Silbione® LSR</b> is designed to remain processable for a minimum of 2.5 days at temperatures less than 35°C. Should the injection molding machine need to be remain idle for more than 2.5 days, the injection unit and cold runner should be purged with the Part A component to prevent polymerization of the silicone. Injection molding machine parts holding mixed material could also be kept in a freezer to prevent curing of the silicone for longer time periods. Care should be taken to ensure that if these steps are taken, condensation inside the machine parts does not occur.</p> <p>A regular preventive maintenance schedule is recommended for the mixer and injection unit. Even if the injection molding machine is used nearly without interruption, the mixer and injection unit should be cleaned at least every three months to ensure that cured particles do not accumulate and interfere with flow through the colder runner. Cured particles could detach and enter the tool cavity.</p>
<b>Cleaning</b>	<p>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.</p>

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## Common Contaminates

**Silbione® LSR** may not cure properly if they come in contact with certain substances. Some common cure inhibitors include:

- chlorinated solvents, acetone, MEK
- adhesive tapes (i.e. duct tape)
- peroxide and peroxide by-products
- sulfur compounds
- amines
- urethanes
- tin based compounds (condensation cure silicones)
- most substances with highly electronegative atoms: N, S, P, Cl
  - that are soluble or partially soluble in silicone
  - some gaseous inhibitors such as some amines, eg, NH<sub>3</sub>
- butyl and chlorinated rubbers
- strong acids
- strong bases



## Troubleshooting the Injection Molding Process

Problem	What to look for	Cause	Solution
Silicone is not cured	Molded parts feel tacky. Molded part sticks in the cavity. Low durometer.	Cure time too short.	Increase cure time.
		Tool temperature too low.	Raise tool temperature.
			Check temperature consistency in each cavity.
		Cure inhibited.	Refer to Table 1 for list of contaminants for platinum-cured silicones. Ensure that none of these chemicals are in contact with the Silbione LSR. Ensure that sulfur or amine-based products are not being used in the area.
Mix ratio not 1:1.	Clean supply lines and static mixer of any gelled particles.		
	Ensure that meter mixer is delivering both components at same rate.		
Gelled particles (lumps) in finished part	Gritty/lumpy appearance of part. Cured sprue visible inside the part.	Temperature at injection point is too high.	Lower tool temperature at the gate.
			Improve cooling of the cold runner.
		Silicone is curing in static mixer, screw, or injection unit and is being pushed into the part.	Clean static mixer, screw, and injection unit.
Under-fill	Uneven surface on part. Part is not correct size or weight.	Injection speed or pressure not optimized.	Increase injection speed and injection pressure.
		Shot size insufficient.	Increase shot size.
		Poor mold venting.	Clean mold vents.
		Tool temperature too hot.	Lower tool temperature.
		Pre-curing in the injection unit.	Clean injection unit and supply lines.
		Machine problems.	Check mixing screw clearance and non-return valve.
		Cold runner or sprue dimensions are faulty.	Check sprue system for pre-cured silicone.
		Uneven filling of cavities.	Balance runner and gate.
		Holding pressure too low.	Increase holding pressure.



Problem	What to look for	Cause	Solution
Flash / Back Rind	Thin layer of silicone film at parting line or at vents.	Shot size too large.	Decrease shot size.
		Injection speed too high.	Reduce injection speed and possibly injection pressure.
		Holding pressure too high.	Reduce holding pressure.
		Venting channels too big.	Reduce size of vents.
		Tool temperature too low.	Increase tool temperature and ensure consistent heating throughout tool.
		Clamping force too low.	Increase clamping force.
Bubbles or blisters	White (foamy) edges. Blisters visible in finished part. Small bubbles throughout part.	Injection speed too high.	Reduce injection speed and possibly injection pressure.
		Tool temperature too high.	Reduce tool temperature.
		Improper venting.	Clean mold.
			Enlarge vents.
			Reduce clamping force.
		Insufficient vacuum.	Check for vacuum leaks.
			Increase vacuum time.
		Air in meter mix system.	Check for leaks.
Uneven mold filling.	Balance runner and gate.		
Small bubbles throughout part - Silicone curing too slowly.	Increase tool temperature. Or use faster curing silicone system.		
Scorch	Orange-peel appearance. Flow lines or streaks in part.	Injection speed too low.	Increase injection speed and possibly injection pressure.
		Tool temperature too high.	Reduce tool temperature.
Problems demolding	Part is not ejecting properly. Runner is not separating from part.	Tool temperature too high.	Reduce tool temperature.
		Holding pressure is too high or held too long.	Reduce holding pressure or time.
		Curing time too long.	Reduce curing time.
		Imperfection in tool finish.	Have tool refinished.
Incorrect part dimensions	Parts are too small or too large. Part is deformed.	Insufficient curing.	Optimize tool temperature.
			Increase cure time.
		Incorrect shot size.	Optimize shot size and filling of cavities.
		Shrinkage change.	Optimize injection pressure and speed.
Check for temperature consistency throughout tool.			



