

Silbione® LSR*

for food contact, pharmaceutical contact and health care applications

The Silbione® LSR range is well adapted to pharmaceutical and health care applications due to the good biocompatibility of silicones and their ability to produce non-polar surfaces which therefore have very little interaction with biological systems. Due to their high level of mechanical properties and clarity, Silbione® LSRs are particularly suited for highly transparent molded parts such as baby nipples, pacifiers, stoppers and valves. These grades show an excellent resistance to standard sterilization technologies.



● Baby nipples



● Sport and leisure goods



● Kitchenware

> Advantages of Silbione® LSR

■ Most important properties are:

- > Very high physical stability on a wide range of temperature (-50°C to 200°C)
- > Very good resistance to thermal ageing and oxidising agents (oxygen, ozone, UV)
- > Excellent resistance to sterilization
- > Very high level of transparency
- > Biocompatibility
- > Non-toxic residues or by-products
- > A very good level of mechanical properties

■ All these properties are associated with the advantages of easy processing

- > Automatic injection molding process similar to thermoplastic injection molding
- > Higher curing rate than other rubber grades with low scrap level
- > Highly productive cycle times without scorch
- > Easy demolding with good hot tear
- > High level of transparency or easy to pigment

* Liquid Silicone Rubber

Silbione® LSR

	Properties	Standards	Units	LSR 4330 A/B	LSR 4340 A/B	LSR 4350 A/B	LSR 4360 A/B	LSR 4370 A/B
General characteristics	Appearance			Transparent	Transparent	Transparent	Transparent	Transparent
	Specific Gravity at 25 °C	ISO R1183	(g/cm ³)	1.11	1.12	1.12	1.13	1.14
Mechanical properties after post-curing 4 hours at 200 °C	Viscosity (shear rate 1 s ⁻¹)		(Pa.s)	550	1 800	2 000	2 000	1 800
	Viscosity (shear rate 10 s ⁻¹)		(Pa.s)	270	650	700	700	600
	Pot life at 25 °C		days	> 3	> 3	> 3	> 3	> 3
	Hardness, shore A	ASTM D 2240		31	40	50	61	70
	Tensile strength	NFT 46 002	(MPa)	9.3	8.6	8.8	8.6	8.3
	Elongation at break	NFT 46 002	(%)	750	605	530	430	400
	Tear strength	ASTM D 624 B	(kN/m)	36	50	51	41	35
	Compression set	ASTM D 395 B	(%)	-	10	12	15	24
Rebound resilience	ISO 4662	(%)	60	52	57	60	60	

Silbione® LSR series have an excellent balance between properties and easy productive process.

The following testing has been conducted on our Silbione® LSR materials

Product	FDA 21 CFR 177.2600 ^A	Cytotoxicity ^A	USP Class VI ^B	FDA 7117.11 Nitrosamines ^C
Silbione® LSR 4330 A/B		OK ⁽¹⁾	OK ⁽¹⁾	
Silbione® LSR 4340 A/B	OK ⁽¹⁾	OK ⁽¹⁾	OK ^{(1) (3)}	OK ⁽¹⁾
Silbione® LSR 4350 A/B	OK ⁽¹⁾	OK ⁽¹⁾	OK ⁽¹⁾	OK ⁽¹⁾
Silbione® LSR 4360 A/B	OK ⁽²⁾	OK ⁽¹⁾	OK ⁽²⁾	OK ⁽²⁾
Silbione® LSR 4370 A/B	OK ⁽²⁾	OK ⁽¹⁾	OK ^{(1) (4)}	OK ⁽²⁾

Regulatory support

A. Water and hexane extract tests conducted on final product (A+B).
 B. Testing conducted on final product (A+B). Tests include sensitization, intracutaneous toxicity, systemic toxicity, muscle implant, & genotoxicity.
 C. Total nitrosamines tested on final product (A+B).

OK⁽¹⁾. The test was performed on the material; test was successfully passed.
 OK⁽²⁾. The test was not performed on the material. However, it is substantially equivalent to another tested Bluestar Silicones LSR material. Test results are adequate for subject material.
 OK⁽³⁾. Additional tests performed and successfully passed include pyrogenicity and hemocompatibility.
 OK⁽⁴⁾. Additional tests performed and successfully passed include pyrogenicity.

> Conformity with regulation

Silbione® LSR 4300 series can be used for food contact, pharmaceutical contact and health care applications. Due to the low volatile content in Silbione® LSR, these products conform to legislation after short post-curing cycles such as 4 h at 200 °C. The recommended minimum amount of air is 100l/min per kg rubber.

Food contact

The substances contained in the elastomers obtained by curing and post-curing 4 hours at 200 °C Silbione® LSR grades conform with these requirements:

- > USA: FDA - code of Federal Regulation 21 - Chapt. 177.2600 and FDA 7117.11 Nitrosamines
- > Germany: Bfr Part XV Silicones
- > France: Journal Officiel dated Nov. 25, 1992- brochure 1227

Health Care

Silbione® LSR 4300 series is formulated to meet USP class VI and/or ISO 10993 requirements for health care applications (see enclosed table).

Certified quality

Bluestar Silicones takes special care in both manufacturing and quality control. Bluestar's production locations are certified ISO 9001.

In all cases, it is up to the manufacturer of the finished product to check its conformity with tests stipulated in the appropriate regulations. The use of these elastomers is prohibited by Bluestar Silicones for the following medical applications:

- > Devices implanted for more than 29 days
- > All devices in contact for more than 29 days with blood, and mucus membranes (contraception, obstetrics)
- > Plastic surgery



A Silbione® HCR range is also available.
Refer to the data file Silbione® HCR.