Problem	What to look for	Cause	Solution
Silicone cures in injection unit	Longer injection times at start-up. Start-up difficulties after a long break.	Silicone in mixer and injection unit has started to cure.	Check cooling on the screw.
			Purge with Part A before a down-time of more than 3 days.
			Disconnect injector from hot mold during breaks.
			Ensure that Part B has been stored properly in tightly sealed container.



## The Molded Silicone Article

### Post Curing

**Silbione® LSR 43xx Series** products were designed to give high strength, stable physical properties without the need for post curing.

Higher physical properties can be obtained with the older generations of **Silbione® LSR** by undergoing a post curing process.

A typical post curing process takes place at 200°C for 4 hours in an oven with fresh air supply. The post curing times and temperatures may be reduced depending on the requirements of the finished article.

If the finished silicone-molded article must meet the requirements of certain FDA or BGVV guidelines, a post curing process may be required to remove any remaining volatile components. The purchaser has the responsibility to identify and comply with all applicable statutory, regulatory and industry requirements and standards for compatibility, extractability, testing, safety, efficacy and labeling.

### Bio-compatibility

**Silbione®** is Bluestar Silicones' designation for skin contact safe products.

Extensive toxicology testing on **Silbione®** products has demonstrated their adequate biocompatibility and suitability for the recommended applications. Our evaluations according to EN/ISO 10993 showed that **Silbione®** products are non-skin irritating, nor skin sensitizing materials. They satisfy regulatory requirements in several countries, in particular those of Class I Medical Devices as in 93/42/CEE European Directive, or those of US Pharmacopoeia Class VI. Toxicological summaries, statements, and specific regulatory status are available upon request from your Bluestar Silicones Representative.

### Sterilization

In the healthcare field, silicone-molded medical devices that will contact the body or bodily fluids must be sterilized to prevent the growth and spread of harmful microorganisms. During the sterilization process, the silicone-molded parts are exposed to one of several types of treatments, such as autoclaving, ethylene oxide, electron beam, or gamma radiation. While these treatment processes are necessary for sanitizing purposes, they can often affect the molecular structure of the silicone rubber resulting in an adverse effect on the physical properties of the molded part.

Molded silicone rubber is very stable in boiling water. The hydrophobic properties of silicone prevent penetration of water such that the increase in volume remains less than 1 %, even after prolonged exposure.

Silicone rubber behavior in steam is not uniform for all grades of LSR. In general, steam sterilization (steam autoclaving) at 120°C - 130°C can be carried out continuously for most LSR grades.

At temperatures of approximately 212°C and above, oxidative degradation begins to occur. The organic substituents are cleaved from the silicon atoms to form free-radicals. These free-radicals create additional crosslinking between polymer chains, which in turn changes the physical properties of the silicone rubber. Shrinkage of the molded part is evident along with an increase in hardness and embrittlement. Tensile strength, elongation, and tear strength typically decrease.

Although ethylene oxide (EtO) treatment is effective in eliminating bacteria at the surface of silicone parts, residual EtO gas can be absorbed by the silicone rubber upon prolonged

exposure. This method of sterilization, however, has no significant negative effect on the properties of the silicone rubber.

The effects of electron-beam and gamma radiation are comparable to the effects of exposure to high temperatures. Silicone rubbers exposed to high dosages and long treatment cycles of gamma or electron radiation will undergo oxidative degradation resulting in molecular changes to the silicone and its physical properties. One could expect that a 2.5 Mega-Rad dose of gamma irradiation to have  $\pm 15\%$  effect on first order physical properties (durometer, tensile strength, tear strength, elongation at break) of most **Silbione® LSR**. Testing of the actual molded article should be conducted to confirm effects of the gamma or electron irradiation and final fitness for use.

## Primers & Self-Bonding

### Over-molding onto Silicone Rubber

**Silbione® LSR 60** is chemically formulated to provide silicone rubber -to- silicone-rubber bonding without the use of a primer. This product is effective in applications where over-molding onto another silicone is required.

Contact your Bluestar Silicones Representative for similar products in other durometers.

### General Purpose Primer

**Silbione® M&P Primer** is a 10% active adhesion promoter dispersed in xylene that improves adhesion of silicone elastomers to some substrates such as metals, ceramics, glass and plastics. This product is well-suited for coupling Bluestar Silicone's Liquid Silicone Rubbers, High Consistency Rubbers, and Adhesives to metals, fabrics, plastics, ceramics, and other substrates.

<i>Typical Properties</i>	
<b>Color</b>	Clear
<b>Specific Gravity</b>	0.86 – 0.88
<b>Non-volatile Content, %</b>	2
<b>Flash Point, °F</b>	80

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#### Warning to the users

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